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Global On-line, Interactive and Simulated Learning Techniques via BIRS

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GLOBAL ON-LINE, INTERACTIVE AND SIMULATED LEARNING TECHNIQUES VIA BIRS

by

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This dissertation is dedicated to my husband, Gary.

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GLOSSARY

Activity Theory–Activity Theory is developing conceptual tools to understand networks of interacting activity systems, dialogue, and multiple perspectives and voices (Engestrom,1987, p. xv).

Adjustment−Integration of others' ideas when working with those from multiple cultural backgrounds (May, Wold, & Moore, 2016. p. 523).

BIRS–Biotechnology Innovation Regulatory Science

Communication−Creation of a strong network bond because each of the participants are present at the same time to communicate (Ahern, 2008. p. 99).

Connection and Development–What is useful in the working of products, what is usable in the fit of a product to the capabilities of human beings, and what is desirable for the emotional satisfaction of human beings. It is the task of development, building concrete prototypes, refining the idea, and bringing together all the elements that are necessary for production or implementation (Buchanan, 2015, p. 15).

Constructivist Theory–Learning is an active process in which learners construct new ideas or concepts based upon their current or past knowledge. The learner selects and transforms information, constructs hypothesis, and make decisions, relying on a cognitive structure to do so (Culatta, 2015, p. 1).

Distributed Cognition–Extends the reach of what is considered cognitive beyond the individual to encompass interactions between people and with resources and materials in the environment (Hollan, Hutchins, & Kirsh, 2000, p. 175).

Empathy−Ability to understand what another person is experiencing from within the frame of reference of that other person (Strobel, Hess, Pan & Watcher Morris, 2013, p. 138).

Evaluation–Components that assure that tasks will function properly; processes that control the generation of designs; and evaluation procedures that ensure effective utilization of knowledge (Jonassen, 2000, p. 80).

Integration−Ability to adjust behaviors and integrate others' ideas when working with those from multiple cultural backgrounds (Downey & Lucena, 2005, p. 258). Combined with the analysis of design problems and situations, and uses the results as both framing and explanatory constructs (Goel & Pirolli, 1992, p. 399).

Invention–On which the discipline depends, how the discipline may be developed within different kinds of organizations, and the strategies by which the discipline engages the external world of users, bringing innovation through policies and practices (Buchanan, 2015, p. 9).

Judgment–How to frame the situation, who to listen to, what to pay attention to, what to dismiss, and how to explore, extract, recognize, and choose useful information from all these potential sources (Stolterman, 2008, p. 57).

Negotiation−Discussions based on the current scientific and technical knowledge in the Field (Food and Drug Administration, 2013, p. 3).

Recognition−Assessment of similarity or dissimilarity of requirements (Regulatory Affairs Certificate, 2016, p. 22).

Regulatory Intelligence−Processing targeted information and data from multiple sources, analyzing the data in its relevant context and generating a meaningful output to the regulatory strategy. The process is driven by business needs and linked to decisions and actions (Aslam, 2015, p. 4).

Regulatory Risk−Determination of adequacy of data analysis to support regulatory Requirements (Regulatory Affairs Certificate, 2016, p. 17).

Regulatory Science–The science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products (Framework, 2010, p. 3).

Regulatory Strategy−Advisement regarding drug development timelines, risks, safety and financial implications of the proposed product submission (Regulatory Affairs Certificate, 2016, p. 20).

Respect−Education of ethnocentrism and promotion of acceptance of the needs and approaches used from other cultures (Downey & Lucena, 2005, p. 256).

Technology–In person cross-cultural and cross-class experiences in networked-computer environments...email, distance learning, websites...to maintain “virtual” inter-group contact (Waks, 2006, p. 292).

ABSTRACT

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Role-playing simulations have been effective techniques to encourage global skills in the engineering and design classrooms. May, Wold and Moore (2014), defined global skills as student display of respect, recognition, adjustment and integration. Gray, Debs, Exter, and Krause (2016), took this one step further and looked-for empathy in the design classroom. This has yet to be realized in the regulatory science education realm. Therefore, there is a need for on-line, interactive regulatory science education focusing on global skill outcomes. To assess the gap, four sets of data are collected. The first set was a review of evaluations from a regulatory science course teaching documents and dialogues necessary for drug and device approvals. The evaluations stated that more global skills, problem-solving and innovation needed to be a part of the curricula. The course was reformatted and an interactive simulation called the *BIRS Experience* included. The second data set came from the student's final assignments after the *BIRS Experience* was delivered. The assignments were analyzed for global skills and creative inquiry movements. The students participating in the *BIRS Experience* were both from the United States and Tanzania. Both sets of participants again answered questions after a regulatory intelligence workshop. This was the third data set. The comments from the questionnaire were analyzed for global skills and creative inquiry movements. The fourth data set was answers to a world café experience delivered at a quality and

regulatory affairs summit. In this case, the participants were working professionals asked what competencies were needed for the regulatory science discipline moving forward, again, comments were analyzed for global skills and creative inquiry movements. The theme of needing both global skills and creative inquiry movements was consistent in all four data sets.

CHAPTER 1. INTRODUCTION

1.1 The Research Problem

The ability to interact with different cultures is essential in our modern world economy. Global skills are becoming more important to employers. Managers want to hire individuals who display respect for others' beliefs, share their own beliefs, and recognize that beliefs are different. In addition, these global skills deal with the way to adjust behaviors and combine others' ideas when interacting with people from different career and cultural environments.

Role-playing simulations have been effective techniques to encourage global skills in the engineering and design classrooms. May, Wold and Moore (2014) defined global skills as a student's display of respect, recognition, adjustment and integration. Gray, Debs, Exter, and Krause (2016) took this one step further and looked-for empathy in the design classroom. This has yet to be realized in the regulatory science education realm. Therefore, there is a need for on-line, interactive regulatory science education focusing on global skill outcomes.

1.2 The Research Question

What is the outcome of an on-line, interactive and simulated learning technique implemented in a globally offered Biotechnology Innovation and Regulatory Science (BIRS) university course?

1.3 Scope

The scope of this research will include three different educational strategies. The first strategy is implemented to teach global skills in the Biotechnology Innovation and Regulatory Science (BIRS) program. This strategy is an interactive role-playing

simulation created by the researcher called the *BIRS Experience*. The *BIRS Experience* is about a global issue – getting a medicine to market. The medicine is a pretend drug called ClaseaByrnib, a biological molecule for osteoarthritis. Participants are Purdue University Polytechnic Institute BIRS Master's degree students taking the course Technology Leadership Innovation (TLI) 524 *Documents and Dialogues for Drug Delivery and Registration*. This course is intended to be the BIRS program capstone before the students write their thesis or directed project.

The second teaching strategy was presenting an intensive session to students from materials used for the Regulatory Affairs Certification (RAC) and concepts from regulatory intelligence. The focus of the teaching session was global regulatory science with an emphasis on standards from the International Conference on Harmonization (ICH), World Health Organization (WHO), and International Standards Organization (ISO).

The third teaching strategy was presenting questions to participants at the 2017 First Annual Summit for Academic Excellence in Quality Assurance and Regulatory Science. Questions were presented in an interactive session on the summit's second day.

For the first and second teaching strategies, participants were Purdue University Polytechnic Institute BIRS Master's degree students in Moshi, Tanzania, as well as, students from Purdue's main campus in the United States, located in West Lafayette, Indiana. For the third teaching strategy, participants were regulatory and quality professionals attending the 2017 First Annual Summit for Academic Excellence in Quality Assurance and Regulatory Science.

1.4 Significance

May, Wold, and Moore (2014) focused on the global skills of respect and recognition in engineering courses. In addition, student displays of adjustment and integration were studied by the previous researchers. Gray, Debs, Exter, and Krause (2016) examined the global skill of empathy in design courses. A thorough review of the literature has demonstrated that the global skills - adjustment, empathy, integration, recognition, respect - have not been taught in the Biotechnology Innovation and Regulatory Science (BIRS) classroom. The BIRS program has a global footprint. To fill this gap, the researcher has developed the *BIRS Experience*, an interactive, role-playing teaching strategy to foster global skill development. Objectives of the *BIRS Experience* are as follows:

- Prepare regulatory drug development documents and conduct "mock" dialogue during negotiations with "pretend" ministries of health.
- Explain the capability to effectively communicate both written and oral.
- Explain the capability to think critically, creatively and to take leadership to solve problems in the regulatory science discipline.
- Apply quality leadership strategies to real-life drug development situations.
- Recognize risk and take leadership to develop risk mitigation solutions.

This research is ground-breaking because no other studies have looked at these objectives mapped to global skills in the regulatory science education discipline. Table 1.1 maps the *BIRS Experience* objectives to this research focused global skills.

Table 1.1

BIRS Experience Global Skills

BIRS Experience Objectives	Global Skill
Prepare regulatory drug development documents and conduct "mock" dialogues during negotiations with "pretend" ministries of health.	• Respect • Recognition • Adjustment • Integration
Demonstrate the ability to effectively communicate both written and oral.	• Adjustment • Integration • Empathy
Demonstrate the ability to think critically, creatively and to take leadership to solve problems in the regulatory science discipline.	• Respect • Adjustment • Integration
Apply quality leadership strategies to real-life drug development situations.	• Recognition • Adjustment • Integration
Recognize risk and take leadership to develop risk mitigation solutions.	• Respect • Recognition • Adjustment • Integration • Empathy

Similarly, looking at global regulatory information from a regulatory intelligence viewpoint is an innovation not yet used in the regulatory science classroom. Regulatory intelligence has the capacity to acquire facts and experiences to apply to drug device and diagnostic approvals. Just finding FDA information online is the raw data used to create intelligence; a data download, no analysis.

What makes regulatory intelligence unique is that it can take the raw data and turn them into active and related analyses. This data analyses and integration into company practices and procedures produces regulatory intelligence which enhances commercialization approvals.

The regulatory intelligence teaching strategy instructs students how and why to acquire drug development submission considerations:

- Markets impacted
- Type of regulatory change
- What documentation is required for submission package
- Timeframe for approval
- When can the change be implemented
- Commercial, quality and supply chain impacted
- Improved quality of drug
- Reduced cost
- Increased productivity.

After gathering important pharmaceutical considerations, the students are instructed how to compile an information gap analysis and address serious implication questions from a global perspective (Regulatory Affairs Certificate, 2016):

- Drug development processes through the product lifecycle of medical devices, in vitro diagnostics, pharmaceuticals, medicinal products and biologics
- Critical thinking and analytical skills
- Guidelines and standards from world accreditation organizations.

In further detail, the first part of the intensive deals with global strategic planning. This information is imperative for the Tanzania students because African ministries of health often seek guidance from the EMA. Because Africa mainly imports and exports their medicines, strategy information focuses on evaluating dossiers for similarities or dissimilarities of requirements for market feasibility. Strategy for this area also needs to anticipate regulatory obstacles coming from trade issues. Also, important for the Africa students is learning the information necessary for them to develop their own medicines. This enables alternative opportunities for local product development and regulatory compliance needs.

American students benefit from the global regulatory information as they look to worldwide launches with their products. These students benefit from knowing the regulatory requirements for quality, preclinical and clinical data to meet all global regulations. The Africa students need this information too, as they look to developing their own medicines.

Drug development and product submission requires interfacing with the local and international ministries of health. Negotiation and communication skills needed for these exchanges correspond to the global skills being taught and measured in this research – respect, recognition, adjustment, integration and empathy.

Both the African and American students bring their cultural experiences to the negotiation and communication exchanges. Both groups are a mix of female and male students, and come from a variety of pharmaceutical backgrounds. Purdue University's Polytechnic Institute BIRS program is the vehicle to bring the drug development information to Africa. This Master's program focuses on the knowledge required to

develop, manufacture, and analyze quality medicines. This Master's program has already been identified by several regional African authorities as a key pillar for the build-out of regional manufacturing capabilities desperately needed in a region struggling with poverty and disease. Further this program focuses on supporting the education and leadership of women.

Additionally, to assist in framing global problems, Buchanan's (2015) creative inquiry movements are used. These are integration, judgment, connection and development, invention and evaluation.

The third teaching experience again takes a strategy and delivers it in a unique way. This is the 2017 First Annual Summit for Academic Excellence in Quality Assurance and Regulatory Science. Question are posed to the regulatory and quality professionals attending the summit in an interactive session. Questions discussed are:

- Given the rapidly changing nature of our industry, what challenges do you regularly face when recruiting new talent?
- What do you see as next steps to address those challenges?
- How can academia partner with industry and government to better prepare students into the fields of regulatory science, quality assurance and regulatory affairs?
- How can we work together to provide a highly effective and productive work force in these areas?

1.5 Assumptions

The assumptions for this project include:

- Sub-Saharan Africa pharmaceutical companies submit drug dossiers to the European Medicines Agency (EMA).
- United States pharmaceutical companies submit drug dossiers to the Food and Drug Administration (FDA).
- Drug approval times between the EMA and FDA differ (Root, 2014).
- Electronic Common Technical Document (eCTD) is a harmonized template for drug dossiers that is used by both the EMA and FDA. The interpretation of the eCTD is not consistent between the two agencies (Gessert & Neurauter, 2013).
- Sub-Saharan Africa regulatory bodies rely on the International Conference of Harmonization (ICH) guidance.
- United States regulatory bodies rely on the Code of Federal Regulations (CFR) guidance.
- Drug development risk assessment and mitigation strategies are interpreted differently between the EMA and FDA (Lis, Guo, Roberts, Kamble, & Raisch, 2011).
- Time spent with the African students was two-weeks as opposed to the three weekends spent with the United States students.
- Time zone differences between Africa and the United States presented a WebEx scheduling challenge.

- Internet connectivity for using Blackboard Learn and WebEx was unreliable in the eight Sub-Saharan countries where the students lived: Burundi, Congo, Kenya, Lesotho, Nigeria, South Sudan, Tanzania and Uganda.

1.6 Limitations

The limitations for this project include:

- Literature review surveys only engineering and design education strategies pertaining to global skills, and creative inquiry problem solving strategies.
- Data collection from post-course evaluation of Technology Leadership and Innovation (TLI) 524 *Documents and Dialogues for Drug Delivery and Registration* from 2005 to present.

1.7 Delimitations

The delimitations for this project include:

- This project does not focus on global skills other than respect, recognition, adjustment, integration and empathy.
- This project does not analyze the *BIRS Experience* assignments for creative inquiry movements other than invention, judgment, connection and development, integration and evaluation.
- This project does not expect the final assignments collected from both subject groups to be anything other than narrative in form.
- This project does not expect the data collected from the May 2017, summit to be anything other than narrative in form.

1.8 Chapter Summary

The researcher has presented in this chapter a rationale for the research undertaken. This chapter explained the need for and the gap of global skill instruction in the BIRS classroom. To fill the gap, the chapter highlighted innovative teaching strategies that have not been employed before in the regulatory science discipline. Lastly, the chapter outlined research challenges since the focus of the study has participating students from both the United States and Sub-Saharan Africa.

CHAPTER 2. LITERATURE REVIEW

2.1 Introduction

The Food and Drug Administration (FDA) defines regulatory science as, "the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products" (Framework, 2010, p. 3). Regulatory science is a discipline involved with the following groups (Moghissi, Straja, Love, McBride, & Stough, 2014):

- People that develop government regulations. These people may work in ministries of health or other regulatory agencies.
- People whose job it is to comply with regulations. These people typically work in regulated communities.
- People who work in product research and development. These people have regulation parameters to follow.

When regulatory science is applied, it happens in three phases (Moghissi et.al., 2014):

1. Regulators who create legislation based on their scientific judgement.
2. Scientists who develop regulatory technologies to improve global health outcomes.
3. Scientists who use the technologies created in the second phase to validate decisions.

Regulatory science is an emerging discipline used in the pharmaceutical industry to oversee the shaping, creating and implementing of guidelines pertinent to global

human health (Framework, 2010). The tools developed by regulatory scientists reflect product safety, efficacy, quality, risk-benefit, and transparent decision-making (Framework, 2010). Regulatory science is forward thinking and continually challenging current constructs on medicinal availability and approval processes. It is the key to unlock biotechnology challenges since it uses concepts such as creative inquiry and global skills.

2.2 The Key of Regulatory Science

Figure 2.1 illustrates the key of regulatory science unlocking biotechnology challenges that result in useful innovations.

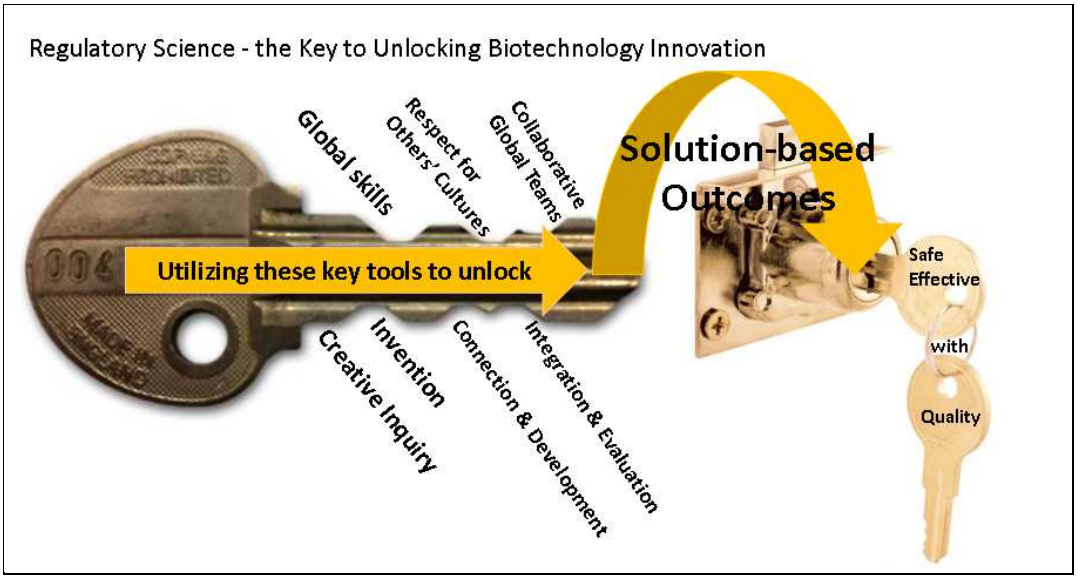

Figure 2.1

The Key of Regulatory Science and its Tools to Unlock Biotechnology Challenges

Figure 2.1 depicts the regulatory science key as the means to developing new technologies to unlock the safety, efficacy and quality of new drug and device related products (Framework, 2010). There are tools to foster unlocking the challenges. The bottom notches to the key depicts the tools of creative inquiry. These are creative inquiry movements originated by Nelson (1957) and continued by Buchanan (2015). The creative inquiry notches signify the importance of using creativity in an organized way by first using invention, then judgment, then connection and development, and lastly integration and evaluation (Buchanan, 2015). The top of the key notches depicts the skills necessary for useful biotechnology innovation in today's global pharmaceutical community. These are the engineering competencies listed by Parkinson (2009) of appreciation of other cultures and for worldwide issues. Parkinson (2009) also lists the importance of communication across cultures and effectiveness in transnational teams. The key unlocks the solution-based outcomes lock. Yet, there is innovation with the constraints of safety, efficacy and quality.

2.3 Creative Inquiry towards a Technology Philosophy of Regulatory Science

The key of regulatory science figure depicts using creative inquiry as a tool to unlock biotechnology challenges. Creative inquiry is one way that regulatory science has a pragmatic instrumentalism philosophy of technology. Here is why. Per Buchanan (2015), creative inquiry involves movements of action after purposeful reflection. If the action involves technology design, the design needs to have utility with both the user and the environment (Buchanan, 2015). In Sub-Saharan Africa, an example of technology design interacting with both the people and the environment, is advances in controlling the tsetse fly population (Morin, 2014).

The fact that creative inquiry involves purposeful action, corresponds with the modern view of technology or instrumentalism (Feenberg, 2006). The philosophy of science's instrumentalism, is the stance that values scientific theories and concepts. However, instrumentalism views scientific concepts with a pragmatic lens. A pragmatic lens values scientific innovation per its usefulness in society and its adaptation to the environment. In other words, the criterion for evaluating scientific theory is based on its usefulness (Hickman, 1990). It is the same with regulatory science. A scientist working in drug development wants their molecule to cure a disease state. Instrumentalism believes in experimenting to see whether scientific predictions are rigorous or not. Similarly, the scientist working on a medicine will try the innovation in clinical trials to test safety and effectiveness. Instrumentalist believe experimentation is fallible, but the risk is mitigated by further creative inquiry (Hickman, 1990). This is true for the drug development scientist as they continually evaluate the risk versus benefit of the product.

Additionally, Dewey's pragmatism approaches problem solving like Buchanan's (2015) creative inquiry movements as a tool for regulatory science problem solving. For example, Dewey distinguishes three phases of his inquiry process. His process begins with a problem. This is like the creative inquiry movements beginning with invention. Dewey stressed that problems can be uncertain and not obviously cognitive, but nevertheless, practical and existential (Dewey, 2015). Similarly, Buchanan (2015) defines invention strategies that engage "the external world of users, bringing innovations through policies and practices" (p. 9).

The second phase of Dewey's process, looking at the data or subject matter, involves establishing the guidelines to solve the problem (Dewey, 2015). Again, this

corresponds to Buchanan's (2015) creative inquiry movements of connection and development. For Buchanan, solving a problem takes connecting and developing solutions that both fit the capabilities of people and meet their satisfaction. Regulatory science uses this same format for problem solving health solutions. An example is the drug development process outlined by the FDA (Drug Development Process, 2015):

1. Discovery and Development – Research begins on a new drug. Research begins per the global need to meet unmet biotechnology challenges.
2. Preclinical Research – Drugs are tested on computer models and animals to determine basic concepts of safety and efficacy.
3. Clinical Research – Drugs are tested in humans to determine safety and efficacy.
4. FDA Review – FDA examines the submitted dossier of the drug's development and determines if it is safe and effective for public use.
5. Post-marketing Review – FDA continues to monitor the safety of the drug once it enters the public domain.

FDA's drug development process is a pragmatic step-by-step system of gathering information about the drug, and continually monitoring the information through its lifecycle. Thus, it follows Dewey's (2015) and Buchanan's (2015) pragmatic instrumentalism processes of looking at the problem, gathering information about the problem, and developing a problem solution.

The last step in Dewey's (2015) process to solve problems is determining how the solution meets the social need. For Dewey, it is only when the solution becomes useful that it becomes a part of human life. Buchanan's (2015) creative inquiry movements of

integration and evaluation look at the solution with substantial critique. Per Buchanan, integration must not only serve a need, but must also be integrated into the culture of everyday life. Then the solution can be evaluated to "ensure effective utilization of knowledge" (Buchanan, 2015, p. 80) to continue the advancement of technology.

This viewpoint is also used in drug and medical device development. For example, a drug is usually approved with a primary indication of use. However, if that drug also shows promise during development for another disease state, the originators will likely approach the FDA for another approval of a second indication of use. With further research and testing, there could be a third and fourth indication, and so on. Or, once the drug becomes generic, scientists may probe how they can repurpose the drug to meet yet another disease state that has yet a treatment regimen. Such building on existing technology, advances drug development knowledge and benefits the society by placing in the public domain more ways to fight disease.

The example of drug repurposing fits the pragmatic instrumentalism view that technology is only advantageous if it is useful (Dewey, 2015). Regulatory science needs tools to become useful to society and so looks to creative inquiry as one way to organize and solve unmet biotechnology challenges.

2.4 Global Skills towards a Technology Philosophy of Regulatory Science

Creative inquiry movements need to combine with global skills to produce useful, pragmatic biotechnology solutions. When working in global teams for these outcomes, unintended conflicts can arise between cultures as they interact with each other.

For example, an unintended conflict between cultures is when a person enters a new foreign environment. This often happens when regulatory science professionals negotiate with foreign ministries of health for drug or device approvals. An inexperienced regulatory science professional can learn the language and rituals of the new environment, but it may be hard to assimilate into the underlying values. The new professional may have to learn things from the very beginning which can lead to frustration and hostility with the new culture (Hofstede, Hofstede, & Minkov, 2010). Hofstede, Hofstede and Minkov (2010) say it is the responsibility of culturally diverse institutions like global companies or universities to integrate people together. These remarks correspond to two definitions used in this research related to global skills. The first definition is by May, Wold, and Moore (2015, p. 523), who say adjustment is the "integration of others' ideas when working with those from multiple cultural backgrounds." The second definition is by Downey and Lucena (2005, p. 258), who say integration is the "ability to adjust behaviors and integrate others' ideas when working with those from multiple cultural backgrounds."

Hofstede, Hofstede and Minkov (2010), say that the language used in teaching internationally can foster or hinder instructional pedagogy and business relationships. For example, these researchers describe a business acumen case study examined in an adult populated classroom in both French and English. The French version of the case

study led to lively discussion. However, the same business case study delivered in English was dull. The students claimed that it lacked pragmatic application. Hofstede, Hofstede and Minkov (2010) conclude from this case study example that, "Information is more than words: it is words that fit into a cultural framework" (p. 394).

In considering global negotiation situations, Hofstede, Hofstede and Minkov (2010) report the following similarities:

- Global negotiations involve two or more people coming together for an equally useful agreement.
- Global negotiations involve communication between the involved people.
- Global negotiations usually have decision-making parameters on either side of the involved people linked to their institutions, whether they be academic or business.

However, the negotiators need to be pragmatic in assuming their respective institution's support. Per Hofstede, Hofstede and Minkov (2010):

> Assuming sufficient institutional support, intercultural encounters in the context of development cooperation will be productive if there is a two-fold flow of know-how: technical know-how from the donor to the receiver, and cultural know-how about the context in which the technical know-how should be applied, from the receiver to the donor. A technical expert meets a cultural expert, and their mutual expertise is the basis for their mutual respect (p. 419).

Building on this, Hofstede, Hofstede and Minkov (2010) continue by saying there are three phases to learning the needed global communication for team interactions and problem-solving. These are (p. 419):

1. Awareness
2. Knowledge
3. Skills

For these researchers, awareness is the mental picture of the environment people carry in their minds. This mental picture can be influenced by the way they experience their environment. This view of awareness corresponds to Strobel, Hess, Pan and Wachter Morris's (2013, p. 138) definition of empathy used in this author's research. Strobel et. al. (2013) say empathy is the "ability to understand what another person is experiencing from within the frame of reference of that other person."

Per Hofstede, Hofstede and Minkov (2010), knowledge should follow awareness. These researchers say that knowledge is learning about the culture or cultures in which we collaborate. To be effective in a global team environment, it is important to have an "intellectual grasp of where their values differ from ours" (p. 420). This view of knowledge is like Dewey's (2015) pragmatic instrumentalism. For Dewey, gathering information and learning about the problem is a key step to useful solutions. Both Dewey's (2015) and Hofstede, Hofstede and Minkov's (2010) view of knowledge again refers to the interpretation of recognition used in this research. Per the Regulatory Affairs Certification (2016, p. 22), recognition is the "assessment of similarity or dissimilarity of requirements" for problem-solving biotechnology challenges.

The last phase to learning global communication is skills. Hofstede, Hofstede and Minkov (2010), define skills as the ability to:

> Recognize and apply the symbols of the other culture; recognize their heroes, practice their rituals, and experience the satisfaction of getting along in the new

> environment, being able to resolve first the simpler and later some of the more complicated problems of life among the others (p. 420).

Again, this corresponds to Dewey's (2015) view of pragmatic instrumentalism. Per Dewey, the test of if problems are solved adequately is if the solutions are useful to society. Then, and only then, can the solutions become a part of human life.

Going back to the graphic of the regulatory science key to solve biotechnology challenges – global skills plus respect for other cultures enables effective global teams to meet and work on resolutions to the "complicated problems of life" (Hofstede, Hofstede, & Minkov, 2010, p. 420). In this research, the used definition of respect agrees with Dewey (2015) and Hofstede, Hofstede and Minkov (2010). Per Downey and Lucena (2005, p. 256), respect is the "education of ethnocentrism and promotion of acceptance of the needs and approaches used from other cultures."

Therefore, combining creative inquiry movements and global skills for effective team problem-solving will foster solution-based biotechnology outcomes. Discussion will continue how the solution-based outcomes are pragmatic, useful and instrumental to society now and in the future.

2.5 Solution-based Outcomes toward a Technology Philosophy of Regulatory Science

The best way to illustrate solution-based outcomes being both pragmatic and instrumentalist in technology theory is to give a real-world example. Zacklad (2003) tells of solution-based activities in a multinational healthcare network. The setting is a hospital which Zacklad says is a structurally open environment. However, this hospital is experiencing administrative challenges and so Zacklad is proposing a computer-supported cooperative work (CSCW) solution. Since a hospital is a complex work

setting, Zacklad opens the definition of cooperative activities to suit a fluid environment. Per Zacklad (2003), for a dynamic setting such as a multinational hospital, cooperative activity is, "collective activities oriented toward goals in which means of designing and attaining the goals are neither completely formalized not standardized. The actors therefore have a significant amount of autonomy and are free to define their modalities of coordination and to adapt themselves to emergent situations" (Zackland, 2003, p. 191).

Zacklad (2000) continues to describe cooperative activities involving "intellectual transactions" that focus on communications between small teams working to achieve similar goals. The involvement of communications corresponds to Hofstede, Hofstede and Minkov (2010), when they speak of international negotiations involving people coming together for a common purpose. Both Zacklad and Hofstede, Hofstede and Minkov, view the transactions as ones of mutual sharing of knowledge. Zacklad (2000) associates the transactions of knowledge like both Dewey's (2015) and Buchanan's (2015) creative inquiry movements.

However, when intellectual transactions occur in a complex environment like a hospital, an attempt to coordinate activities between departments is necessary. Zacklad (2003) describes different levels of this organizational coordination (p. 191):

- Mutual Knowledge – Where organization is carried out by means of gathering and transferring information between the health care partners and their sphere of operations.
- Standard Knowledge – Where coordination is consistent and stable. An example in a hospital might be weekly lunch meetings with the nurse practitioners.

- Abstracted Knowledge – Where coordination becomes important to the health care partners and they see their knowledge exchanges as impactful to the whole organization.

Zacklad brings another definition into his research to foster usable solutions to both the patients and healthcare providers. The goal for this hospital is to develop a useful community of action. The goals for the hospital's community of action is for its members to benefit from shared knowledge (Zacklad, 2003). Zacklad (2003) furthers that the community of action, "develop an explicit, systematic body of knowledge which can be used to extract the know-how and the informal relations required to be able to recurrently redefine both the nature of the services they are supposed to provide and the internal organization on which they rely in the context of structurally open cooperative situation" (Zackland, 2003, p. 193).

The three forms of knowledge (Zacklad, 2003) can be compared to Dewey's (1938) distinctions of intellectual transactions, and thus, pragmatic instrumentalism. For example, Dewey (1938) speaks of interactions between people that are "drawn from operations of inquiry as existential and empirical occurrences" (p. 163). Dewey continues by saying these occurrences can be experienced based, therefore, not always factual. It is then that the receiver of the information must determine if the dialogue is logical or not. Sometimes, logical determination is based on mutual perception between the members of the interaction. Zackland (2003) says this existential knowledge is more local and situated. This kind of knowledge also corresponds to Zackland's mutual and standard knowledge. In Zacklad's hospital setting this is the operational activities. For a hospital, this might be performing patient services or adhering to hospital regulations. The

relational piece of the activities could be constructing social networks with other healthcare providers on different wings of the hospital.

Dewey (1938), continues by saying from logical determination of the content of the conversation the receiver can then universalize the information. Thus, moving the information to a broader and more abstract application. Going to a more universal interpretation of the information agrees with Zacklad's (2003) abstract knowledge. Applying this to the hospital setting could mean moving from short-term to more long-term plans. The relationship aspect of the planning could have the possibility to affect the quality of patient care for the entire network.

Local knowledge can be operational activities such as standardizing the registration information given to patients, for example. The local knowledge can then become more generalizable and deal with communications with the health network stakeholders. Local knowledge can also be relational such as the use of instant messaging between the doctors. Progressing relational local knowledge can then become more abstract turning into a possible electronic medical record interface for the entire network.

For practical application to the hospital in Zacklad's (2003) research, the knowledge activities can be categorized into four areas: operational, situational, integrative and relational (OSIR). An example of OSIR in the healthcare network might look like the following (Zacklad, 2003):

- Operational Activities – Treating patients.
- Situated Activities – Characterizing the kind of patient services, for example, their pathologies.

- Integrative Activities – Defining the roles of the healthcare providers in the network.
- Relational Activities – Organizing ways to get the healthcare providers acquainted.

Perhaps a series of meetings to execute the intention of the OSIR pattern would be useful, such as:

- Contributing to the treatment of a patient with documentation for requirements gathering.
- Provide opportunities through forums like lunch and learns for sharing on system usability issues.
- Discussing roles and expectations of all users of the technology.
- Provide necessary system training on policies and procedures.

This meeting strategy agrees with Beer, Eisenstat, and Spector (1990), who offer a checklist for effective organizational system change:

1. Galvanize resolution to system revitalization through collaborative diagnosis of outcome goals and problems.
2. Develop a shared vision of how to organize and manage the system for effectiveness.
3. Garner consensus for the revitalization system vision, and training to implement it.
4. Push competence to all departments impacted.
5. Construct formal policies and procedures.
6. Keep change management of problems current and prioritized.

Lastly, to anchor this back to Dewey's (2015) pragmatism, and the instrumentalist theory of technology. Table 2.1 illustrates the similarities between the OSIR model and the instrumentalism theory.

Table 2.1

OSIR Model compared to Instrumentalism

OSIR Activities	Instrumentalism Activities
Operational	Identifying a problem that requires solution-based outcomes
Situated	Gathering requirements to solve the problem
Integrative	Adapting the solution to an expanded societal need
Relational	Making sure the solution is useful to society

2.6 Why Creative Inquiry and Global Skills for Regulatory Science?

If regulatory science is to move forward implementing solution-based outcomes, it must communicate that the discipline can initiate problem solving thinking that is transferable to global and diverse health outcomes.

The regulatory science professional can apply critical inquiry movements and global skills to solve complex health related problems. Additionally, the learning of critical inquiry problem solving skills can be transferable to any future areas the regulatory science professional finds themselves. For example, they may move from drug development to devices. Or, from devices to nanoparticles. With the combination

of critical inquiry and global skills, the regulatory science professional can work in the world environment to foster positive multinational health outcomes.

Back to *Figure 2.1* at the beginning of this discussion. The key depicted is leading to a lock of biotechnology innovation. Note that the key's utility is coming from the creative inquiry movements, the global skills and the solution-based outcomes. All leading to the potential for positive global health outcomes, now and in the future.

2.7 Innovation with Constraints

The graphic depicts regulatory science as giving innovation some purposeful constraints. These are the constraints of safety, efficacy and quality. As pragmatic instrumentalism is the regulatory science's philosophy of technology because it stresses usefulness, so is the imposed constraints important for society. The following three examples depict situations in the biotechnology realm where innovation without safety considerations were harmful.

Example number one – sulfanilamide. "People today design their lives – that is, they try to think out in advance how to go about doing something, and in the process to bring to bear as much scientific information and technical competence as possible" (Mitcham & Holbrook, 2006, p. 107-108).

Sulfanilamide is an antibiotic used in World War Two and still today (Kent, 2000). However, there was a crisis with this drug in the 1930s, due to a product formulation with diethylene glycol. The drug had been used safely in tablet and powder form (Ballentine, 1981). In June 1937, a pharmaceutical salesman reported a demand for a liquid version of sulfanilamide. To meet the need, the company's chemist experimented and found that sulfanilamide would dissolve in diethylene glycol. The

chemist found it acceptable since the flavor was that of raspberries. The company immediately made more and shipped it across the country. The problem was the formation had not been tested in animals. Because of this, the company did not know that the liquid sulfanilamide was toxic.

In the early 1930s, the food and drug law did not require safety testing for new drugs or formulations. So, selling the toxic formulation was not illegal. Unfortunately, the chemist forgot to note one critical point. Diethylene glycol is deadly poisonous (Ballentine, 1981). As a result, more than 150 people died after ingesting this liquid version of sulfanilamide. Many were children (Ballentine, 1981).

Because of this tragedy, Congress passed the 1938 Food, Drug and Cosmetic Act. This act required that medicines on the market shall be safe for use under the directions listed on the drug label (Ballentine, 1981). Thus, the government had more control over drugs while still encouraging medical research. This brings us to the next example.

Example number two – thalidomide. "Design thus turns making (not to say living) into thinking – a thinking beforehand about how to make (or how to live). Is this simply an unqualified good? Or is it as problematic as that more here – and now making (and living) that it progressively replaces?" (Mitcham & Holbrook, 2006, p. 108).

Thalidomide was marketed in Europe as a mild sedative. The drug manufacturer claimed it was safe even during pregnancy (Science Museum, 2017). However, women using the drug were having babies born with severe limb deformities. The unsafe use of the drug was revealed in 1962. Before this, as mentioned earlier, drugs needed to be safe. But, now the question was if they were beneficial.

A German company was the originator of the drug. Thalidomide was an anticonvulsive. It made its users sleepy and relaxed. The company thought it would be perfect marketed as a new tranquilizer (Science Museum, 2017). It was also around this time that an Australian doctor started prescribing thalidomide off-label for morning sickness (Fintel, Samaras, & Carias, 2009). By 1960, the drug was marketed in many countries overseas, with sales as high as those for aspirin (Fintel, Samaras, & Carias, 2009). It was in 1961 that the Australian doctor began to associate severe birth defects in the babies born to mothers taking thalidomide. The problem was phocomelia which resulted in "flipper-like" shortened or absent limbs. Germany soon reported more than one hundred babies with defects associated to thalidomide. This caused the German manufacturer to stop marketing the drug. Soon, other countries followed and by 1962, it was banned.

The United States was spared from the tragic birth defects since Francis Kelsey, an FDA reviewer felt that even though the animal trials said the drug was safe, the human trials were inconclusive. Therefore, thalidomide was not approved for sale in the United States. Kelsey's wise refrain from approving the drug helped motivate changes. In 1962, legislators passed the Kefauver-Harris Drug Amendments Act. This act tightened up regulations around drug approvals saying new drugs needed both animal and human trials that displayed safety and efficacy (Fintel, Samaras, & Carias, 2009). Another case where research has needed more restrictions for innovation effectiveness. This brings us to our last situation.

Example number three – tegenero. "No engineer can be expected to be able to predict all aspects of the future. The future, and the future consequences of designs can be studied" (Mitcham & Holbrook, 2006, p. 115).

In 2006, a phase one clinical trial was conducted in six healthy human subjects. The drug was an antibody named TGN 1412. It had safe studies in its preclinical primate animal studies (Attarwala, 2010). No animals suffered from immunogenicity reactions which is an important consideration for biologic antibody drugs such as TGN 1412. Because of the safe animal trials, the antibody could proceed to human trials in Germany and the United Kingdom (Attarwala, 2010).

The six healthy subjects were given a "dose 500 times smaller" than the dose found safe in the primate preclinical trials. However, within minutes after receiving TGN 1412, all the subjects experienced life-threatening immunogenicity responses. The subjects were rushed to intensive care with multiple organ failure. Due to this catastrophe, there have been many learning points moving forward with innovative new drugs. Again, showing the importance of innovation with boundaries for optimal effectiveness and safety. Examples of lessons learned are the following (Attarwala, 2010):

- Using primates in preclinical studies for a biologic – Use caution in assuming primates are the best preclinical model.
- Lacking more human studies – Perform many *in vitro* trials on human material like the targeted tissue.

- Selecting the starting dose – Remember that animal studies can prove to be unreliable especially with biologics. It is important to provide extra safety precautions with antibodies.
- Timing for dosing of subjects – By the time the last subject was dosed with TGN1412, the first patient was showing immunogenicity. The first patient should be dosed and watched for a set time with blood work performed. Then, and only then, if not severe adverse events reported, should the next patient be dosed.

These three case studies illustrate that biotechnology innovation is important but with constraints.

2.8 Appropriate Time to foster a Regulatory Science Philosophy of Technology

It is an appropriate time to foster a regulatory science philosophy of technology. More and more demands are occurring around the world related to healthcare needs. Pragmatic problem solving with a combination of global awareness is necessary for advancement in the multinational healthcare environment. As described, the regulatory science philosophy of technology is one of instrumentalism. Instrumentalism is a "modern view according to which technology is a tool or instrument of the human species as a whole" (Feenberg, 2006, p. 11). Dewey (2015) added pragmatic in front of instrumentalism to mean a logical way to gather information about a problem, solve the problem, and then assess whether it is useful for society. An example was given to illustrate the pragmatic instrumentalist approach to solving administrative challenges in a multinational hospital. However, as shown in the examples of innovation without constraints, it is important to remember safety and quality for societal good. Thus, this

research suggests the pragmatic instrumentalism theory of technology for the regulatory science discipline. Such approaches can lead to positive global health outcomes, now and in the future.

Keeping pragmatic instrumentalism in mind, and the instruction of this philosophy in the regulatory science classroom, a thorough review of the literature was performed on the points below:

- On-line regulatory science learning techniques.
- Interactive regulatory science learning techniques.
- Global regulatory science learning techniques.
- Interaction between on-line, interactive and global regulatory science learning techniques.

As with lack of literature on the theory of technology for regulatory science, nothing was found regarding these specific query points above. Further, there is no previous research pertaining to role-playing simulations in the regulatory science classroom focusing on global skills. There is limited research on these concepts in the engineering and design classrooms. Thus, this literature review focuses on two disciplines in the technology field: engineering and design learning. This is logical because regulatory science is considered a technology field in Purdue University's Polytechnic Institute discipline. Further, regulatory science global skills resonate with design. The regulatory science problem solving similarities with the design's creative inquiry movements are outline below (Nelson, 1957):

- Invention – This step is the creation of new ideas in design. Likewise, this is the step to think of new medicines to meet unmet medical needs.

- Judgment – This step determines the probability of design project success. Like a designer, a scientist also needs to determine the feasibility of putting their molecule into clinical trials, and the viability of how the molecule can be taken to market.
- Connection and Development – This step connects the design with human satisfaction. Similarly, scientists, especially working with medical devices, consider the patient and how the device is used in daily living.
- Integration and Evaluation – This step evaluates the design for its worth. The same is true for a new medicine. Is it effective? Is it safe? Is it sustainable?

Global skills are another topic that links regulatory science learning to engineering and design learning. The ability to interact with different cultures is essential in our modern world economy. Global skills are becoming more important to employers. Managers want to hire individuals who display respect for others' beliefs, share their own beliefs, and recognize that beliefs are different. In addition, these global skills comprise the capability to orient behaviors and combine others' ideas when interacting with people from diverse career and cultural environments (Chan & Fishbein, 2009; Jesiek & Woo, 2011; Parkinson, 2009).

To tie these similarities together, this literature review is organized in several instructional strategy sections. The first section describes the need for global skills in technical areas like engineering and design. A connection to regulatory science is made throughout this section. The next section of instructional strategy examines the instructional delivery of global skills via on-line, interactive techniques. Again, a connection to regulatory science is made in this section.

2.9 Global Skills

Progress in computers and communications are significant catalysts for globalization. Extensive wireless networks with the internet have made it possible for more information to come into developing countries as they no longer need to depend on landline infrastructure (Parkinson, 2009). Theodore Kennedy, founder of B.E. & K., Inc., an engineering construction firm has said:

> Businesses need graduates who know something about working with others not just teamwork, which is a given – but a basic understanding that our culture is not the only one around! We must prepare engineers to be global citizens. They must learn to translate ideas and plans into reality for cultures that may not look, sound or dress the way we do (Kennedy, 2006, p. 16).

Many projects have tried to predict what competencies future professionals need. Such was the case with educating the engineer of 2020 project. Engineering education is essential to the discipline‘s success. In order to meet the engineering demands of 2020 and beyond, the engineering professionals that contributed to the project accepted as a given (National Academy of Engineering, 2004):

- Engineering instruction needs to produce innovative graduates.
- Engineering institution needs to develop its own curriculum.
- Engineering curriculum needs to address a global economy.
- Engineering research is needed because of the ever-changing technologies of social and economic structures.

Yet, the question remains how to approach these recommendations. Again, the engineering professionals recommended (National Academy of Engineering, 2004):

- Engineering education beyond the four-year degree to be considered the "professional" degree.
- Universities should encourage engineering education research so that new standards for faculty qualifications can be established.
- Institutions need to teach their students how to be lifelong learners.
- Case study examples of engineering successes and failures should be used as instructional tools.
- Universities should present to incoming students a "marketplace" of available engineering programs.

The key is innovation and it is argued that for engineering to be successful with new trends its students need flexible, adaptive education. An important step in developing adaptive curriculum is to re-brand the engineer's educational image. The re-branding needs to include images of engineering education as the path to future career opportunities. In addition, the re-branding needs to show engineers as life-long learners. The effort to predict the future competencies of engineers has been apparent with the engineers' 2020 project forcasting. However, after doing a thorough literature review, there is nothing to forecast competencies for regulatory professionals. When adding the competencies of quality to regulatory professionalism, the research of this dissertation is breaking new ground. What follows is first a grounding in the existing literature for engineering professionals.

Every decade, scientific and engineering knowledge doubles due to cycle time increases and ocassionally new disruptive technologies. New technologies are making existing technologies obsolete. Per the National Academy of Engineering (2004):

> "Recent and emergent advances, such as those in biotechnology, nanotechnology, information and communications technology, material science and photonics, and other totally unanticipated technologies will be among the changes with which engineering and engineering education will need to contend leading up to 2020 and beyond" (p. 7-8).

Corresponding with the National Academy of Engineering, the Central Intelligence Agency (CIA) predicts these trends for the future to impact the geopolitical landscape (CIA, 2001):

- Aging population.
- Demands on healthcare system.
- Heightened labor force contracts.
- Political instability.

With this in mind, an explosion in technology will encourage stakeholder "customerization." Per Wind and Rangaswamy (2001, p. 1), customization is a "buyer-centric business strategy that combines mass customization with customized marketing." This means more social interaction between the engineer and the customer necessitating the engineer to have robust people skills, along with the ability to solve problems. Since technology is ingrained in our everyday life, this necessitates the engineer to realize their skill set is also emeshed in social policy.

Engineering education needs to connect other disciplines for an holistic approach. The following are considerations:

- Engineering solutions need to employ scientific, professional, and technical solutions.

- Engineers need to have problem-solving skills.
- Engineers need to have set goals with the customer and can interact with the public.

Correspondingly, the engineer's education system should include:

- Assessment processes to propel students from level to level of knowledge acquisition.
- Instructors ascribing to new technologies, curricula, and laboratories.
- Goals of stakeholders employing engineering students.
- Continuous improvement processes to curricula as technology advances.

Quality is embedded in the future educational process by identifying what the final outcome is to look like and then reverse engineering to build back up to the desired state. Per the National Academy of Engineering (2004, p. 18-19), "Quality is measured in terms of both the product (Did we meet our specifications?) and the process (Is it simple, integrated, efficient?)."

An holistic approach to education including a quality foundation needs help beyond the university to reach this positive outcome. Both engineering and quality skills denotes a person of professional status. Engineering students and graduates are encouraged to maintain a professional identity. One way to do this is by joining a professional organization. Engineering faculty can take advantage of the "Excellence in Engineering Education" (EXCEED), a teaching workshop facilitated by the joint efforts of The American Institute of Engineers, the American Society of Civil Engineers, the American Society of Mechanical Engineers, and the Institute of Electrical and Electronics Engineers (ASCE, 2017).

Objectives for the workshop are the following:

- Assessing the classwork and curricula from both the instructor and student viewpoints.
- Creating and supervising student teams.
- Distance education best practices.
- Project based design and learning.

In addition, a collaboration between universities and professional societies fosters a research base for new innovation. This is in agreement with the National Science Board (NSB) which stated:

> The organizational stuctures and processes for educating, maintaining skills, and employing science and engineering talent in the workforce are diverse and their interrelationships complex and dynamic. As a result, production and employment of scientists and engineers are not well understood as a system (NSB, 2003, p. 26).

This perspective resonated with Williams (2003) who asserted that engineering as a profession is undergoing a revolutionary transformation. To meet the demands of the transformation, engineering practices need to understand evolving environment models. Examples exist. The University of Western Australia's (UWA) Engineering and Mathematical Sciences currently provides engineering research opportunities. For example, UWA has a research group devoted to Engineering for Remote Operations (ERO). Since UWA is globally located, its ERO research is appropriate for environmental changes. The program is described as follows, "ERO provides an integrated approach and solutions to the challenges of mining development and

production, offshore engineering, agriculture, health, transport, energy, water supply and community development. It is highly relevant to Western Australia and the Indian Ocean Rim and provides clear and measurable results for economics, industry, government and the community at a local and national level" (UWA, 2017, ERO website).

Other engineering research titles available at UWA are (UWA, 2017, ERO website):

- Advanced Sensing Technologies.
- Big Data Processing and Mining.
- Complex Data Modeling.
- Engineering Communities and Environment.
- Engineering System Health.
- Fluid Sciences and Resources.
- Offshore Facilities and Ocean Systems.
- Real-time Optimization, Scheduling and Logistics.
- Robotics and Automation.
- Structural Mechanics, Geomechanics and Computation.
- Bioengineering.
- Energy and Minerals Institute.
- Oceans Institute.

Similarly, the Integrated Teaching and Learning Laboratory (ITLL) located at the University of Colorado Boulder, is a sample of innovative strategy. This lab contains computers, personal computers (PCs), and workstations, all with the capabilities for simulations, data acquisition, data analysis, control of experiments, and multimedia

instruction (UCB, 1997). At the lab, students have the opportunity to design and build projects. They are able to test their products and rework if necessary. Students learn through reverse engineering, a concept mentioned previously in this paper.

Even the ITLL building has an innovative "inside-out" design. The structure exposes steel and concrete structural systems. Students can see strain gauges to measure deflection and loading by simply looking at the columns, beams and trusses. The windows have different types of glazing so that the students can observe differences in heat lose and solar gain. Students can even measure the structure's response to wind, heat, and cold. Fire protection, electric, and plumbing systems are also readily apparent (UCB, 1997).

The entrepreneurial role is another skill that the innovative professional needs, along with the innovation skill of communication. A case study of Olin College's School of Engineering illustrated that this approach produced positive outomes. Olin's School of Engineering was new and so they started with a blank slate for both the curiculum and faculty. It was a chance to be creative and innovative. Starting with the faculty, the provost searched for the subsequent traits (Kerns, 1999):

- Passion for education and teaching.
- Commitment to impacting student lives.
- Creativity as demonstrated through research, publications, and entrepreneurship.
- Integration of creativity in the classroom.
- Evidence of life-long learning.
- Risk taker.

To develop the curriculum, the project had four stages (Miller, 2000):

- Discovery – This phase investigated the best practices of other institutions.
- Invention – This phase adapted creative ways to develop the curriculum and to continuously evaluate the outcomes.
- Development – This phase made the goals and objectives a reality in the classroom.
- Test – This phase continuous tested for intended outcomes.

The goals and objectives for the innovative curriculum included:

- Participative design projects.
- Senior capstone projects to represent real-life professional practice.
- Team leadership opportunities.
- International and intercultural experiences.
- Contribution to society opportunities.
- Communication instruction both oral and written.
- Development of individuals that can communicate a new vision and bring it to reality.
- Business acumen instruction.
- Ability to demonstrate artistic expression.

Different from other curriculums was the idea that engineering students should have an arts and humanities education too. Also different was that engineering students have a basis of business principles. To achieve this was to cross-discipline with the humanities and business school. This was a breaking of discipline tradition and boundaries.

To update this case study, Olin College was successful in their approach to engineering education. The college now has a 4+1 engineering program so that students can continue from their bachelor's degree straight to a Master's. In addition, the college is a part of the Coalition for Access, Affordability and Success. The goal of this coalition is to broaden admission access and encourage students to enter the engineering profession from a holistic approach aquiring global competencies along the way (Olin College of Engineering, 2015).

Similarly, per Parkinson (2009), global competence means the following for engineering students:

- Appreciate other cultures – Understanding and circumventing the concept that your own culture is superior over another.
- Communicate across cultures – Realizing that each culture has their own way of communicating.
- Work effectively in transnational teams – Understanding that much work is done in teams, students need to value members from different cultural origins.
- Appreciate concerns facing mankind such as poverty, public health and sustainability – Accepting that solutions to these issues are worldwide.

To test this list with research, Parkinson (2009) gave a survey to industry and academic participants to determine which global competence was the most important. His findings ranked the following global competencies necessary for engineering students:

1. Appreciation of other cultures.
2. Effectiveness in transnational teams.

3. Communication across cultures.
4. Appreciation for worldwide issues.

Parkinson's (2009) study corresponds to the global BIRS skills examined in this research. Those being respect, recognition, adjustment and integration. Parkinson's (2009) global competencies are mapped in Table 2.2.

Table 2.2

BIRS Global Skills Mapped to Parkinson's (2009) Engineering Competencies

Parkinson's (2009) Engineering Competencies	BIRS Global Skills
Appreciation of other cultures	• Respect • Recognition • Adjustment • Integration
Effectiveness in transnational teams	• Respect • Recognition • Adjustment • Integration
Communication across cultures	• Respect • Recognition • Adjustment • Integration
Appreciation for worldwide issues	• Respect • Recognition • Adjustment • Integration

May, Wold, and Moore (2015) agreed with Parkinson (2009). These researchers explored the ability for engineering students to interact with different cultures in the modern world economy. Just as in this research with regulatory science students, May,

Wold, and Moore (2015) focused their study with the premise that engineering students needed interactive role-playing simulations in global environments to help them develop transnational skills.

After given a transnational problem to role-play, student interviews were transcribed and coded using the "respect, recognize, adjust and integrate" (Fourman, 2017, p. 6) domain in NVivo software. Written surveys were also used for qualitative purposes. Like this research, May, Wold, Moore's (2015) participants represented students both from the United States and abroad.

Regarding the respect domain, several students began the class displaying interest in knowing about other cultural viewpoints. For the recognize domain, the student comments indicated they all recognized differences exist among people from multiple cultures. In the adjust domain, all students studied adapted to a discussion format and became active participants during the role-playing. Lastly, for the integrate domain, no students were unwilling to participate (May, Wold, & Moore, 2015).

May, Wold, and Moore (2015) concluded that creators of engineering curricula should incorporate in their courses more situations of active dialogue with transnational students on real-world problems. This research confirmed that it is important in today's global workplace for students to acquire the skill to display respects for others' beliefs. Further, students need to be able to share their own beliefs appropriately and recognize that beliefs are culturally different (Fourman, Clase, Byrn, Ekeocha, Umberger, & Terruso, 2017).

Empathy is another BIRS global skill that this research is examining. There has been a lack of research regarding empathy in the discipline of engineering. However,

holistic engineering has embraced many empathic and caring attitudes (Strobel, Hess, Pan & Wachter Morris, 2013). For example, Strobel et al. (2013) listed several of these characteristics from the engineering literature (p. 138):

- "Flexibility, receptiveness to change, and mutual respect" (National Academy of Science, 2005, p. 10).
- "Respect for ways of life different from ours" (National Academy of Science, 2005, p. 152).
- "High ethical standards" (National Academy of Engineering, 2004, p. 56).
- "Interaction with increasingly interdisciplinary teams, globally diverse team members, public officials, and a global customer base" (National Academy of Engineering, 2004, p. 55).
- "Well-developed people skills in addition to their ability to solve problems" (National Academy of Science, 2005, p. 10).
- "Capacity to hear and to develop relationships that provide the basis for partnering to solve problems, both within the academy and without" (Koshland, 2010, p.66).

Strobel et al. (2013) searched the literature for references to empathy in the engineering education literature. They compared their findings to Kunyk and Olson's (2001) five conceptualizations of empathy: "empathy as a human trait, empathy as a professional state, empathy as a communication process, empathy as caring, and empathy as a special relationship" (p. 138).

Regarding "empathy as a human trait" (Kunyk & Olson, 2001, p. 138), the researchers concluded that engineering faculty did not mention this skill in their

scholarship. The engineering faculty assumed that empathy is a part of certain design acts (Strobel et al., 2013). Further Strobel et al. (2013) were unclear if engineering faculty felt this could be taught in the classroom.

In contrast, "empathy as a professional state" (Kunyk & Olson, 2001, p. 138) resonated with participants in the study. However, rather than citing how empathy could be taught, participants wrote that empathy should be stressed in the concept of successful engineering design (Fourman et al., 2017). The participants felt it could give engineering students an advantage over the competition if they displayed empathy in organizational team activities. Based on this finding, Strobel et al. (2013) found that "empathy as caring" (Kunyk & Olson, 2001, p. 138) had an action connotation. The study participants made a distinction between empathy and caring. The act of doing was associated with caring. Empathy, on the other hand, was associated with an attitude. Yet, the participants in the study had concrete examples of empathetic activities in the workplace (Fourman et al., 2017).

"Empathy as a communication process" (Kunyk & Olson, 2001, p. 138) was deemed as an asset in team-oriented activities. Again, there was no suggestion on how to teach this process. However, empathic communication was found to be useful, not only with teams, but with all stakeholders, as well (Strobel et al., 2013).

Lastly, Strobel et al. (2013) found that "empathy as a special relationship" (Kunyk & Olson, 2001, p. 138) was a way for engineers to solve a problem. In conclusion, empathy was a means to an end to achieve a goal. Strobel et al. (2013) also concluded that outside of the engineering education platform, the concept of empathy as a skill was

scare. This is important to the regulatory science discipline since this research is exploring the gap of empathy as a teachable skill (Fourman et al., 2017).

As stated previously, May, Wold, and Moore (2015) used effectively role-playing simulations in the engineering classroom. This technique was also effective in the design classroom. Gray, Debs, Exter, and Krause (2016) took a role-play instructional technique one more step and looked-for empathy in the interaction. The researchers framed the design problem which allowed the students to identify a global project content, and research to drive insights to a transnational solution (Fourman et al., 2017).

Students had many tools at their disposal to solve the problem. Nevertheless, the students experienced an empathy barrier and filtered the class information through their own lived experiences in egocentric ways (Fourman et al., 2017). They tended to revert to familiar viewpoints of analyzing the design situation. One student even recommended more linking of the empathy material to the final project. Gray et al. (2016) observed that students put their cultural and social locus much closer to North America rather than the region that they picked to explore. Whether that area of exploration was Southeast Asia, Sub-Saharan Africa or another third-world environment (Fourman et al., 2017).

Gray et al. (2016) determined that using McDonagh-Philp and Denton's (1999, p. 22) "empathic horizon" was helpful to encourage the students to employ empathic skills within the problem solution. This framework has the design student in the center of a complex environment with many confounding factors such as culture, nationality, education, and background experiences (Gray et al., 2016). When students understand that they need to expand their cultural horizon, they become more involved in the problem solution process (Gray et al. 2016).

McDonagh-Philp and Denton (1999) based their study on Hopkins and Bollington's (1985) five-part structure: "a preliminary, anticipatory stage; immersion in data and the generation of categories/hypotheses; validation of categories/hypotheses; interpretation by reference to theory, practice or professional judgment; and action for improvement" (p. 70).

This is an appropriate way to end this section discussion because Hopkins and Bollington's (1989) five-part model for framing global problems maps back to Nelson's (1957) creative inquiry movements, which maps back to the BIRS global skills studied in this research. This integration of concepts is illustrated in Table 2.3.

Table 2.3

BIRS Global Skill Integration

Hopkins & Bollington's (1989) Five Part Structure	Nelson 's (1957) Creative Inquiry movements	BIRS Global Skills
Preliminary anticipatory stage	Integration	Integration
Immersion in data and the generation of categories/hypothesis	Judgment	Recognition
Validation of categories/hypothesis	Connection and development	Adjustment
Interpretation by references to theory, practice or professional judgment	Invention	Empathy
Action for improvement	Evaluation	Respect

2.10 Instructional Delivery

The next section of this literature review discusses in more detail the components of learning strategies examined in this research. Those being global on-line, interactive and simulated learning techniques. Though role-playing is mentioned in the first part of the literature review, it is cited in conjunction with global skills, especially empathic learning. This part of the literature review looks at learning using role-playing as a simulated learning technique in more detail.

Keegan (1996) started this discussion with characteristics of distance education:

- "The quasi-permanent separation of teacher and learner throughout the length of the learning processes (this distinguishes it from conventional face-to-face education);
- The influence of an educational organization both in the planning and separation of learning materials and in the provision of student support services (this distinguishes it from private study and teach-yourself programs);
- The use of technical media – print, audio, video or computer – to unite teacher and learner and carry the content of the course;
- The provision of two-way communication so that the student may benefit from or even initiate dialogue (this distinguishes it from other uses of technology in education); and
- The quasi-permanent absence of the learning group throughout the length of the learning process so that people are usually taught as individuals rather than in groups with the possibility of occasional meetings, either face-to-face or by electronic means, for both didactic and socialization purposes" (Keegan, 1996, p. 50).

Table 2.4 compares Kegan's (1996) definition of distance learning to the *BIRS Experience* at the Kilimanjaro School of Pharmacy (KSP) in Moshi, Tanzania.

Table 2.4

BIRS Experience Comparison to Keegan (1996, p. 50)

Keegan (1996) Definition of Distance Learning	*BIRS Experience* at KSP
Quasi-permanent separation of teacher and learner	Educators are on-site for only two-weeks of the semester. The rest of the semester is spent using Blackboard Learn and WebEx.
Influence of education organization for planning	The BIRS Center at Purdue University Polytechnic Institute organizes the teaching material. This was the case with the *BIRS Experience*.
Use of technical media	During the two-weeks at KSP, lectures were recorded and posted to Blackboard Learn. Students also had internet access so that they could view both the lecture screen and Blackboard Learn simultaneously.
Provision of two-way communication	When not on site at KSP, WebEx was used to connect with the students. This was a way for the students to ask questions. Students were also encouraged to ask questions via email or phone conversation.
Occasional meetings with learning group	WebEx was always open to students and faculty of the *BIRS Experience*. This gave the opportunity for class discussion, as well.

Similarly, Benson and Samarawickrema (2009) examined case studies from globally located universities to explore the impact of distance learning.

> These issues arise from the separation between learners, and between teacher and learner, which occurs when learning is undertaken wholly or partly online. There may be important implications that emerge from aspects of separation, depending on whether students are studying primarily on-campus, off-campus, transnationally, or in specific contexts such as the home, the workplace, fieldwork locations, or other places made possible by mobile learning technologies (Benson & Samarawickrema, 2009, p. 5).

After their case study analysis, Benson and Samarawickrema (2009) proposed ways to enhance distance education. Their first recommendation was to structure the content of the instruction in such a way as to optimize student interaction. This was apparent with the *BIRS Experience* simulation. After the *BIRS Experience*, the students presented their ultimate project to a mock ministry of health.

Another recommendation from Benson and Samarawickrema's (2009) research was to supplement the face-to-face teaching with brief on-line support. This was true from the transnational element of the *BIRS Experience*. Our Africa students did not always have reliable internet during a WebEx. For this reason, each WebEx was only scheduled for approximately an hour (Fourman et al., 2017). They were also recorded and posted to Blackboard Learn in the event parts of the WebEx could not be heard. By posting to the TLI 524 site on Blackboard Learn, the students had the opportunity to refer to the conversation when their internet came back.

Like the *BIRS Experience*, Andersson and Andersson (2010) developed an engineering role-play simulation. They too, constructed the simulation like a real-world engineering experience for university students. Upon evaluating their simulation, they concluded that:

- Professional skills being taught should be explained to the students at the beginning of the role-playing simulation.
- The simulation should be the culminating activity in the course.
- The supplemental exchanges with the students are to encourage the students to do their best.
- The rules and time-line for the role-playing should be as real-life as possible.

However, Andersson and Andersson (2010) felt that professional skills seem to be an elusive concept. Thus, they encouraged more research in teaching real-world skills. Again, the BIRS Experience can be directly mapped to Andersson and Andersson's (2010) role-playing recommendations. The comparisons are depicted in Table 2.5.

Table 2.5

BIRS Experience Comparison to Andersson and Andersson (2010)

Andersson and Andersson's (2010) Role-playing Recommendations	*BIRS Experience* Role-playing Characteristics
Professional skills being taught should be explained to the students at the beginning of the role-playing simulation.	Objectives of the *BIRS Experience* are given to the students at the beginning of the simulation.
The simulation should be the culminating activity in the course.	The *BIRS Experience* has a final paper and students give a presentation at the conclusion.
The supplemental exchanges with the students are to encourage the students to do their best.	Students ask questions during WebExs and had supplemental information on Blackboard Learn.
The rules and time-line for the role-playing should be as real-life as possible.	The *BIRS Experience* is about a real-life situation of getting a drug to market. Here is what the students are told at the beginning of the simulation: • The role-play is about a pretend drug called ClaseaByrnib, a biological treatment for osteoarthritis. • It is a type of medication that functions by inhibiting the activity of one or more of the Janus kinase family of enzymes (JAK1, JAK2, JAK3, TYK2) thereby interfering with the JAK-STAT signaling pathway. • The therapeutic application is the treatment of inflammatory diseases. • The dosage form is parenteral. • The intended population is pediatrics through elderly. • The development team is after clinical trial Phase 2 and has a dosage strength. • ClaseaByrnib has breakthrough efficacy.

The research of Kozma (2003) supports the *BIRS Experience* from a global perspective. In his research, innovative learning strategies were studied in 28 countries. The research examined 174 case studies worldwide on how technology is being used to change the practices of students and instructors. The research was to demonstrate that technology is impacting institutions where students search for information and publish their research. Kozma (2003) cited the research of Bransford, Brown and Cocking (2000), that claimed using new technologies was consistent with learning innovations. They posited that the new technologies could bring global real-life problems to the classroom. To this end, OECD (2001) said students have enhanced means to learn necessary skills for the modern economy such as problem-solving, collaboration and communication.

To look at how technology is different in the classroom around the world to achieve these enhanced communication skills, Kozma (2003) used a global team of scientists to help study the use of technology to foster learning strategies. The focus of this expert panel was on the innovative technology pedagogy themes practiced in the classroom. Cases were selected in each country that demonstrated a set of internal criteria. The criteria included (Kozma, 2003):

- Impactful changes in curricula, instruction and student learning.
- Technology as a catalyst in fostering instructional change.
- Technology used to enhance positive educational outcomes for both instructors and students.
- Changes are innovative, yet sustainable and can be transferred.

As stated previously, the cases were analyzed by a global panel of researchers, instructors and policy makers. The analytic techniques were both a blend of quantitative and qualitative strategies (Tashakkoni & Teddlie, 1998). The cases were read and coded by the panel of experts based on similarities and differences of technology, instructional strategies and outcomes. Of the 94% of computers used for learning strategies, software packages were employed to create presentations and products (80%). E-mail was used to enhance instructor and student communication (55%) (Kozma, 2003). Per Kozma (2003), the innovative technology enhanced collaboration skills by 63%, communication skills by 29%. This study corresponds to the global skill student expectations of the *BIRS Experience*. The similarities are software used to create reports and give presentations. Along with technology like Blackboard Learn to enhance instruction.

Because the *BIRS Experience* is about drug development, it is logical to also look at simulations focusing on a laboratory environment. Perez, Dormido and Vlacic (2011) explored how universities could give real-world simulated experience to students when building physical, bench top teaching laboratories. This study is also pertinent because the researches used participants from a transnational setting, the University of Newcastle, Australia. Another similarity with Perez, Dormido and Vlacic's (2011) research and the *BIRS Experience* is that the researchers created their own supplemental materials to use during the simulation. They created two resources. One was titled an *Animated Control Systems Tutorial* (Perez, Dormido, & Vlacic, 2011, p. 7269) and the second tutorial was titled a *Virtual Control Systems Design Laboratory* (p. 7272).

The researchers hypothesized that the *Animated Control Systems Tutorial* (p. 7269) and the *Virtual Control Systems Design Laboratory* (p. 7272) would reduce the

"fail" grade in two introductory engineering classes. In these two tutorials, a set of 24 control system examples depicting real-life simulations were created. The examples further explained control concepts that the students had mastered in course discussions. The examples were organized in three principle phrases: problem definition, solution and animation. The animation phase used FLASH multimedia software. Using this software allowed students to visually relate to real-world problems, understand the solution proposed and interact with the situation dynamics.

After using this teaching technique, the students were asked in their evaluation the measured questions – "Overall, how effective was this course in helping you to learn?" (Perez, Dormido, & Vlacic, 2011, p. 7273) and, "Overall, how effective was this lecturer/tutor in helping you to learn?" (p. 7273). A "fail" grade in the courses was also annually tallied from 1997 to 2011.

The results of Perez, Dormido and Vlacic's (2011) research found that both real-world simulation tutorials attributed toward minimizing the class "fail" grade from approximately 12.5% to zero in the introductory engineering course, and from approximately 9% to zero in the digital control systems introductory course over a period of 15 years. In addition, course evaluation scores increased from approximately 60% to 80%. This shows a rise in course content satisfaction after implementing the simulation tutorials. The research suggests that interactive and simulated laboratory simulations can be used to improve "fail" grades. Simulations of real-world experiences also contribute to increased student satisfaction with course content.

Another example is from Wilck and Kauffmann (2013). These two researchers looked at two courses that had the same content, but were delivered differently. One

course was delivered on-line and the other one was the traditional student with teacher, in a classroom setting. What makes this study pertinent for this research is that the *BIRS Experience* is delivered to the KSP students in Moshi, Tanzania, mostly on-line via Blackboard Learn. The United States students had the *BIRS Experience* delivered in a traditional classroom setting at Purdue University, Polytechnic Institute, West Lafayette, Indiana.

Wilck and Kauffmann (2013) wanted to see if the two different delivery methods had comparative learning outcomes. In addition, they looked at ways to improve the course regardless of delivery methods. Like the *BIRS Experience*, efforts were made to keep the lectures delivered to the classes consistent. Also, like the *BIRS Experience*, supplementary materials for the classes were posted on Blackboard Learn.

To obtain their results, Wilck and Kauffman (2013) used two data sets: student surveys and certain assignments. The final grade in the two sections was also compared. The average final grade for the traditional classroom was 79.1% and for the on-line classroom 78.1%. The researchers suggest that this indicates a slight dissatisfaction with the on-line course. However, this was not statistically significant. The student surveys told a different story. Approximately 30 % of the on-line student surveys had negative responses while the rest were positive. Wilck and Kauffmann's (2013) results are consistent with prior literature regarding on-line courses versus traditional classrooms (Mackey & Freyberg, 2010; Peercy & Cramer, 2011).

As we have seen, the use of technology in the instructional setting may provoke an organizational culture shift (Buchanan, 2015). Both using and designing technology for instruction is enhanced by what Buchanan terms "design thinking." Both

administrator and instructor need to collaborate for technology implementation to be successful. This puts both parties in leadership roles. Senge (2006) wrote:

> The essence of the new role (of leaders), I believe, will be what we might call manager as researcher and designer. What does she or he research? Understanding the organization as a system and understanding the internal and external forces driving change. What does he or she design? The learning process whereby managers throughout the organization come to understand these trends and forces (p. 299).

Design thinking is the bridge spanning community involvement and classroom technology implementation. Per Simon (1996), this type of thinking is creative inquiry. Creative inquiry has concern for the limits of cognitive load of information that is held by an individual. It is also concerned with the movement in communication among those involved in the new technology (Buchanan, 2015). Thus, creative inquiry is the discipline and practice of asking and answering question about "the purpose, form, materials and efficient production of a desired result to reach a specified outcome" (Buchanan, 2015, p. 14).

Correspondingly, this section will examine research employing creative inquiry movements as data gathering paradigms. Kimbler and Melloy (2008) have used creative inquiry in industrial engineering at Clemson. The researchers have developed a creative inquiry rubric with the following objectives (Kimbler & Melloy, 2008, p. 52):

- Provide creative inquiry experience to all undergraduates at all academic levels.

- Improve the value of senior year experiences by integration with creative inquiry in earlier years.
- Inspire students to consider advanced degrees earlier.
- Provide a model for creative inquiry in engineering bachelor's degrees.

Table 2.6 matches this rubric with Nelson's (1957) creative inquiry movements.

Table 2.6

Clemson Rubric Matched to Creative Inquiry Movements

Clemson Rubric (Kimbler & Melloy, 2008, p. 52)	Creative Inquiry Movements (Nelson, 1957)
Provide creative inquiry experience to all undergraduates at all academic levels.	Invention
Improve the value of senior year experiences by integration with creative inquiry in earlier years.	Judgment
Inspire students to consider advanced degrees earlier.	Connection and Development
Provide a model for creative inquiry in engineering bachelor's degrees.	Integration and Evaluation

From these objectives, the Clemson engineering students will have the following competencies (Kimbler & Melloy, 2008):

- Ability to engage in critical thinking for engineering research or design.
- Constructively integrate and evaluate engineering discovery processes.

- Communicate the creative inquiry outcomes.

Kimbler and Melloy (2008) have integrated creative inquiry into the engineering curriculum. This integration is an on-going data collection project since the creative inquiry program is voluntary. Research results on the effectiveness of the program are anecdotal. However, it is suggested that the researchers' perception is that student research is growing because of the creative inquiry curriculum. Final evaluation of the program has yet to be conclusive.

Mulvihill and Swaminathan (2011) employed technology to enhance a qualitative research class. The researchers wanted to engage students into using educational technology for research data designs, collection, analysis, and display. One technology that the researchers used was blogs. Mulvihill and Swaminathan (2011) posted assignments on the blog. However, they found that the digital discussion became data itself. Thus, they could conduct a "metro-analysis to examine not only the content of the blog, but also the multi-vocal content within which the blog content is being constructed" (Mulvihill & Swaminathan, 2011, p. 23). In addition, social media tools were used such as Facebook, Twitter and Surveymonkey. From these tools, qualitative transcripts were generated.

These methods can be put into the creative inquiry framework:

- Invention – Technology used to enhance qualitative research class.
- Judgment – Determining how data can be collected from the technology.
- Communication and Development – Students were more likely to use social media since their peers use these tools.
- Integration and Evaluation – Meta-analysis from the blogs was an option.

The researchers felt that there is positive ways technology can help with qualitative data collection. Mulvihill and Swaminathan (2011) are continuing to research the intersection of electronic technologies and creative inquiry in this field. Costantino (2015) used creative inquiry in the form of an in-process critique to enhance creative problem solving in a design studio classroom. This researcher was focused on analyzing ill-structured problems. Per Costantino, artists and designers are interested in problem finding and framing. The researcher used solution-based techniques to identify open-ended, ill-structured problems. Solution-based instruction consists of the following six steps (Costantino, 2015, p. 119):

1. Overview in which the facilitator describes the focus of the session.
2. Presentation of the artifact, observation, or issue by the presenter (who is different from the facilitator) in which the presenter explains what is to be "tuned" to the question or concerns that should focus the feedback.
3. Opportunity for participation to ask the presenter clarifying questions.
4. Discussion of the artifact or issue during which the presenter remains silent, listening and taking notes.
5. Presenter reflects on the feedback.
6. Facilitator debriefs the session.

Critiques can be carried on between teacher and student or, student and group. Often critiques serve as a part of a project's final assessment. Different ways to conduct the critique can be used. For example, the teacher can ask the student questions or classroom peers can do so. Regardless, the critique is an important part of the design

studio pedagogy (Sutton, 2013). Table 2.7 aligns the solution-based steps to the creative inquiry framework.

Table 2.7

Problem-Based Learning Matched to Creative Inquiry Movements

Problem-Based Learning (Costantino, 2015, p. 119)	Creative Inquiry Movements (Nelson, 1957)
Overview in which the facilitator describes the focus of the session. Presentation of the artifact, observation, or issue by the presenter (who is different from the facilitator) in which the presenter explains what is to be "tuned" to the question or concerns that should focus the feedback.	Invention
Opportunity for participation to ask the presenter clarifying questions. Discussion of the artifact or issue during which the presenter remains silent, listening and taking notes.	Judgment
Presenter reflects on the feedback.	Connection and Development
Facilitator debriefs the session.	Integration and Evaluation

Costantino (2015) commented that future strategy is warranted to determine the potential for in-process critique as a tool of student learning.

Activity theorists have always addressed practical needs, putting their efforts towards education, design and evaluation. Contrary to its name, Activity

Theory is a distinctive platform other than a robust probable theory. Activity Theory helps us comprehend the connection of activity and cognizance. To do this, Activity Theory builds on intentionality, history, mediation and collaboration. Through these activities, consciousness is built around everyday activities. People do everyday activities in a social matrix made of social interactions and artifacts. Artifacts can be tangible tools or symbols like language. "Understanding the interpenetration of the individual, other people, and artifacts in everyday activity is the challenge activity theory has set for itself" (Nardi, 1996, p. 4). Researchers studying these classrooms have used Activity Theory to qualitatively determine educational outcomes.

Similarly, creative inquiry movements use techniques of asking and answering pivotal question about the goals of a desired result to obtain a specific outcome. It employs looking at structure, materials and forms of inquiry but also at reflection and action. This will lead to a discussion of educator distributed cognition regarding technology use with a compare of Activity Theory and creative inquiry movements.

To give background information, a discussion follows on constructivist theory regarding people using computers to enrich information delivery and storage. The use of any computer program to collect, store and distribute information in a classroom can be disruptive (Ramos, Berry & Carvalho, 2005). With the disruption, user resistance is often apparent. This is clear in a classroom where the educator has traditionally maintained control, especially in a university setting. When a computer system is implemented, an educator is expected to display behavior such as "flexibility, creativity, collaboration and continuous learning" (Ramos, Berry & Carvalho, 2005, p. 481). The computer system is to encourage the educator to be motivated and more efficient. If this

viewpoint is overlapped with constructivist theory, which examines how people come to share an assumption about reality, then we see educators expected to embrace computer programs.

At times, the institution's management will initiate the computer programs. Management have their goals. However, the management's goals may not be the same as the educators. Yet, both management and the educators make up the learning institution. If the learning institution is deploying the software, then it is expected that the computer with its software becomes part of the constructed reality (Ramos, Berry & Carvalho, 2005). Therefore, how an institution integrates the new technology will result in it being well rated and used by both educator and student. Thus, while "creating new learning environments or learning communities, it is not just a matter of implementing and putting into use new technology but in many cases, also applying simultaneously new practices of learning and instruction" (Lipponen, 2002, p. 6).

These concepts are further confirmed in the article titled "A Cultural-historical Approach to Distributed Cognition," by Michael Cole and Yrjo Engestrom (1993). In this article, the authors explored approaches to distributed cognition from an historical and cultural perspective. The intended audience for this article is educators and other people interested in how cognition impacts collaborative education and work systems. This makes sense since both authors are interested in cognition distributed across people and their environments. For example, Michael Cole is the head of the Laboratory for Comparative Human Cognition at the University of California, San Diego. He is presently working with the intellectual and social development of children. His laboratory is a center of interdisciplinary people who share interests in the human mind,

culture, history, and problems of social inequality. The other author, Yrjo Engestrom runs the Center for Activity Theory and Developmental Work Research at the University of Helsinki. He is currently working on co-figuration of work activities in disconnected environmental settings. Engestrom's interests are in culture and history and how both influence the workplace.

The authors have compiled their article around historical interpretation of distributed cognition. They start with Wilhelm Wundt. Per Cole and Engestrom (1993), Wundt studied accumulated, culturally organized knowledge as revealed in the written accounts of explorers and early anthropologists, philosophers and historians. Wundt came up with a system he called "physiological psychology" which, per Cole and Engestrom (1993), is the study of immediate experience constructed around the scientific method. Wundt conducted experiments where the subjects were presented carefully controlled stimuli whose results could be traced back to physiological principles. Wundt then broke down the physiological principles into simple reactions that he claimed took place inside of individual people's minds. He concluded that human language was a very complex system.

Wundt continued by saying that complex human systems such as language could not be studied by laboratory methods. Rather, such physiological systems needed to be studied by descriptive sciences. Further, that experimental sciences and descriptive sciences could complement each other, then and only then could "full psychology" be achieved. Cole and Engestrom (1993) continued by saying, "In modern terms, Wundt was arguing that while elementary psychological functions may be considered to occur in

the head, higher psychological functions require additional cognitive resources that are to be found in the sociocultural milieu" (p. 3).

The authors next discussed Hugo Munsterberg. Munsterberg argued that understanding happens not only in people's minds but also in the purposefulness of communication. Per Munsterberg (1914),

> A letter, a newspaper, a book, exists outside of the individuals themselves, and yet it intermediates between 2 or between millions of persons in the social group...The book remembers for the social group, and the experiences of the group, objectively recorded in it, shape the social action and the social thought. The letter can connect any distant social neurons; the paper may distribute the excitement from one point of a social group to millions of others. Every objectified expression becomes a social short cut (p. 267-268).

Vygotsky's viewpoints of distributed cognition were next. Per Cole and Engestrom (1993), Vygotsky (1978), explained that what was thought of in the past as "two-sided notion of tool mediation" is the same phenomenon. In other words, mediation through signs is more inwardly focused toward "the self," whereas, mediation through tools are more outwardly focused. Vygotsky continued by saying artifacts are both symbolic and material. These artifacts regulate interaction with one's environment. Tools are broadly determined with the main tool being human language.

Cole and Engestrom (1993) continued with their discussion by mentioning Gregory Bateson. Bateson was interested in brain activity he felt was determined by the environment. To show how essential the environment was to cognition, Bateson offered the description of a blind man and his walking stick. Bateson (1972, p. 459) said,

"Suppose I am a blind man, and I use a stick. I go tap, tap, tap. Where do I start? Is my mental system bounded at the hand of the stick? Is it bounded by my skin? Does it start halfway up the stick?"

Bateson continued by saying that the blind man's interpretation of the stick changes with his environment. For example, when he sits down to eat, the blind man's thoughts are not totally on the stick, but on the silverware at his place-setting. However, when the blind man leaves the lunch room, he is again one with his stick. So, it is that, "the notion that mediation of activity through artifacts implies a distribution of cognition among individual, mediation, and environment, as well as, the fundamental change brought by artifact-mediated activity" (Cole & Engestrom, 1993, p. 13).

The authors pointed out that a distributed idea of cognition also stems from the paradigm of knowing who in your culture will distribute needed information. Geertz (1973) proposed that, "culture is best seen not as complexes of concrete behavior patterns – customs, usages, traditions, habit clusters...but as a set of control mechanisms – plans, recipes, rules, instructions (what computer engineers call 'programs') – for governing behavior" (p. 44).

Continuing with tool mediation, D'Andrade (1986) referred to tools as helping a person accomplish cognitive tasks. An example of such a tool is a checklist. From this, Cole and Engestrom (1993) said we see the progression to modern times of the concept of distributed cognition between a person, a tool or artifact, and his/her surroundings. The article highlighted two case studies regarding distributed cognition. The first pertained to reading acquisition. Cole and Engestrom (1993) claimed the process of reading acquisition remained disputed. Especially disputed was the challenge of "reading

with comprehension" as opposed to just word recognition. The authors said that the problems with research on reading was the fact that the studies did not consider distributed properties of cognition. In addition, the studies were minimal in their framing of reading as a joint cognitive activity between teacher and students.

Modern reading studies have a conscripted series of levels. The levels start with the learning of letters, then words, and then sentences. It can be said that the levels of reading move in a bottom-up pattern. Reading comprehension, on the other hand, moves in a top-down process. There lies the problem of how to also put reading comprehension as a teachable skill at the bottom of the process. That way, comprehension can move-up with the fundamentals of letter and word recognition. One way that this can be accomplished is with the student and teacher reading the text together. They can then jointly discuss the text. The teacher can ask the student about the main idea, and what will happen next. Ideally, the dialogue between the teacher and student will ease the cognitive load.

Cole and Engestrom (1993) tested this cognitive distributed learning to reading ideas with a system called Question-Asking-Reading. Using this system, small-groups of students and instructors are created. Within the group, each person takes a role:

- A student who asks the instructor regarding words that are difficult to pronounce.
- A student who asks the instructor about the words that are hard to understand.
- An instructor who asks the students about the main idea.
- A student who asks other students what is going to happen next.

To assess how Question-Asking-Reading works, Cole and Engestrom (1993) collected data from videotaped recordings of the reading sessions. Quizzes were given at the end of the sessions, as well as, other reading tests.

King (1988) replicated the study and found that children retained more in the Question-Asking-Reading group, then did the no-treatment control group. King also found that students in the Question-Asking-Reading cluster demonstrated more enthusiasm for the reading content.

The second case study is regarding distributed cognition in a Finnish health center. This facility provides primary healthcare to a middle-sized city (Engestrom, 1990). The study started by interviewing 16 physicians. The interview survey contained questions about the physician's conception of the object of their work. The questions also asked hypothetical opinions about medical judgement. For example, a patient comes to the physician for no apparent reason. Another judgement question concerns a patient that comes in with non-descript symptoms. Another question regards a patient with mental problems, and a patient with a self-made diagnosis. Answers to the interview were categorized into five frames of reference from the literature. These were from "culturally deep-seated theoretical patterns of thinking about illness" (Cole & Engestrom, 1993, p. 31).

It is important to note that any patient can see any doctor. The doctors had no permanent patient list which caused disunity and anonymity in the doctor-patient relationship. The fact that a patient saw whatever doctor was on duty caused strong production pressure and encouraged an atmosphere of urgency. To make matters worse, the physicians had no time to discuss with each other complex patient cases. The only

tool that brought medical cases into a narrative was the patient's electronic record. However, these were entered by a nurse as she or he assisted each physician. It was unusual for the physician to even look at past medical records. This was because the scheduling of patients was so tight, there was not enough time for any research and/or reflection.

Engestrom (1990) said this healthcare facility had the following ruptures in their distributed cognition system:

- Each doctor is separated from the other.
- The facility required speedy consultation and diagnosis on only current medical symptoms.
- The medical record did not serve its full purpose.

Engestrom (1990) externally represented the facility's disconnections. From this representation, he convinced the facility's overseers that cognitive distribution reform was needed. Key features of the proposed new system follow:

- Each physician to be assigned a geographic town area with the population being approximately 2,000 to 2,500 people.
- A team to be formed from adjoining geographical area physicians.
- The team to have its own consulting area in the facility.
- The team to meet regularly to discuss patients.
- The team to be responsible for its own functioning and governance.

The implementation was successful. Thus, the long waiting lines were eliminated. Also reduced was the walk-in patient load.

The authors claimed the re-organization of the facility was due to the new relationship between doctor and patient. Instead of urgent care being the norm, the doctors were now responsible for the long-term health of their designated geographical area. One doctor commented, "In this new model of work, it makes sense to treat patients who have prolonged problems actively from the beginning. You can't deal with the problem shortsightedly, like here is medicine and come back if it continues because the patient comes back to you. It's better to spend a bit more time the first time, you'll get the benefit when it continues. I mean, do it properly right away. Previously, we were tempted to do it more superficially and we hoped that the patient would go to someone else if the problem continued" (Cole & Engestrom, 1993, p. 39-40).

This article will also introduce the reader to a new term of distributed cognition – expansive cycle. The expansive cycle is a developmental process that combines previous cultural characteristics with the creation of new tools and ways of interaction. The expansive cycle can only be achieved with comprehensive data collection as in the Finnish healthcare facility environment. The authors continued to call the research necessary for an expansive cycle to be constructed – "creative externalization" (Cole & Engestrom, 1993).

Cole & Engestrom (1993) tied this back to the beginning of their article by claiming this creative externalization is like going through Vygotsky's Zone of Proximal Development. The gap being the space between what an individual can do without assistance, and what they cannot do. This corresponds to how educators perceive cognition.

Per Sfard (1998), the way educators perceive the learning task can be described in two metaphors – acquisition and participation. In the acquisition metaphor, educators package the information and transmit it to the students. In the participation metaphor, the learning process is collaborative. Yet, the participation metaphor seems to skip the step that learning is acquired. Koschmann (1999) said these two metaphors are too segmented. Instead, Koschmann (1999) proposed a "transaction metaphor" that incorporated both participation and acquisition. Correspondingly, Gifford and Enyedy (1999), argued that learning should not be perceived as a social or individual activity. Instead, these researchers suggested the term "Activity Centered Design" whose platform is based on Vygotsky's Activity Theory (Kaptelinin, 1996). "Activity is mediated by cultural artifacts, that activity must be analyzed at various levels and that internal activity (thinking) first occurs in the social plane (contextual activity)" (Gifford & Enyedy, 1999, p. 4).

Thus, it can be said that many scholars propose that learning begins with social context. Vygotsky (1978) purposed that participatory learning fosters concepts, constructs, attitudes and skills. Activity Theory is a model that can depict Vygotsky's learning claims. Activity Theory offers concepts on both human activity and describing the task. Nardi (2012) affirmed that Activity Theory is a tool that classrooms with new technology and/or existing technology can use when struggling to understand context, practice and the situation's constructivist realities. If technology is to foster learning, then it needs to be more than input-output. This is where models like Activity Theory can help. Activity Theory provides concepts on orientation and perspective. It is also versatile to be adapted to different learning situations. Per Engestrom, as cited by Foot

(2001), Activity Theory's conceptual elements should be adapted per the "specific nature" of the learning's context under scrutiny. Therefore, since technology models have a potential impact on how available technologies are used in the educational setting, Activity Theory will be examined.

Educational innovation in technology education using Activity Theory started in the early 2000s. Before this, innovations in the classroom were dependent on isolated events. There was no consideration that one innovation could be contingent on another innovation. Further, previous efforts in educational innovation had not considered that new efforts were a process. This changed when Russell and Schneiderheinze (2005) used Activity Theory in their research conducted with educators using new technology to foster innovation.

To give a foundational background to their study employing Activity Theory methodology, Russell and Schneiderheinze (2005) discussed contemporary constructivist based learning. Per Jonassen, Peck and Wilson (1999), modern constructivist learning imbibes information that is internalized in activity, and secured in activity circumstances. Information construction can be very impactful to how students interact and respond. When technology is used, it is meant to positively influence learning outcomes. However, there can be a tension between the educator and the mandated use of new technology. The ways the educators respond to these tensions affects the technology's implementation.

To study educator responses to technology, Russell and Schneiderheinze (2005) studied four educators who together created and initiated a constructivist-based learning environment (CBLE). The educators designed two innovations – an electronic

technology and a format for a design process system using constructivist philosophy. Russell and Schneiderheinze (2005) wanted to investigate the implementation effectiveness of launching two innovations at the same time. They also wanted to see how the educators responded to the tension of implementing two innovations simultaneously.

The researchers also used Activity Theory as a qualitative template for data analysis structuring. Activity Theory was used because the tool has built-in layers of artifacts, divisions of labor, sign symbols and activities. These layers have similar characteristics that allow researchers to look for patterns in the Activity Theory situation. For example, the innovations the educators engaged in had a common goal with certain activities. The educators stayed in contact with each other via on-line chat rooms and discussion boards. In addition, regarding technology, each educator had the same equipment – computers, lap tops, projectors, printers and cameras. The educators gave students problems in the form of case studies. Each case study was grouped with like cases in an innovation cluster. Class progress was tracked through interviews, conferences and messages on discussion boards.

Educator one used the mediating tools to teach the innovation cluster but then decided that the activities were not following preset standards. She then decided to follow more of the standard teaching method without the technology. Educator two had trouble staying connected to the technology server and breaking through the institution's firewall. All of this caused her to lose teaching time. Due to the time factor, the educator ended the innovation unit early. The educator realized that connection problems are a

risk when using technology. However, she remained positive about the novel teaching approach.

Educator three had a departmentalized schedule which disrupted her activities. This was an activity rule she could mitigate by requesting a departmentalized pass during the innovation cluster. Her students were successful interacting with the unit activities, even reaching out to the community for support. Educator four completed all units in the clusters. She felt that unit one was pertinent to teaching present standards. However, she described units two and three as "useless" (Russell & Schneiderheinze, 20005). Russell and Schneiderheinze (2005) concluded with the suggestion that student engagement is important. Yet, imperative to successful implementation of innovation is the instructor's agreement to employ novel, technical work activities. The researchers emphasized that the structure of Activity Theory was a successful qualitative measurement paradigm for the study.

Another study to use Activity Theory as a platform happened in 2009. The study focused on fostering teamwork concepts in university computer programming classes (Sancho-Thomas, Fuentes-Fernandez, Fernandez-Manjon, 2009). NUCLEO, an online platform for blended solutions was the learning framework. NUCLEO employs Problem Based Learning as the instructional standard. Activity Theory was used to analyze team dynamics and conflicts that arose between team members. The student interface was a multi-user electronic environment and role-playing simulation.

The following were the elements of Activity Theory in the Sancho-Thomas et al. (2009) study:

- Activity – This is the students' comprehension of both teamwork and technical skills.
- Subjects – The students are the subjects in this activity.
- Objects – The object affected in this activity are problem-solving skills. Also impacted is the students' final grades.
- Communities – The communities are the clusters participating in the simulation. One community group is the student teams. There are communities at other levels too. In this instance, the university is a group. Another community group is the students' society and culture.
- Rules – The rules for this activity are the ones applied to working collaboratively in teams (Baron, 1999).
- Division of Labor – The teams needed to both work independently and collaboratively.
- Tools – The tools used for the activities were face-to-face meetings and the virtual environment.

This research has generated data to make pertinent conclusions. Students' questionnaires pointed out a positive experience learning team skill such as collaboration. 90.91% of the students confirmed that the activities improved their teamwork skills. 65.91% of the students positively commented that the teamwork model was constructive (Sancho-Thomas et al., 2009).

Correspondingly, Anthony (2012) conducted a research study using Activity Theory as a platform to investigate classroom system innerworkings and impact on technology integration. The conceptual framework of Anthony's (2012) study follows:

- Activity – The integration of technology system planning by administration and its implementation by educators in the classroom. This was an implementation of an individual student laptop program.
- Subjects – The subjects for the study are the impacted schools, educators and students.
- Objects – The object is the vision that technology integration is to address.
- Communities – The communities impacted are the educators when they meet to plan the technology implementation.
- Rules – The rules are the school's acceptable technology standards.
- Division of Labor – The division of labor is the technology support team that is to address any connection or interface problems.
- Tools – The tools are the computers' hardware and software.

The researcher asks the following questions (Anthony, 2012):

1. Did administration support of technology systems impact educator's implementation experiences?
2. How did the impacted community interface with the laptop program?

Anthony's (2012) study was longitudinal over a three-year period. Data was collected from classroom educators, a principal, a superintendent, and a technology integration specialist. Interviews were used to collect the data. Anthony (2012) examined the frequency that educators used the technology and how central it was to the classroom routines. The centrality of the technology was coded as either a component or exterior to routine. The study found that there is interest in technology when it is new. However, as time moves along, there is a need to re-evaluate the technology program to

keep it current. It was also found that the administration of a program needs to prepare the implementing educators before they acquire the new technology in their classrooms.

The next technology research study employing Activity Theory was by Gomez and Duart (2012). In this research, Activity Theory was used to analysis subject data. The study looked at the hybrid learning approaches of both face-to-face instruction and online learning. These researchers found that face-to-face sessions are usually oriented to lecture. During e-learning, there was usually a diversity of activities between discussion and independent learning. The students also felt like they had more clarity of information when the e-learning took place since the instructor was more likely to explain how all the technology integrated. Regarding student-student interaction, those interviewed recognized the value of group work. The students said they learned more in a group than individually. Time-management was the hardest thing for students to accomplish while doing group work. Others said they appreciated the pressure with meeting specific deadlines. All students were happy with the diversity of hybrid learning activities.

Anthony (2012) used the Pearson Correlation Coefficient of 0.96 to conclude that student viewpoint regarding learning was greatly relevant and contributed to the learning simulations. The hybrid program received a high score for having activities that integrated "face-to-face, e-learning, and independent learning spaces and time." (p. 268).

Park's (2015) research compliments Anthony's (2015) study as he tested using synchronous computer-mediated classroom discussion (SCMD). Activity Theory was used as the theoretical platform through which the data is analyzed. In this study, the university students had half of their class in a face-to-face interaction with the professor. The other half of the class continued the discussion by using an on-line chat board via

each student's computer. Students met for 14 class sessions using this format. An outline of the Activity Theory for SCMD follows (Park, 2015):

- Activity – The activity was using half a class session with traditional face-to-face student/educator discussion. The other half of the class continued the discussion using an on-line chat board.
- Subjects – The students and instructor that participated in the discussions were the subjects in this study.
- Objects – The objects observed in this study were the utterances from the instructor and student regarding the course topics.
- Tools – The research used both written and electronic tools. The SCMC computer software and hardware were the electronic tools. The students' written assignments were evaluated and used as semiotic tools.
- Community – The community were all those that shared in the classroom discussions.
- Rules – The rules for this study included the rules for tool uses, the university rules and regulations, and the patterns surrounding the topics discussed.
- Division of Labor – The division of labor was dispersed to the instructor and students. Also involved were the university technology support staff who helped with interface issues.

Findings from this study suggested that both the educator and students benefited from the diversity of discussion format.

It is suggested that the research examined in the first part of this document affirmed that students learn from active learning classrooms that employ technology in

novel ways. However, a large part of the success of the technology implementation was giving the instructors ample administrative support. This conclusion resonates with Horne and Murniati (2016). Their research concluded that institutional administration needs to understand the rigor classroom educators experience when using technology infused curricula. Educators felt that since they were expected to implement the technology approach, the content of the information needed to be pertinent and coincide with preset standards. If the administration's goal is a classroom based on technology integration, then the institution needs to address educator technology training, implementation and feedback. The administration needs to also be flexible to adjust their teaching goals and ultimate outputs per educator implementation strategies (Horne & Murniati, 2016).

Another Activity Theory concept to examine is rules. The rules in an activity give it structure and boundaries. This was apparent in Anthony's (2012) research in which the rules applied to what students could and could not digitally access. Similarly, the rules in creative inquiry movements are the judgments assigned to the activity. This was apparent in Mulvihill and Swaminathan's (2011) study in which the judgment was how the data could be collected from the technology. Yet, another Activity Theory term to discern is division of labor. This is the division of activities among the study's participants. In the Park's (2015) study, the division of labor was dispersed among the instructor and students. Also involved was the universities technical support team. Similarly, is the creative inquiry term of integration. In the Kimbler and Melloy (2008) study, the activity of providing creative inquiry to the students was the responsibility of the Clemson faculty. The output of this curriculum responsibility is still being evaluated.

Table 2.8 is a comparison of Activity Theory and creative inquiry terms.

Table 2.8

Comparison of Terms: Activity Theory and Creative Inquiry Movements

Activity Theory Terms (Nardi, 1996)	Creative Inquiry Movement Terms (Nelson, 1957)
Activity	Invention
Subjects	Connection and Development
Objects	Invention
Communities	Connection and Development
Rules	Judgment
Division of Labor	Integration and Evaluation
Tools	Integration

Both Activity Theory and creative inquiry movements are effective ways to evaluate research, especially qualitative. However, in contrast, Activity Theory has more ways to categorize qualitative research as depicted in the above table. Another difference is that Activity Theory has a tangible framework often illustrated as overlapping triangles with arrows going back and forth from points on the diagram (Engestrom, 1999).

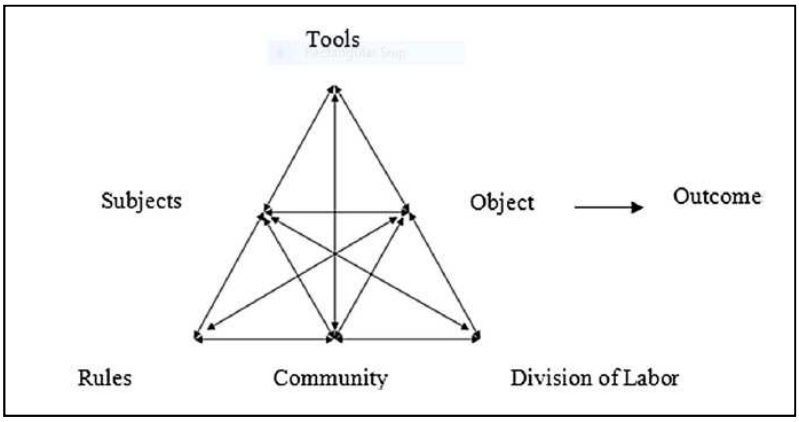

Figure 2.2

Activity Theory Overlapping Triangles

Figure 2.2 depicts activity moving along the Activity Theory triangles. The activity moves along the triangles depending on the action of the research. An example of this is depicted in the Russell and Schneiderheinze (2005) study of educator B (depicted in this paper as educator two) who effectively involved the community and divided labor to achieve the pedagogical goals. The diagram of educator two's Activity Theory strategy follows (p. 46).

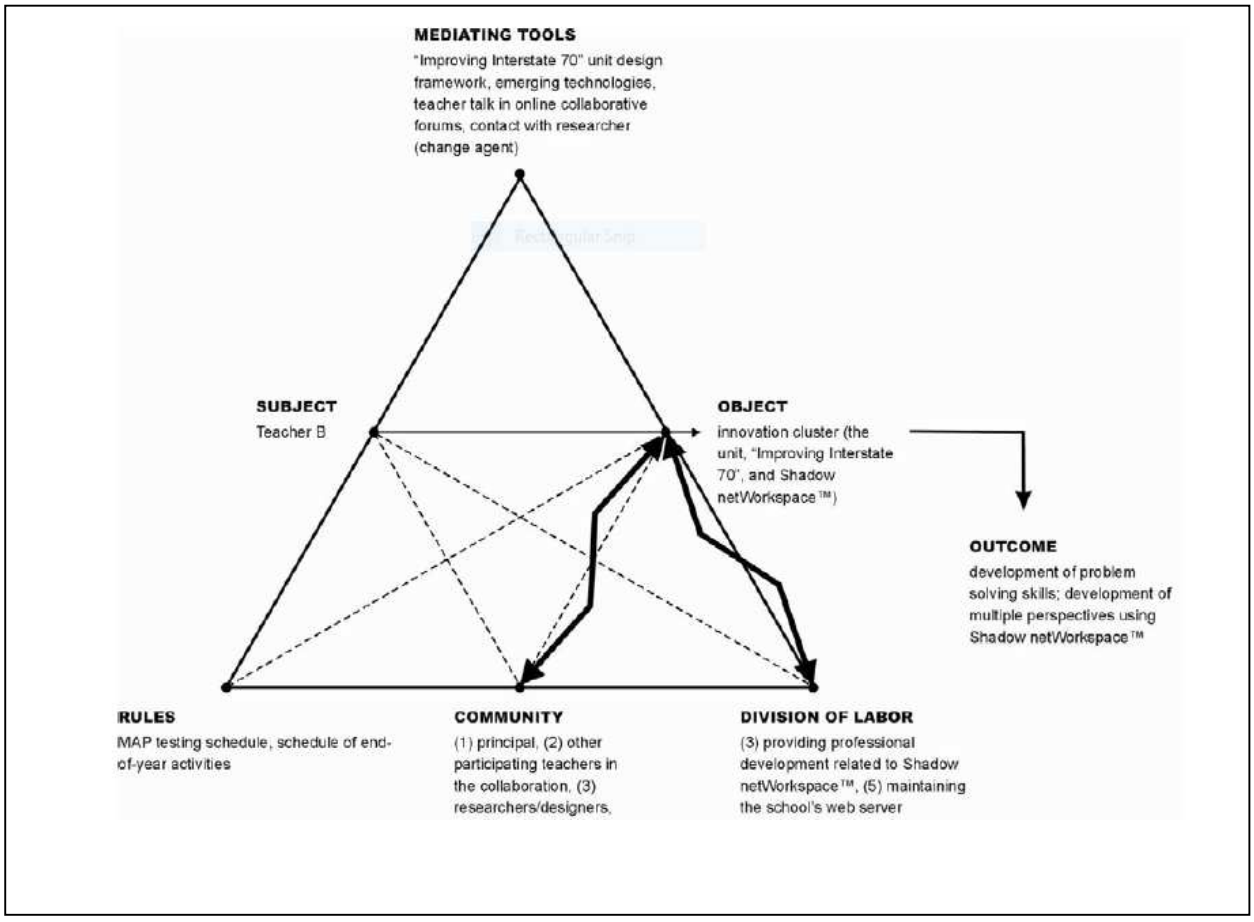

Figure 2.3

Educator Two's Activity Theory Strategy

Figure 2.3 depicts involvement with the community and divided labor to achieve pedagogical goals. In contrast, the creative inquiry movements are not depicted with a diagram. However, they can be externally represented in a table as seen in this essay. Another observed difference from the studies reviewed is that the Activity Theory research resulted in numerical data. The creative inquiry studies concluded with the researchers' opinions that the technology used was effective in their classrooms. Several of the researchers agreed that further studies using creative inquiry are needed.

The learning theory of distributed cognition brings Activity Theory and creative inquiry movements together. This narrative will clarify why this is true. The educators' perception of the new technology was an important aspect of the implementation. There was concern that using the technology and the associated curriculum would not accomplish preset required standards. This was apparent when educator four called some of the innovation "useless" (Russell & Schneiderheinze, 2005). Creativity can be viewed in the teaching profession as risky. Especially teaching with technologies not previously tested for effectiveness. Educators can be pressured to conform to the status of "proper educator" who may or may not use blogs or social media in the classroom (Edwards & Blake, 2007). Per Edwards and Blake (2007), "there are too many competing conceptions of improvement in education to allow smooth progress towards untroubled clarity in the face of indeterminate situation" (p. 47).

However, when the educator has a support team for new technology use in the classroom, team organizational change can happen (Day, 2004). This is also an example of distributed cognition.

Thus, distributed cognition is the learning theory that pulls Activity Theory and creative inquiry together. Per Turner (2016), a classroom using technology is no longer individual cognition but an expanded cognition across many individuals. Such is the case with the educators in our research using technology with the support of other educators, administrators and technical staff. Such support encourages a cognitive system. A busy classroom using new technology is a system of intelligent computer users "interacting with each other by way of a range of artifacts, technology and representations to achieve their goals" (Turner, 2016, p. 79). True, the instructors in this literature review had

responsibilities for their individual classrooms. However, there were impacted communities. For example, in Russell and Schneiderheinze's (2005) research, the community encompassed not only the students but their society and culture as well. The communities engage in activities mediated by the instructor and other small groups involved in the research. This resonates with Stahl (2011) who said, "much of the coordination, decision making, articulation, brainstorming, discovery and knowledge building is accomplished by small groups" (p. 208).

While this was apparent with the research using Activity Theory, it was also apparent with creative inquiry movements. For example, the creative inquiry research at Clemson involved both the faculty and the university curriculum committee. Further, this corresponds with whether educators in this essay had technology support. Per Stahl (2011), Engestrom's (1999) work with Activity Theory "paraphrases how the group deals politically with organizational management issues" (p. 202).

Activity Theory also plays a part in the research of Rose-Anderssen and Allen (2008). These researchers discussed organizational changes in a Norwegian engineering consulting company. Rose-Anderssen and Allen (2008) used the principles of Activity Theory and looked at culture for innovation. Cultural aspects of dialogue were highlighted. The company in this case study provides technical expertise to offshore drilling. The offshore drilling technology is advancing rapidly, and the stakeholders in this company felt the organizational model too restrictive and not flexible enough for a changing economy (Rose-Anderssen & Allen, 2008).

The researchers in this study also conducted action research (Elden & Chisholm, 1993). They looked to Activity Theory as a way of depicting the organization's activity

network (Engestrom, 1987). Rose-Anderssen and Allen (2008) also used the global skills of interest in May, Wold and Moore's (2014) research of displaying respect, recognition, adjustment and integration. This was brought forth by observing patterns of communication between the company's multinational employees.

Rose-Anderssen and Allen's (2008) goal was to bring the employees in a mutual location to solve a common problem. Per the researchers, "when people bring together their diversity of experience and understanding of a mutual problem this can expand on the learning they could have done alone" (p. 311). The first step for this company was to realize there was a problem. It is possible to compare this back to Buchanan's (2015) creative inquiry movement of invention. The next step for the company in the case study was to realize they could use better team dynamic skills as a tool to solve problems. This global skill of effective team interactions can serve two purposes. First, team interactions can be a tool for change (Foot, 2002). Second, team interactions can be a tool, but also the object upon which the tool employs action (Foucault, 1972).

However, team interactions have inter-cultural dynamics that can challenge problem resolution (Scollon & Scollon, 1983). For example, culture can have an impact on politeness systems. Per Scollon and Scollon (1983):

> People can choose different strategies for communicative interaction. That is a solidarity politeness strategy would assume both minimal power difference and minimal distance between speakers. A deference politeness strategy on the other hand assumes minimal power difference but high distance between speakers. And thirdly, a hierarchical politeness strategy (Scollon & Wong Scollon, 2001) is experienced where power difference is recognized and where distance between

> people might either be close as between family members and people working close together, or distant as between strangers, people of different professional disciplines, and people of different cultural groups (p. 312).

This can affect the acquisition of global skills necessary for effective solution-based outcomes. For example, Rose-Anderssen and Allen's (2008) ask these questions:

> Of major concern is therefore how discourse/politeness strategies change and how prone they are to intervention for change? How static is individual's choice of discourse strategy? How culturally embedded and embroiled are these strategies amongst individuals and within communities as such? How do eventually distance and power difference change during human interaction? How does communication move from dialogue to monologue to silence and vice versa?

To address these questions, Rose-Anderssen and Allen (2008) held workshops as the author of this dissertation has done. The first workshop that Rose-Anderssen and Allen (2008) hosted dealt with communication and information delivery between co-workers. The instructional delivery stressed the importance of doing the background research necessary to approach problems in an informed manner. The importance of constructive dialogue was modeled to communicate informed ideas. These researchers report an outcome from the workshop, "Managing dialogue for exchange of information therefore became a learning process of challenging each other's views at the same time as adding to them" (Rose-Anderssen & Allen, 2008, p. 319). This outcome corresponds to the global skills of respect and empathy.

The second workshop dealt with stakeholder relationships. These stakeholders are the vendors that supply the company, and the customers that buy the product.

Building a relationship was different for the participants in the workshop because they were used to merely a technical service approach. The added idea of combining respect and empathy to the technical service was a new concept for the employees. Additionally, it was emphasized that stakeholders can mean co-workers in team settings. Effectiveness of teams was also dependent on constructive dialogue that is facilitated by informed ideas and answers. This corresponds to the global skills of adjustment and integration.

The third workshop used a problem-solving simulation. The simulation was a real-life problem that needed to be solved. The participants took roles that were outside of their comfort zones. Or took roles of positions that were higher on the corporate ladder than their current position. The simulation was constructed like the *BIRS Experience*. This was true because the *BIRS Experience* used the real-life ill-structured problem of getting a drug to approval and to market.

Like the *BIRS Experience*, "the context of the role-play...was clearly one of intercultural communication as little was shared and some facts were hidden...It therefore became an exercise for communication interaction in unfamiliar situations" (Rose-Anderssen & Allen, 2008, p. 321).

One difference with this research is that the participants established a purpose statement for their communication improvements. The statement graphically represented by the Activity Model is depicted in Figure 2.4.

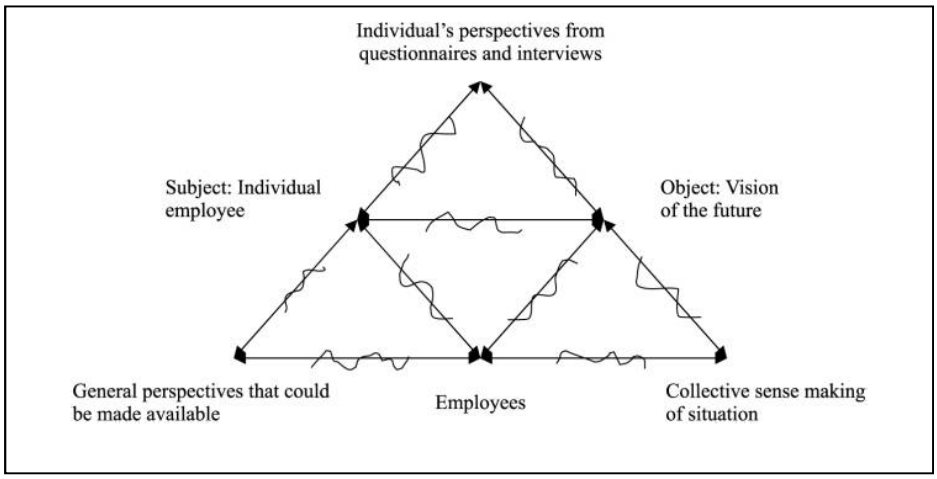

Figure 2.4

Activity Theory of Communication Improvements (Rose-Anderssen & Allen, 2008, p. 316)

In the figure above, the researchers diagrammed their theoretical outcomes to be:

- For the exchange of essential information, it is important for co-workers to initiate and continue conversations until resolution.
- The Activity Theory elements need to be connected and utilized for optimal solution-based outcomes – tools, social rules, division of labor, and the community.
- Co-workers need to keep the awareness that respect and empathy is imperative for solution-based conversational outcomes.

Rose-Anderssen and Allen (2008) improved solution- based outcomes, "the first step for intentional change is therefore the facilitation of a co-developing space for gradual sharing of collective sense making" (p. 325).

The researchers' outcomes confirmed that the global skills of adjustment and integration are important for innovation. Rose-Anderssen and Allen (2008) concluded,

"where creativity and innovation is the object of the activity, strategies that minimize power differences and distance should be chosen" (Rose-Anderssen & Allen, 2008, p. 325). Again, this corresponds to the importance of adjustment and integration.

2.11 Chapter Summary

This literature review confirmed that on-line, interactive role-playing simulations have been effective techniques to encourage global skills in the engineering and design classrooms. May, Wold and Moore (2014) defined global skills as student display of respect, recognition, adjustment and integration. Gray, Debs, Exter, and Krause (2016) took this one step further and looked-for empathy in the design classroom. This has yet to be realized in the regulatory science education discipline. Therefore, there is a need for on-line, interactive regulatory science education focusing on global skill outcomes which will be addressed in this research (Fourman et al., 2017).

In summary, there was no previous literature pertaining to the focus of this research, global skills taught in the regulatory science classroom. However, there was limited research on global skill instruction in the engineering and design classrooms. Since regulatory science is a technology field in Purdue University's Polytechnic Institute discipline, it was logical to examine global skill instruction in both engineering and design courses.

The beginning of the literature review gave a foundation for this research in that it depicted the regulatory science philosophy of technology. That philosophy is pragmatic instrumentalism. The next part of the literature review described the need for global skills and creative inquiry movements in technical areas like engineering and design. A connection to regulatory science was made throughout this section. The last part of the

literature review examined the instructional delivery of global skills and creative inquiry movements via on-line, interactive techniques. Again, a connection to regulatory science was made throughout this literature examination.

CHAPTER 3. METHODOLOGY

This chapter explains the research methodology structure that has been conducted in this study. Added is description of the qualitative research framework, the sample and data sources. Also included are both the data collection procedures and the analysis strategy. This chapter also outlines how the validity and trustworthiness of the analysis is ensured by using NVivo qualitative research software for the data comparisons in this research.

3.1 Research Question

What is the outcome of on-line, interactive and simulated learning techniques implemented in a globally offered Biotechnology Innovation and Regulatory Science (BIRS) university course?

3.2 Qualitative Framework

This research uses a qualitative framework with different strategies of data collection. The qualitative methods used are outlined in Creswell (2014):

> More general steps include organizing and preparing the data; an initial reading through the information; coding the data; developing from the codes a description and thematic analysis; using computer programs; representing the findings in tables, graphs, and figures; and interpreting the findings. These interpretations involve stating lessons learned, comparing the findings with past literature and theory, raising questions, and/or advancing an agenda for reform (p. 212).

3.3 Sample

For this research, participants are Purdue University Polytechnic Institute BIRS Master's degree students in Moshi, Tanzania, as well as BIRS Master's degree students from Purdue's main campus in the United States, West Lafayette, Indiana.

The Africa students totaled 21 and were a mix of male and female. All the students were from mid-level careers in the Africa pharmaceutical industry. The United States students totaled eight and were also a mix of male and female. They too, were mid-level career people from global pharmaceutical establishments headquartered nationally or transnationally. The United States and the African students were admitted to the BIRS Master's program through the Purdue University Graduate School admission process.

Both the Africa and United States students took Technology Leadership and Innovation (TLI) 524 *Documents and Dialogues for Drug Delivery and Registration* from January to May 2016. The Africa students took their course as a two-week intensive at the Kilimanjaro School of Pharmacy (KSP). Instructors also delivered the course information on-line, with supplemental information posted to Blackboard Learn and subsequent WebExs to answer questions. The United States students took the course over three weekends as part of Purdue's ProSTAR program. Again, instructors delivered the course on-site and provided on-line supplementation via Blackboard Learn and WebExs to answer questions.

An additional sample population are attendees at the 2017 First Annual Summit for Academic Excellence in Quality Assurance and Regulatory Science held at Purdue University, May 18-19, 2017. Participants are regulatory and quality professionals from

both industry and academia. Attendees could also be current and past students in the BIRS Master's program from 2005 to 2017.

Twenty-eight registrants enrolled in the conference: 11 locally, 10 from out-of-state, and seven in other parts of Indiana. Of the 28 registrants, six were self-identified students, both undergraduate and graduate, from various disciplines. Twelve self-identified as being part of a regulatory industry, and eight self-identified as working at a university, but not in a student capacity. These eight participants were working in laboratories across the Purdue University campus.

There was a variety of speakers at the summit, giving a wide perspective on the current state of the regulatory and quality field. In addition, speakers were asked to also address a futuristic approach of looking at regulatory practices. Five speakers from industry, an FDA speaker, four speaking on behalf of academia, and one of the academic speakers addressing the Society of Quality Assurance (SQA), the content was vast. Speakers were asked a series of questions ahead of time, such as:

- How are regulatory science, regulatory affairs, and quality assurance taught and implemented at the university level?
- Are we meeting the needs of future researchers and industry?
- For students intending to go into careers of industry, are we helping them to efficiently and successfully transition to the corporate world?

After approximately one and a half days of speakers, the attendees, which included the speakers, were invited to participate in a world café experience. Participants stood in a circle and counted off by fours. Four tables were set-upwith one question on a piece of poster paper. Markers were available beside each piece of poster paper for the partiipants

to write their answers. Depending on the numercounted off, the participant went to the appropriate table. The questions were randomly dispersed to the tables and numbers given to the tables randomy chosen. No person was pre-assigned to be a facilitator at the tables. By randomly assigning individual groups, the chance of the groups being from a diverse background was increased.

3.4 Data Sources

The first data source was post-course evaluations from TLI 524 from 2005 to present. The instructors for the course were consistent throughout this time. The Institutional Review Board (IRB) number for using this survey for data collection is IRB 1602017223. Reviewing these surveys gives context to not only course improvement, but also the frequency of global skill themes this research is focused upon. Those being respect, recognition, adjustment, integration and empathy.

The part of the evaluation analyzed for this study is an open-comment section. Participants can write their opinions freely. The author of this research captured the data. The writing spaces are organized into the following categories, although, not all squares were filled:

- Lectures
- Case studies
- Assignments
- Overall course comments.

The second data source is the students' final TLI 524 assignment written in spring semester 2016. This assignment was the final assessment from an interactive class

exercise called the *BIRS Experience* developed to be an interactive role-playing global simulation. The IRB number to use this exercise for data collection is IRB 1702018747.

The assignments were analyzed for global skill themes. Those themes being consistent throughout the research: respect, recognition, adjustment, integration and empathy. After assessment, the outcomes of the global skill theme search are compared between the United States and African students using Nvivo software. The author of this research collected the data. Similarly, the same assignments are analyzed for creative inquiry movement themes. Like the global skills, the creative inquiry movements are selected from the literature, defined and referenced in this project. Nvivo software is again used for the comparison and the author was the data collector.

Since there are eight United States students and 21 African students, all eight of the United States students *BIRS Experience* assignments are used for analysis. All assignments were stripped of identification. Of the 21 African assignments, eight assignments are selected randomly for analysis. The method of random selection from the 21 assignments was that the author blindfolded herself and after spinning herself around, randomly pointed to the assignments that were spread out on a table. Still blindfolded, she scooted the picked assignment with her finger off the table. When she unblindfolded herself, she picked up the eight assignments for analysis using the Nvivo software.

The third data source for this research is a survey regarding the regulatory intelligence teaching strategy given to both United States and African students. The IRB number to use this survey for data collection is IRB 1702018747. The survey is

discussed at the beginning of the teaching session with the following guidelines verbalized:

- Survey is voluntary and anonymous.
- What will happen with the data?
- There is no direct benefit to the participants.

The regulatory intelligence survey has the following open-ended questions:

- Has your scientific comprehension increased since you took the regulatory intelligence workshop?
- Will you design or redesign existing quality practice having the information you gathered in the regulatory intelligence workshop?
- Will you implement clinical practices differently utilizing information you gathered in the regulatory intelligence workshop?
- Will the regulatory intelligence workshop make you a better communicator at work?
- Will you utilize regulatory intelligence workshop information to integrate or promulgate new regulations?
- Has participating in the regulatory intelligence workshop affected your critical thinking skills?
- Are aspects of the regulatory intelligence workshop relevant to your job responsibilities pertaining to ethical decisions?
- Are aspects of the regulatory intelligence workshop relevant to your job responsibilities pertaining to strategic decisions?
- Is the regulatory intelligence workshop aligned with its stated objectives?

- Is there a part of the regulatory intelligence workshop that stood out as particularly useful to your job responsibilities?

The fourth data source is questions from an interactive session from the 2017 First Annual Summit for Academic Excellence in Quality Assurance and Regulatory Science. The participants are the summit attendees. The attendees answering the questions are both speakers and participants. Questions are posed and the participants write their answers anonymously. It is verbalized before the session what will happen with the data. Also, explained is that there are no direct benefits for the answers. The IRB number to use this data is IRB 1705019228. The answers are coded using NVivo software.

The summit responses are collected using the world café method. This method can be used for large group dialogue. The process begins with two 30-minute time periods of conversation for a small subset of the large group seated around a table. After one 30-minute time, the group moves to another table. There is no pre-determined discussion facilitator for each table.

Each round has one of the above questions to answer. The question is transcribed on poster paper. Respondents also write the answers to the questions on the poster paper. Respondents have two times to comment on each question.

3.5 Data Collection Procedures

All data sets have been collected and analyzed to this point in time. These are the post-course evaluations from 2005 to present regarding TLI 524. The second data set collected is the final assignment from the *BIRS Experience*. The third data set of the regulatory intelligence surveys has been collected in both the United States and Africa. The fourth data set of narrative answers to interactive questions has been collected May

2017, at the First Annual Summit for Academic Excellence in Quality Assurance and Regulatory Science.

All data sets are stripped of any identification. To further decrease bias, each data set has been randomly assigned a letter of the alphabet for tracking. There is no mental or physical risk to the participants.

3.6 Data Analysis Strategy

All surveys are coded using NVivo software. Outcomes are depicted with graphical representations. NVivo is selected because it can organize and manage data sets. NVivo also has a coding structure that will help with the creation of themes.

NVivo is a valid software tool to use in qualitative research (King, 2004). Per King (2004):

> NVivo is invaluable in helping the researcher index segments of text to themes, to link researcher notes to coding, to carry out complex search and retrieval operations, and to aid the researcher in examining possible relationships between the themes (p. 263).

3.7 Trustworthiness

Using NVivo helps with the rigor of the analysis process (Welsh, 2002). It adds to the validity of results by enhancing the fact that all usages of a searched word or phrase are found. For added trustworthiness, the NVivo search is examined with manual scrutiny techniques to ensure a thorough analysis (Hinchliffe, Crang, Reimer, & Hudson, 1997).

3.8 Research Bias

Potential bias areas of this research are the following:

- Bias created by the researcher wanting to find themes in the data.
- Phrasing of some questions could lead respondents to answer in a way wanted by the researcher.
- Africa usually follows the European Medicines Agency (EMA) for their drug approvals; United States depends on the Food and Drug Administration (FDA). This impacted the *BIRS Experience* simulation artifacts received from the Africa and United States students.
- Time spent with the Africa students was two-weeks as opposed to the three weekends with the United States students.
- Time zone differences between the two groups presented were WebEx scheduling challenges.
- Internet connectivity for using Blackboard Learn and WebEx was unreliable in the eight African countries where the students lived – Burundi, Congo, Kenya, Lesotho, Nigeria, South Sudan, Tanzania and Uganda.

3.9 Chapter Summary

This chapter has described the qualitative research methodology of this study. The subjects participating in this research are subjects located in the United States and Sub-Saharan Africa. Different sources of data were evaluated to answer the research question. NVivo software for qualitative research is used to ensure validity and trustworthiness of the data analysis.

CHAPTER 4. ANALYSIS OF DATA

This project is qualitative action research. It fits the characteristics of qualitative research as outline in Creswell (2014). The research for this project occurs in a natural setting, an instructional environment. Data is being collected in multiple ways and includes the qualitative steps of organizing, coding, developing themes from the coding, displaying the findings with visual representations, and reflecting on outcomes. This project can also be classified as action research. It is focused on delivering an educational system that fosters global regulatory science. This project has performed a gap analysis of existing educational strategies. This chapter will present the data findings.

4.1 Concept of Action Research

The concept of action research has historical beginning in the 1940s (Elden & Chisholm, 1992). The term "action research" has been credited to Kurt Lewin (1946) who suggested a style of research to gather information regarding social systems, while in tandem trying to change them. Over the years, action research has changed, moving from social research to "intra-organizational and work-life problems" (Elden & Chisholm, 1993, p. 122). This corresponds to the research in this dissertation since it deals with intra-organizational challenges on a multinational pharmaceutical level.

Action research can be an inquiry process that involves the following steps (Elden & Chisholm, 1993, p. 124):

- Diagnosing a problem situation
- Planning action steps
- Implementing a plan

- Evaluating outcomes

These action research steps are like the creative inquiry movements being researched. The creative inquiry movements are invention, connection and development, integration and evaluation (Buchanan, 2015). Integration corresponds to diagnosing a problem because integration, per Goel and Pirolli (1992, p. 399) is, "the analysis of design problems and situations and uses the results as both framing and explanatory." Invention corresponds to planning action steps because invention, per Buchanan (2015, p. 9), deals with problem solving, "developed with different kinds of organizations, and the strategies by which the discipline engages the external world of users, bringing innovation through policies and practices." Connection and development is like implementing the problem-solving plan. Connection and development, per Buchanan (2015, p. 15), is establishing "what is useful in the working of products, what is usable in the fit of a product to the capabilities of human beings, and what is desirable for the emotional satisfaction of human beings. It is the task of development, building concrete prototypes, redefining the idea, and bringing together all the elements necessary for production and implementation." Both judgment and evaluation align with evaluating outcomes. Stolterman (2008, p. 57) defines judgment as "how to frame the situation, who to listen to, what to pay attention to, what to dismiss, and to explore, extract, recognize, and choose useful information from potential sources." Jonassen (2000, p. 80) continues by saying evaluation possesses "components to assure that tasks will function properly; processes that control the generation of designs, and evaluation procedures that ensure effective utilization of knowledge." These comparisons of means

confirm that this action research is change oriented and proposes to foster positive social value in the regulatory science environment.

The action research depicted in this dissertation is "context-bound inquiry" (Susman & Evered, 1978) since the author is focused on global, realistic problems. Per Susman (1989), this aligns with John Dewey's assertion that creative inquiry starts with a problematic environment. The problem situation in this dissertation research is a biotechnology challenge in the regulatory science discipline. Adding to this, Elden and Chisholm (1993, p. 128) say that "learning how to study and change one's own system is central. In contemporary action research, the process is as important a product as the solution to a scientific and practical problem." Although several treatments will be addressed in this research, one of the treatments, the *BIRS Experience*, is an interactive simulation designed to address the practical challenge of teaching drug development in a global classroom. More details regarding the *BIRS Experience* are given in other chapters of this dissertation. However, what can be mentioned here about the *BIRS Experience* is that the outcomes are like the contemporary action research performed in Whyte (1991). Whyte (1991) demonstrated "how a scientific approach to major, large-scale problems can lead to direct and immediate local benefits for participants and contribute to more general understanding" (Elden & Chisholm, 1993, p. 135). For the *BIRS Experience*, the large-scale problem is global drug development.

4.2 TLI 524 Evaluation

To validate that the *BIRS Experience* would be effective in the TLI 524 class, the researcher went back to past evaluations of the course from 2005 to the last time the course was offered in 2012 (Fourman et al., 2017). Table 4.1 has comments from the

open-comments sections of the evaluations that demonstrate course improvement was needed (Fourman et al., 2017).

Table 4.1

TLI 524 Evaluation Comments 2005 to 2012

Evaluation Category	**Student Comments**
Lectures	• Global aspect should be reviewed with a fair amount of detail. • It would be helpful to split the international lecture into two parts – one for Europe and one for the rest of the world. Also, might be good to have Japan as own topic. • Increase international piece or create a separate course or class.
Case Studies	• On the case study exercise, pick examples that are more relevant, also more real information provided so can more realistically prepare. • Need more facts in the case studies and more time to prepare.
Assignments	• Issues related to clarity of homework assignments. It is hard to figure out all the pieces required for assignments. • If we had the FDA dialogue exercise before turning in talking points, this would have been quite helpful. • The homework assignments sometimes don't make sense until after the lectures. It would be nice to have the lectures first. • Give us guidance on the regulations. • The homework was frustrating in that sufficient lecture material was not given prior to submitting them. Folks not from that part of the industry struggled with fabrication of drug stories that made sense. • The homework assignments were impossible for me. I work in devices and do not have access to all the materials need for this course.
Overall Course Comments	• Communication is not a strong suit. • My understanding of Master's level programs is that they should present materials and assignments that should be focused on the student's ability to interpret and apply concepts. • The pharmaceutical industry involves a lot of interpretation and different companies take different approaches. • Recommend making more courses available as distance learning. • Materials for the course are outdated and non-relevant. • Course needs more diversity to include devices, diagnostics and combination products.

4.3 *BIRS Experience*

For analysis purposes, the following global skills words and themes were investigated from the *BIRS Experience* assignment:

- *Adjustment*−Integration of others' ideas when working with those from multiple cultural backgrounds (May, Wold, & Moore, 2015, p. 523).
- *Empathy*−Ability to understand what another person is experiencing from within the frame of reference of that other person (Strobel et al., 2013, p. 138).
- *Integration*−Ability to adjust behaviors and integrate others' ideas when working with those from multiple cultural backgrounds (Downey & Lucena, 2005, p. 258).
- *Recognition*−Assessment of similarity or dissimilarity of requirements (Regulatory Affairs Certification, 2016, p. 22).
- *Respect*−Education of ethnocentrism and promotion of acceptance of the needs and approaches used from other cultures (Downey & Lucena, 2005, p. 256).

In addition, to analyze the problem-solving strategies of the BIRS Experience final assignment, the following invention moment or creative inquiry movement words and themes were investigated.

- *Connection and Development* – What is useful in the working of products, what is usable in the fit of a product to the capabilities of human beings, and what is desirable for the emotional satisfaction of human beings. It is the task of development, building concrete prototypes, refining the idea, and bringing together all the elements that are necessary for production or implementation (Buchanan, 2015, p. 15).

- *Evaluation* - Components to assure that tasks will function properly; processes that control the generation of designs, and evaluation procedures that ensure effective utilization of knowledge (Jonassen, 2000, p. 80).
- *Integration* – the analysis of design problems and situations, and uses the results as both framing and explanatory (Goel & Pirolli, 1992, p. 399).
- *Invention* – On which the discipline depends, how the discipline may be developed with different kinds of organizations, and the strategies by which the discipline engages the external world of users, bringing innovation through policies and practices (Buchanan, 2015, p. 9).
- *Judgment* – How to frame the situation, who to listen to, what to pay attention to, what to dismiss, and to explore, extract, recognize, and choose useful information from these potential sources (Stolterman, 2008, p. 57).

All final assignments were analyzed for word or themes employing NVivo software. NVivo was used since it is a valid and rigorous tool for qualitative research (Hinchliffe et al., 1997; King, 2004). For added trustworthiness, the NVivo search was examined with manual scrutiny techniques to ensure a thorough analysis (Hinchliffe et al., 1997).

For NVivo searching, the previous global skills definitions and creative inquiry movement definitions were parsed, and the words validated in the category by use of an international thesaurus (Kipler & Chapman, 2011). All words and themes were set at the NVivo "exact" search setting. Table 4.2 depicts how the definitions were parsed for global skills. It is important to remember the definition of "recognition" in this research

denotes the need for solution-based policies and procedures necessary for solution-based outcomes.

Table 4.2

Global Skills Theme Comparisons

Global Skill	**Global Skill Words/Themes Searched**
Adjustment	Adjustment
	Integration of other's ideas
	Working with those from multiple cultural backgrounds
Empathy	Empathy
	Understanding
	Person is experiencing
	Frame of reference
Integration	Integration
	Ability to adjust behaviors
Recognition	Recognition
	Requirements
Respect	Respect
	Ethnocentrism
	Acceptance
	Needs
	Approaches

Table 4.3 depicts how the definitions were parsed for creative inquiry movements.

Table 4.3

Creative Inquiry Movements Theme Comparisons

Creative Inquiry Movement	**Creative Inquiry Movement Words/Themes Searched**
Connection and Development	Connection
	Development
	Useful in the working of problems
	Usable in the fit of a product
	Capabilities of human beings
	Task of development
	Building concrete prototypes
	Refining the idea
	Bringing together all the elements
	Necessary for production or implementation
Evaluation	Evaluation
	Components to assure that tasks will function properly
	Processes that control the generation of designs
	Evaluation procedures that ensure effective utilization of knowledge
Integration	Integration
	Analysis of design problems and situations
	Uses the results as both framing and explanatory
Invention	Invention
	Discipline depends
	Different kinds of organizations
	Strategies by which the discipline engages
	External world of users
	Bringing innovation through policies and procedures

Judgment	Judgment
	How to frame the situation
	Who to listen to
	What to pay attention to
	What to dismiss
	How to explore, extract, recognize and choose useful information
	Potential sources

Figure 4.1 is a graphical representation of the totals from the global skills theme comparisons. The words and phrases were searched using NVivo software under the "exact" setting. Words and phrases were also examined manually for a thorough analysis.

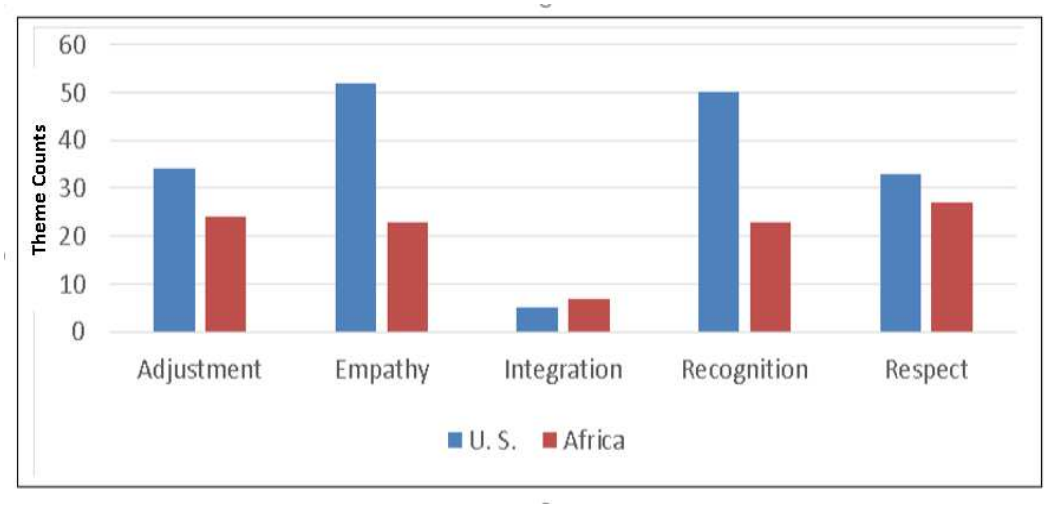

Figure 4.1

Global Skills Theme Count Comparisons

Per Fourman et al. (2017), regarding the data results of the global skill theme comparisons, the American students' final BIRS Experience projects contained more global skill words and themes. The exception was the integration theme. In integration, the ‘‘ability to adjust behaviors" was mentioned more in the African papers. However, there are specific areas in the other global skill themes in which the African students had more thematic entries. For example, with the global skill adjustment, there was one more African entry of ‘‘adjustment." Similarly, in the empathy skill, the African students also had one more mention of ‘‘recognition," and nine more mentions of ‘‘respect" (Fourman et al., 2017).

Regarding the creative inquiry movement themes, the American students had more mentions of the words and themes than did the African students. However, again, there were specific words/themes that the African students included more than the Americans. For example, in connection and development, the African students mentioned ‘‘capabilities of human beings" more times than the American students. Also, in connection and development, the African students had more entries of ‘‘refining the idea," and ‘‘necessary for production or implementation" than the American students.

Per Fourman et al. (2017), continuing with the creative inquiry movements, in the evaluation theme, the African students included ‘‘processes that control the generation of designs" more the American students, and in the invention theme, included more ‘‘discipline depends" and ‘‘bringing innovation through policies and procedures." Of note, in the creative inquiry integration theme, the African students included ‘‘using the results as both framing and explanatory" more times in their final papers than did the American students (Fourman et al., 2017).

Figure 4.2 is a graphical representation of the totals from the creative inquiry movements theme comparisons. Again, the words and phrases were searched using NVivo software under the "exact" setting. Words and phrases were also examined manually for a thorough analysis.

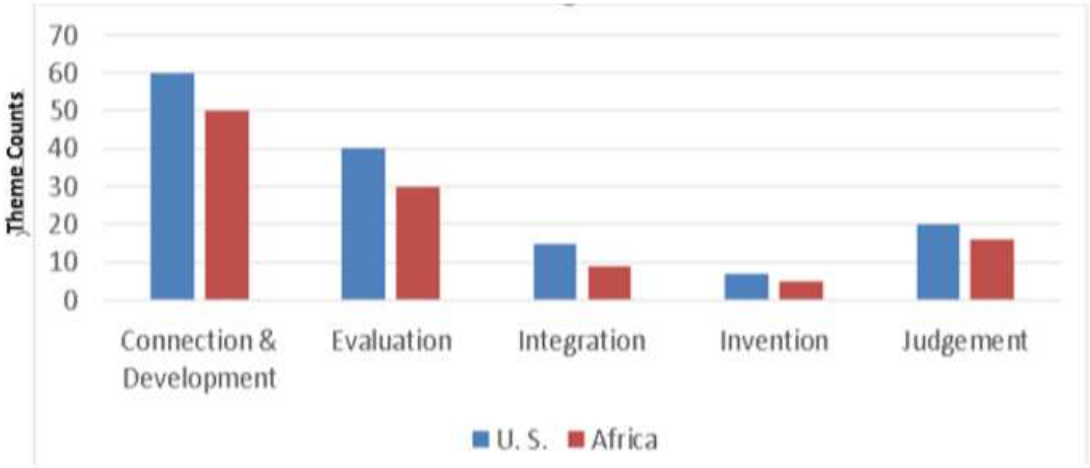

Figure 4.2

Creative Inquiry Movements Theme Count Comparisons

4.4 Regulatory Intelligence Surveys

Surveys were collected from the United States and Africa groups after a regulatory intelligence workshop. The delivery of the workshop was identical in both places. The number of collected surveys were the same number in both places, 18. The subjects were the BIRS Master's degree students. The surveys were anonymous and had both a "yes" or "no" way to answer each question and an open comment section immediately following each question.

The 10 questions asked were the following:

- Has your scientific comprehension increased since you took the regulatory intelligence workshop? Yes or no. If yes, please give an example. If no, please explain why not.
- Will you design/redesign existing quality practice using the information you gathered in the regulatory intelligence workshop? Yes or no. If yes, please give an example. If no, please explain why not.
- Will you implement clinical practices differently utilizing information you gathered in the regulatory intelligence workshop? Yes or no. If yes, please give an example. If no, please explain why not.
- Will the regulatory intelligence workshop make you a better communicator at work? Yes or no. If yes, please give an example. If no, please explain why not.
- Will you utilize regulatory workshop information to integrate or promulgate new regulations? Yes or no. If yes, please give an example. If no, please explain why not.
- Has participating in the regulatory intelligence workshop affected your critical thinking skills? Yes or no. If yes, please give an example. If no, please explain why not.
- Are aspects of the regulatory intelligence workshop relevant to your job responsibilities pertaining to ethical decisions? Yes or no. If yes, please give an example. If no, please explain why not.

- Are aspects of the regulatory intelligence workshop relevant to your job responsibilities pertaining to strategic decisions? Yes or no. If yes, please give an example. If no, please explain why not.
- Is the regulatory intelligence workshop aligned with its stated objectives? Yes or no. If yes, please give an example. If no, please explain why not.
- Is there a certain part of the regulatory intelligence workshop that stood out as particularly useful to your job responsibilities? Yes or no. If yes, please give an example. If no, please explain why not.

Table 4.4 displays the responses of yes or no answers for the United States students.

Table 4.4

Regulatory Intelligence Survey United States Yes or No Responses

Survey Question	Yes	No	No Response
Has your scientific comprehension increased since you took the regulatory intelligence workshop?	16	2	0
Will you design/redesign existing quality practice using the information you gathered in the regulatory intelligence workshop?	9	6	3
Will you implement clinical practices differently utilizing information you gathered in the regulatory intelligence workshop?	7	8	3
Will the regulatory intelligence workshop make you a better communicator at work?	16	2	0
Will you utilize regulatory workshop information to integrate or promulgate new regulations?	6	7	5
Has participating in the regulatory intelligence workshop affected your critical thinking skills?	14	3	1
Are aspects of the regulatory intelligence workshop relevant to your job responsibilities pertaining to ethical decisions?	9	7	2
Are aspects of the regulatory intelligence workshop relevant to your job responsibilities pertaining to strategic decisions?	12	4	2
Is the regulatory intelligence workshop aligned with its stated objectives?	16	1	1
Is there a certain part of the regulatory intelligence workshop that stood our as particularly useful to your job responsibilities?	16	1	1

Table 4.5 displays the responses of yes or no answers for the Africa students.

Table 4.5

Regulatory Intelligence Survey Africa Yes or No Responses

Survey Question	Yes	No	No Response
Has your scientific comprehension increased since you took the regulatory intelligence workshop?	18	0	0
Will you design/redesign existing quality practice using the information you gathered in the regulatory intelligence workshop?	14	3	1
Will you implement clinical practices differently utilizing information you gathered in the regulatory intelligence workshop?	8	10	0
Will the regulatory intelligence workshop make you a better communicator at work?	17	0	1
Will you utilize regulatory workshop information to integrate or promulgate new regulations?	15	2	1
Has participating in the regulatory intelligence workshop affected your critical thinking skills?	16	1	1
Are aspects of the regulatory intelligence workshop relevant to your job responsibilities pertaining to ethical decisions?	16	1	1
Are aspects of the regulatory intelligence workshop relevant to your job responsibilities pertaining to strategic decisions?	16	1	1
Is the regulatory intelligence workshop aligned with its stated objectives?	16	1	1
Is there a certain part of the regulatory intelligence workshop that stood our as particularly useful to your job responsibilities?	17	0	1

Figure 4.3 depicts the difference in the yes responses to the survey questions by the United States versus the African students.

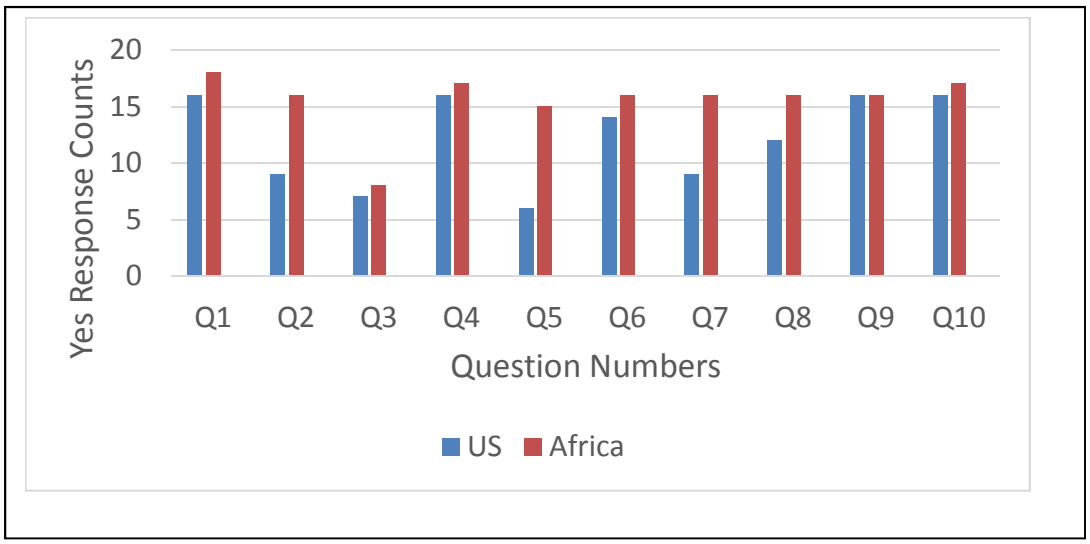

Figure 4.3

Regulatory Intelligence Survey Yes Answers Comparison

Figure 4.4 depicts the difference in the no responses to the survey questions by the United States versus the African students.

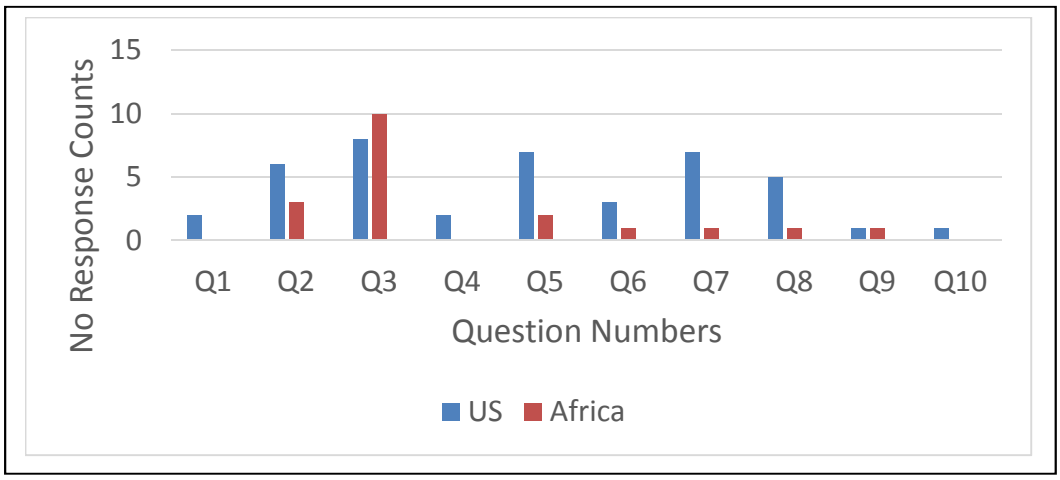

Figure 4.4

Regulatory Intelligence Survey No Answers Comparison

Figure 4.5 depicts the difference in the no response answer to the survey questions by the United States versus the African students.

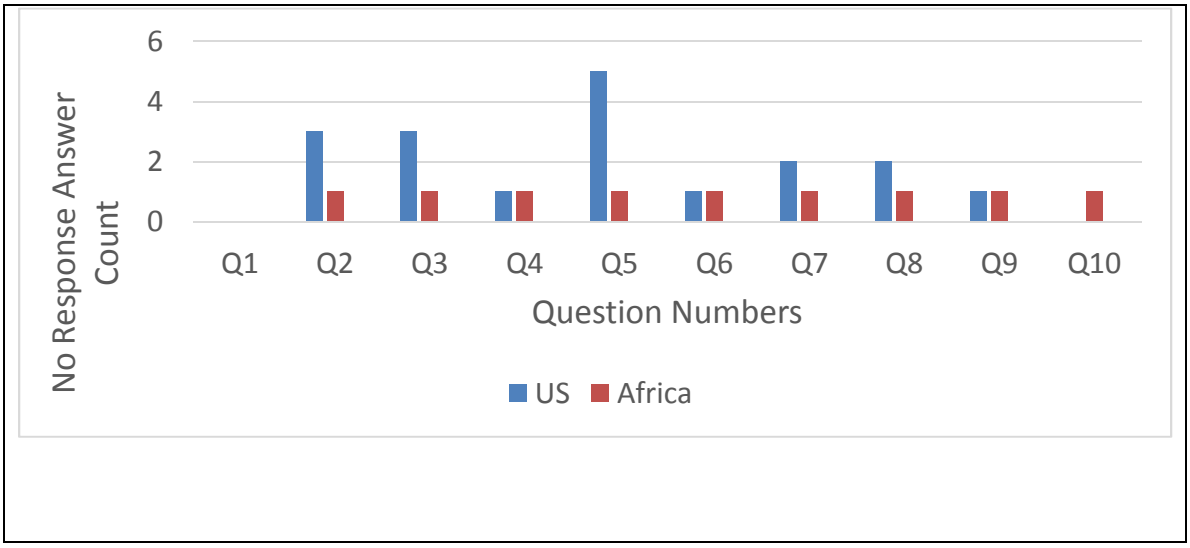

Figure 4.5

Regulatory Intelligence Survey No Response Answers Comparison

The yes answers of the African students are, in general, higher to the survey questions than the students from the United States. Correspondingly, the no answers of the African students are, in general, lower than those from United States students. More United States students gave a no response answer to the survey questions than did the African students.

Regarding the open comment sections. Analysis was done on the comments with the global skill words and themes used with the *BIRS Experience*. Again, the words and phrases were searched using NVivo software under the "exact" setting. Words and phrases were also examined manually for a thorough analysis. In Table 4.6, the global skill theme comparisons are depicted illustrating the number of occurrences between the

United States and African students. Note, this is the total number of comments from all 10 questions. The details of the breakdown of global skill themes per question of both the United States students and the African students follows in separate tables.

Table 4.6

Global Skill Theme Comparisons in the Regulatory Intelligence Survey

Global Skill	**Global Skill Words/Themes Searched**	**Occurrence in US Student Survey Comments**	**Occurrence in Africa Student Survey Comments**
Adjustment	Adjustment	0	0
	Integration of other's ideas	1	2
	Working with those from multiple cultural backgrounds	15	30
Empathy	Empathy	0	0
	Understanding	11	5
	Person is experiencing	1	1
	Frame of reference	0	2
Integration	Integration	0	0
	Ability to adjust behaviors	0	3
Recognition	Recognition	0	0
	Requirements	4	10
Respect	Respect	0	1
	Ethnocentrism	0	0
	Acceptance	0	0
	Needs	1	2
	Approaches	0	1

Table 4.7 depicts the number breakdown per survey comments pertaining to global skills from the United States students. Again, it is important to remember the definition of "recognition" in this research denotes the need for policies and procedures necessary for solution-based outcomes.

Table 4.7

Number of Global Skill Comments per Question for United States Students

Global Skill Category	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Total
Adjustment	0 0 0	0 0 3	0 0 2	0 0 2	0 0 2	0 0 6	0 0 1	0 0 1	0 0 0	0 1 0	0 1 15
Empathy	0 6 0 0	0 0 0 0	0 0 0 0	0 4 0 0	0 0 0 0	0 1 1 0	0 0 0 0	0 0 0 0	0 2 0 0	0 0 0 0	0 11 1 0
Integration	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0	0 0
Recognition	0 1	0 0	0 0	0 1	0 1	0 0	0 0	0 0	0 0	0 1	0 4
Respect	0 0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 1 0	0 0 0 1 0

Table 4.8 depicts the number breakdown per survey comments pertaining to global skills from the African students.

Table 4.8

Number of Global Skill Comments per Question for African Students

Global Skill Category	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Total
Adjustment	0 0 1	0 0 1	0 0 6	0 0 6	0 0 2	0 1 2	0 0 5	0 0 3	0 1 2	0 0 2	0 2 30
Empathy	0 0 0 0	0 1 0 1	0 0 1 0	0 1 0 0	0 0 0 1	0 1 0 0	0 1 0 0	0 0 0 0	0 1 0 0	0 0 0 0	0 5 1 2
Integration	0 1	0 0	0 0	0 0	0 1	0 0	0 0	0 0	0 1	0 0	0 3
Recognition	0 1	0 0	0 5	0 0	0 0	0 1	0 0	0 1	0 2	0 0	0 10
Respect	0 0 0 0 0	0 0 0 0 0	0 0 0 0 0	0 0 0 0 1	1 0 0 0 0	0 0 0 1 0	0 0 0 0 0	0 0 0 0 0	0 0 0 1 0	0 0 0 0 0	1 0 0 2 1

Of interest after looking at the comparison of the global skill comment analysis, is the outcomes for adjustment. Specifically, the outcome for "working with those from multiple cultural backgrounds" (Fourman et al., 2017, p. 6). The United States comments in this cluster had 15 comments, and the African comments in the same cluster totaled 30. The African total was double that of the United States total. However, the United States total for "understanding" in the empathy cluster was 11, while the African total for

"understanding" was five (Fourman et al., 2017). This was of interest since this instance showed the United States total approximately double that of the African total. Opposite of what was seen with the "adjustment" cluster. Last of interest is in the cluster "recognition" (Fourman et al., 2017). As with the "adjustment" cluster, the African total for "requirements" in the "recognition" cluster (Fourman et al., 2017) was approximately double that of the United States total. Here, the African total was 10 and the United States total was four.

Going back to the open comment sections of the regulatory intelligence workshop survey. analysis was done on the comments with the creative inquiry movements words and themes used with the *BIRS Experience*. Again, the words and phrases were searched using NVivo software under the "exact" setting. Words and phrases were also examined manually for a thorough analysis. In Table 4.9, the creative inquiry movements theme comparisons are depicted illustrating the number of occurrences between the United States and African students. Note, this is the total number of comments from all 10 questions. The details of the breakdown of creative inquiry movements themes per question of both the United States and the African students follows in separate tables.

Table 4.9

Creative Inquiry Movements Theme Comparisons in the Regulatory Intelligence Survey

Creative Inquiry Movement	**Creative Inquiry Movement Words/Themes Searched**	**Occurrence in US Student Survey Comments**	**Occurrence in Africa Student Survey Comments**
Connection/Development	Connection	3	2
	Development	0	0
	Useful in the working of problems	12	26
	Usable in the fit of a product	3	6
	Capabilities of human beings	0	1
	Task of development	0	4
	Building concrete prototypes	0	0
	Refining the idea	0	3
	Bringing together all the elements	5	17
	Necessary for production or implementation	4	9
Evaluation	Evaluation	2	1
	Components to assure that tasks will function properly	3	11
	Processes that control the generation of designs	0	3
	Evaluation procedures that ensure effective utilization of knowledge	5	24
Integration	Integration	0	0
	Analysis of design problems and situations	3	14
	Uses the results as both framing and explanatory	0	18

Invention	Invention	2	0
	Discipline depends	0	0
	Different kinds of organizations	2	11
	Strategies by which the discipline engages	5	12
	External world of users	2	14
	Bringing innovation through policies and procedures	4	18
Judgment	Judgment	2	0
	How to frame the situation	6	4
	Who to listen to	0	3
	What to pay attention to	7	6
	What to dismiss	3	5
	How to explore, extract, recognize and choose useful information	7	33
	Potential sources	4	0

Regarding the creative inquiry movements, Tab1e 4.10 depicts the number breakdown per survey comments pertaining to these movements from the United States students.

Table 4.10

Number Creative Inquiry Movements Comments per Question for United States Students

Creative Inquiry Movements	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Total
Connection	1	0	0	0	0	0	1	1	0	0	3
&	0	0	0	0	0	0	0	0	0	0	0
Development	1	4	1	2	2	1	0	1	2	0	12
	1	0	0	0	0	0	0	0	0	0	3
	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0
	2	1	0	0	1	0	0	0	0	1	5
	0	0	0	0	0	0	1	1	0	2	4
Evaluation	0	0	0	1	0	0	0	0	0	1	2
	1	0	0	0	1	0	1	0	0	0	3
	0	0	0	0	0	0	0	0	0	0	0
	1	0	0	2	2	0	0	0	0	0	5
Integration	0	0	0	0	0	0	0	0	0	0	0
	1	0	0	0	2	0	0	0	0	0	3
	0	0	0	0	0	0	0	0	0	0	0
Invention	0	0	0	0	0	0	1	1	0	0	2
	0	0	0	0	0	0	0	0	0	0	0
	0	1	1	0	0	0	0	0	0	0	2
	1	0	1	1	0	1	1	0	0	0	5
	0	0	0	1	0	1	0	0	0	0	2
	1	0	1	1	0	0	0	1	0	0	4
Judgment	0	0	0	0	0	1	1	0	0	0	2
	0	1	1	0	0	0	1	0	2	1	6
	0	0	0	0	0	0	0	0	0	0	0
	1	0	0	1	1	1	1	0	1	1	7
	0	0	0	0	0	0	1	0	1	1	3
	1	1	0	0	0	1	1	1	1	1	7
	0	0	1	1	0	0	1	1	0	0	4

Tab1e 4.11 depicts the number breakdown per survey comments pertaining to the creative inquiry movements from the African students.

Table 4.11

Number Creative Inquiry Movements Comments per Question for Africa Students

Creative Inquiry Movements	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Total
Connection	2	0	0	0	0	0	0	0	0	0	2
& Development	0	0	0	0	0	0	0	0	0	0	0
	2	1	1	4	2	2	4	6	2	2	26
	2	4	0	0	0	0	0	0	0	0	6
	0	0	0	1	0	0	0	0	0	0	1
	0	0	0	1	0	0	2	1	0	0	4
	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	1	1	0	1	0	3
	2	0	0	2	1	2	2	4	2	2	17
	2	3	0	0	1	1	0	2	0	0	0
Evaluation	0	0	1	0	0	0	0	0	0	0	1
	0	0	0	1	5	3	2	0	0	0	11
	0	2	0	1	0	0	0	0	0	0	3
	2	1	1	6	3	1	2	4	1	1	24
Integration	0	0	0	0	0	0	0	0	0	0	0
	2	0	1	0	0	1	2	3	4	1	14
	0	4	0	3	2	1	1	4	2	1	18
Invention	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0
	1	1	2	2	1	0	3	2	0	0	11
	0	0	1	1	2	1	0	0	4	4	12
	0	0	3	3	2	1	1	4	2	1	14
	6	4	2	2	2	0	0	0	2	0	18
Judgment	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	1	1	0	0	2	0	4
	0	0	0	0	0	0	0	3	0	0	3
	0	0	2	0	1	0	2	0	1	0	6
	0	0	2	0	0	0	2	0	1	0	5
	3	7	0	8	3	3	1	4	2	2	33
	0	0	0	0	0	0	0	0	0	0	0

The African students had higher numbers of creative inquiry movements comments in the following clusters (Fourman et al., 2017, p. 7);

- Connection and Development – Useful in the working of problems, and bringing together all the elements.
- Evaluation – Components to assure that tasks will function properly, and evaluation procedures that ensure effective utilization of knowledge.
- Integration – Analysis of design problems and situations, and uses the results as both framing and explanatory.
- Invention – Different kinds of organizations, strategies by which the discipline engages, external world of users, and bringing innovation through policies and procedures.
- Judgment – How to explore, extract, recognize and choose useful information.

Both groups had zero comments regarding the following global skills words and themes (Fourman et al., 2017, p. 6):

- Adjustment
- Empathy
- Integration
- Recognition
- Ethnocentrism
- Acceptance

Under the creative inquiry movements, both groups had zero comments for the following words and themes (Fourman et al., 2017, p. 7);

- Development

- Building concrete prototypes
- Integration
- Discipline depends

The author of this research suggests there are several reasons why both groups had zero comments. The first reason is that the words are difficult to interpret for international audiences. For example, there are other words for adjustment that the subjects in this research might be more accustomed to use. According to Kipler and Chapman (2011), other words for adjustment are:

- Rehabilitation
- Orientation
- Habituation
- Fitting
- Compact
- Accommodation
- Compromise
- Good condition
- Adaptation
- Equating
- Organization
- Change
- Conformity

Likewise, other more common words for empathy that the subjects may use in their everyday language are (Kipfer & Chapman, 2011, p. 949):

- Sensitivity
- Sympathy
- Accord

Continuing, other more familiar words for integration are (Kipfer & Chapman, 2011, p. 1035):

- Affiliation
- Adjustment
- Equating
- Whole
- Mixture
- Combination
- Oneness
- Notation

Other words that are may be more familiar for recognition with the subjects are (Kipler & Chapman, 2011, p. 1158):

- Thanks
- Acknowledgement
- Commendation
- Due
- Repute
- Plot
- Cognizance
- Discovery

- Identification

The word ethnocentrism is a difficult word to understand. In fact, there is no other words for it in the international thesaurus (Kipler & Chapman, 2011). Whereas, acceptance has many other words that can be used in its place (Kipler & Chapman, 2011, p. 815):

- Composure
- Contentment
- Patience
- Admission
- Assent
- Acknowledgement
- Ratification
- Adoption
- Lenience
- Submission
- Consent
- Receiving
- Approval
- Usage
- Negotiable instrument

Under the creative inquiry movements, the word development had zero comments for both the United States and Africa students. Per Kipler and Chapman (2011), the word

development had zero comments for both the United States and Africa students. Per Kipler and Chapman (2011), the word development can also be expressed by (p. 927):

- Increase
- Growth
- Maturation
- Refinement
- Amplification
- Training
- Passage
- Plot
- Conversion
- Evolution
- Effect

The word integration was previously addressed with the global skills words regarding zero comments with both sets of students. This word occurs in both the global skills themes and the creative inquiry movements.

The phrase "building concrete prototypes" (Fourman et. al., 2007, p. 7), can be subdivided into the three separate words – building, concrete, and prototype. Words for building might be the following (Kipler & Chapman, 2011, p. 868):

- Composition
- Construction

Concrete has many different words to use such as (Kipler & Chapman, 2011, p. 898):

- Ground covering

- Pavement
- Conglomeration
- Solid
- Hardness
- Building material
- Plaster
- Floor
- Thicken
- Solidify
- Substantial
- Cohesive
- Particular
- Dense
- Hard

Even the word prototype has words that can be used in its place (Kipler & Chapman, 2011, p. 1145):

- Model
- Original
- Philosophy
- Standard of perfection

Lastly, the phrase “discipline depends” (Fourman et al., 2017, p. 7), has zero comments from both sets of student groups in this research. Again, the two words in this

phrase can be examined. The word discipline can also be expressed by the following (Kipler & Chapman, 2011, p. 931):

- Limitation
- Self-control
- Strictness
- Training
- Study
- Punishment
- Govern
- Temperance
- Occupation
- Orderliness
- Science
- Limit
- Punish
- Conform

Of interest is that the word "depends" has one word that can be used in its place. That is the word "hangs" (Kipler & Chapman, 2011, p. 923). The second reason for the zero comments is that the English language is not internationally standard in its usage as evident from the listing of words from the international thesaurus (Kipling & Chapman, 2011). The author suggests that what one thinks is common English usage is not always true, especially if working with international subjects.

4.5 World Café Responses

The last data collected for this research is the world café responses. These responses were collected at the 2017 First Annual Summit for Academic Excellence in Quality Assurance and Regulatory Science.

The First Annual Summit of Academic Excellence in Quality Assurance and Regulatory Science was held at Purdue University May 18-19, 2017. Twenty-eight registrants enrolled in the conference: 11 locally, 10 from out-of-state, and seven in other parts of Indiana. Of the 28 registrants, six were self-identified students, both undergraduate and graduate, from various disciplines. Twelve self-identified as being part of a regulatory industry, and eight self-identified as working at a university, but not in a student capacity. These eight participants were working in laboratories across the Purdue University campus.

There was a variety of speakers at the summit, giving a wide perspective on the current state of the regulatory and quality field. In addition, speakers were asked to also address a futuristic approach of looking at regulatory practices. Five speakers from industry, an FDA speaker, four speaking on behalf of academia, and one of the academic speakers addressing the Society of Quality Assurance (SQA), the content was vast. Speakers were asked a series of questions ahead of time, such as:

- How are regulatory science, regulatory affairs, and quality assurance taught and implemented at the university level?
- Are we meeting the needs of future researchers and industry?
- For students intending to go into careers of industry, are we helping them to efficiently and successfully transition to the corporate world?

After approximately one and a half days of speakers, the attendees, which included the speakers, were requested to participate in a World Café experience. By counting participants into groups, there were tables set up for everyone to discuss their opinions to the questions below. By randomly assigning individuals groups, the chance of the groups being from a diverse background was better. Attendees were actively participating in this process and seemed to enjoy the interaction and the questions.

The questions given to the world café participants are:

- What will a quality and regulatory professional (scientists, pharmacists, those in healthcare industry) look like in 2027?
- How do you (as a leader in your organization, as a student, as a faculty member) plan to prepare for the changes you have heard about at the symposium?
- How are emerging technologies, including both scientific and technological advances, impacting the new biotechnology?
- Given the regulatory challenges for emerging technologies, what are your recommendations to help universities bring the innovation to industry and ultimately the patient?

Each question answers were examined for the global skills words and phrases used consistently in this research. Again, the words and phrases were searched using NVivo software under the "exact" setting. Words and phrases were also examined manually for a thorough analysis. Table 4.12 displays the number of global skills words and themes found in the world café question responses.

Table 4.12

World Café Global Skill Question Comparisons

Global Skills	Global Skill Words/Themes Searched	Q1	Q2	Q3	Q4	Total
Adjustment	Adjustment	0	0	0	0	0
	Integration of other's ideas	0	19	7	11	37
	Working with those from multiple cultural background	3	10	4	9	26
Empathy	Empathy	0	0	0	0	0
	Understanding	0	1	1	1	3
	Person is experiencing	4	1	0	0	5
	Frame of reference	7	0	7	11	25
Integration	Integration	0	0	0	0	0
	Ability to adjust behaviors	8	1	1	0	0
Recognition	Recognition	0	0	0	0	0
	Requirements	1	0	0	0	0
Respect	Respect	0	1	0	0	1
	Ethnocentrism	0	0	0	0	0
	Acceptance	0	0	0	0	0
	Needs	0	0	0	1	1
	Approaches	3	0	0	3	6

Three scores were on the high side. There were two high scores in the adjustment cluster: Integration of other's ideas and working with those from multiple cultural background (Fourman et al., 2017, p. 6). The other high score was under the empathy cluster: Frame of reference (Fourman et. al., 2017, p. 6).

Regarding the creative inquiry movements, Table 4.13 displays the number of creative inquiry movement words and themes found in the world café question responses.

Table 4.13

World Café Creative Inquiry Movements Question Comparisons

Creative Inquiry Movements	Creative Inquiry Movement Words/Themes Searched	Q1	Q2	Q3	Q4	Total
Connection & Development	Connection	0	1	0	0	1
	Development	0	2	0	0	2
	Useful in the working of problems	6	14	12	12	44
	Usable in the fit of a product	2	1	3	2	8
	Capabilities of human beings	0	0	0	2	2
	Task of development	0	2	0	0	2
	Building concrete prototypes	0	1	0	2	3
	Refining the idea	0	1	0	1	2
	Bringing together all the elements	3	2	5	3	13
	Necessary for production or implementation	1	19	7	12	39
Evaluation	Evaluation	0	0	0	0	0
	Components to assure that tasks will function properly	1	1	0	0	2
	Processes that control the generation of designs	6	3	4	7	20
	Evaluation procedures that ensure effective utilization of knowledge	8	14	10	7	39
Integration	Integration	0	0	0	0	0
	Analysis of design problems and situations	6	0	1	0	7
	Uses the results as both framing and explanatory	1	0	0	4	5
Invention	Invention	0	0	0	0	0
	Discipline Depends	0	0	0	1	1
	Different kinds of organizations	6	3	8	9	26
	Strategies by which the discipline engages	0	2	1	2	5
	External world of users	7	0	11	7	25
	Bringing innovation through policies and procedures	0	1	4	3	8

Judgment	Judgment	0	0	0	0	0
	How to frame the situation	1	2	2	3	8
	Who to listen to	1	0	1	0	2
	What to pay attention to	0	0	0	0	0
	What to dismiss	0	0	0	0	0
	How to explore, extract, recognize, and choose useful information	2	2	5	3	12
	Potential sources	1	2	0	2	5

Six scores were on the high side. There were two high scores in the connection and development cluster: Useful in the working of problems, and necessary for production or implementation (Fourman et al., 2017, p. 7). The two high scores in the evaluation cluster were: Processes that control the generation of designs, and evaluation procedures that ensure effective utilization of knowledge (Fourman et. al., 2017, p. 7). Lastly, there were two high scores in the invention cluster: Different kinds of organizations, and external world of users (Fourman et al., 2017, p. 7).

4.6 Discussion

After understanding that course improvement was needed from the TLI 524 evaluation comments, the *BIRS Experience* was implemented. This interactive experience was delivered in both the BIRS Master's degree classes in West Lafayette, Indiana, and Moshi, Tanzania. The same *BIRS Experience* instructional delivery was given in both locations. This was validated by observation from the BIRS Director Purdue University Polytechnic Institute.

To have a basis for output analysis, global skills words and themes were searched for using NVivo software. The same method of analysis was employed for the creative inquiry movements. In both cases, the data was also examined manually. For data

collection clarification, the West Lafayette, Indiana, class represents the United States students, and the Moshi, Tanzania, class represents the Sub-Saharan Africa students.

Figure 4.1 Global Skills Theme Count Comparisons displays the differences in the NVivo count for the global skill themes. As the histogram shows, there were differences in both the empathy and recognition clusters. The United States students scored higher in both. *Figure 4.2 Creative Inquiry Movements Theme Count Comparisons* shows the NVivo count for the creative inquiry movements words and themes. The scores were similar with the United States students scoring slightly higher in each cluster.

The regulatory intelligence survey responses were the third set of data collected. The survey had 10 questions with a "yes" or "no" answer choice and an open-comment area under each question. *Figure 4.3 Regulatory Intelligence Survey Yes Answers Comparisons* displays the Africa students answering "yes" to the questions more than the United States students. Similarly, *Figure 4.4 Regulatory Intelligence Survey No Answers Comparisons* displays the Africa students answering "no" less often than the United States students. "No response" was an option which the Africa students used less than the United States students.

The survey comments were again analyzed for the global skills words and themes. NVivo was used, as well as, manual examination of the data. "Working with those from multiple cultural backgrounds" (Fourman et al., 2017, P. 6), was again a common response. Regarding "working with those from multiple cultural backgrounds" (Fourman et al., 2017, p. 6), the Africa comments were higher than those from the United States. In the empathy cluster, "understanding" displayed the highest amount of comments.

Although, with "understanding," the United States students had more responses. In the recognition cluster, "requirements" had the most comments. For "requirements," the Africa students had more comments than the United States.

The analysis on the creative inquiry movements with the regulatory intelligence survey was completed as the global skills analysis. Both NVivo and manual examination was used. For the creative inquiry movements, the Africa students had higher number of comments in the following clusters (Fourman et al., 2017, p. 7):

- Connection and Development – Useful in the working of problems, and bringing together all the elements.
- Evaluation – Components to assure that tasks will function properly, and evaluation procedures that ensure effective utilization of knowledge.
- Integration – Analysis of design problems and situations, and uses the results as both framing and explanatory.
- Invention – Different kinds of organizations, strategies by which the discipline engages, external world of users, and bringing innovation through policies and procedures.
- Judgment – How to explore, extract, recognize and choose useful information.

It is noted as a possible limitation of the regulatory intelligence survey that the phraseology of either the questions or the comments had zero responses in several clusters. It is suggested that the language used could have been a more common form of the intended words or meanings.

The last data collected was the world café responses from the 2017 First Annual Summit of Academic Excellence in Quality Assurance and Regulatory Science. A high

number of comments for the global skills words and themes follow (Fourman et al., 2017, p. 6):

- Integration of other's ideas.
- Working with those from multiple cultural backgrounds, and
- Frame of reference.

Regarding the creative inquiry movements words and themes, the high number of comments follow (Fourman et al., 2017, p. 7):

- Connection and Development – Useful in the working of problems, and necessary for production or implementation.
- Evaluation – Procedures that ensure effective utilization of knowledge.
- Invention – Different kinds of organizations, and external world of users.

4.7 Chapter Summary

In summary, four sets of data were collected. The first set of data confirmed the need for more global awareness in the BIRS curriculum. The second data set was an interactive teaching strategy called the *BIRS Experience*. Student output from the experience was analyzed for global skills and creative inquiry movements words and themes. The third data set was a survey given to participants in a regulatory intelligence workshop. Responses from the survey were also analyzed for global skills and creative inquiry movements words and themes. The fourth data set was responses to questions answered by participants at the 2017 First Annual Summit of Academic Excellence in Quality Assurance and Regulatory Science. Again, the world café responses were analyzed for global skills and creative inquiry movements words and themes.

A consistent theme with the data results was that of the need to interact with those from multi-cultural backgrounds. Also, apparent in the data was the need to integrate others' ideas in problem-solving, and to see the problem from others' frames of reference. Other consistent themes from the data occurred around the need to connect and develop problem-solving frameworks to produce and implement solution-based outcomes. Data showed that evaluation is important per innovation. Plus, to innovate effectively, the regulatory science professional needs to be aware of what is happening in the biotechnology world, both internally and externally.

CHAPTER 5. CONCLUSIONS AND RECOMMENDATIONS

Miles and Huberman (1994) suggested that narrative text can provide a framework for reporting qualitative research outcomes. To that end, robust description is used to analyze the data for this project with the purpose to create a lens through which the reader can understand the challenges of global regulatory science instruction.

5.1 Concluding Discussion

The foundation for this research is pragmatic instrumentalism. This type of philosophy finds problems, implements solutions, and evaluates their outcomes. The goal of the outcomes is usefulness to society (Dewey, 2015). However, when we think of society, it is not the local neighborhood. Today, it is the world (Waks, 2006). Therefore, the research in this dissertation is important.

Per Waks (2006, p. 286), "Globalization has integrated most nations...into the world economy...as networked enterprises spread, networked computers are found throughout the workplaces of the developing world, and are spreading to schools." This is a key reason why regulatory science education needs to be integrated into the global health care environment. As the BIRS Center has a presence in sub-Saharan Africa, the opportunity is not to facilitate regulatory science education using technology and other interactive strategies. As the world's health needs to change, so does the way we teach regulatory science. Global skills are imperative. Waks (2006, p. 287) confirms this when he says, "soft skills in cross-group communication are understood to be essential in work settings."

This research has examined the global skills needed in engineering and design education to transfer this to regulatory science instruction. In doing so, this research is

breaking new ground. To confirm this need, course evaluations from TLI 524 *Documents and Dialogues* were examined. One of the leading comments was that the global aspect of regulatory science needed to be reviewed in detail. Other comments stated that examination of problem-solving from different perspectives and approaches was necessary. Plus, the course needed to be continually updated with what was happening in the global biotechnology environment, as well as, the pharmaceutical industry. Other comments pertinent to this research was that TLI 524 *Documents and Dialogues* needed to have more on-line and distance learning options. Clearly, the evaluations demonstrated improvement was needed (Fourman et al., 2017).

To improve the course, a treatment was implemented called the *BIRS Experience*. The *BIRS Experience* was "an interactive role-playing global simulation" (Fourman et al., 2017, p. 4) of getting a fictitious drug to market. Final assignments from the experience "were analyzed for global skill themes which were selected from the literature...those themes being consistent throughout this research: respect, recognition, adjustment, integration and empathy" (Fourman et al., 2017, p. 4). The analysis of the global skill themes was administered to final *BIRS Experience* papers from both the United States and Africa students enrolled in TLI 524. The United States students took the course in West Lafayette, Indiana, and the Africa students took the course in Moshi, Tanzania. However, not all the *BIRS Experience* delivery was given in-person. Supplemental materials were accessible via Blackboard Learn. In both locations, the students had access to the instructor (the author of this research) via email, and WebEx.

Reviewing the global skills words and themes comparison between the United States and Africa students, per Fourman et al. (2017), the American students final paper

contained more global skills words and themes, than the Sub-Saharan students. Those global skills being "adjustment, empathy, integration, recognition and respect" (Fourman et al., 2017, p. 6). However, the Sub-Saharan students had more mentions of "integration" (Fourman, et al., 2017). This is a logical outcome. To understand why this is logical, it is important to look back at the "integration" words and themes. In this research, those "integration" words and themes are the word "integration" itself, and the "ability to adjust behaviors" (Fourman et al., 2017, p. 6). Looking at Merriam-Webster's (2017) definition of "integrate" is, "to end the segregation of and bring into equal membership in society or an organization." Such a definition corresponds with Markus and Conner (2013). These researchers suggested that Americans think differently than Africans about how they express themselves and work in experiences begetting collaboration. Markus and Conner (2013) further suggested that American workers are expected to create, think and design problem solutions more independently. In the opposite, African workers create, think and design more interdependently (Markus & Conner, 2013).

Per Fourman et al. (2017), African workers feel relationships with co-workers are important. Africans are cognizant that others may need help. This corresponds to Rao and Walton (2004), who said, "survival of the kinship was considered almost as important as physical survival" (p. 6). Fourman et al. (2017), confirms, "any development that would benefit one person in Sub-Saharan Africa, needs to benefit all" (p. 8).

In addition, the African students scored lower overall in the creative inquiry movements. As the creative inquiry movements were meant to be a problem-solving

framework, the interdependence of the African students' culture may explain the lower scores. One reason may be that the students from this culture bring into the classroom their interdependence from the home environment (Mesquita, 2001). Per Mesquita (2001), family members from interdependent societies, celebrate together member successes and grieve together over losses. Another explanation why the African and American student entries differed comes from the GLOBE study. This study confirmed that members of the Sub-Saharan culture have strong attachments to groups such as work and school (House, Hanges, Javidan, Dorfman, & Gupta, 2004).

The author suggests therefore creative inquiry movements are more interdependent for the African students and more independent for the United States students (Markus & Conner, 2013). Hofstede, Hofstede and Minkov (2010) confirm this by calling the Sub-Saharan culture a "collectivist" society. Previous in this research, Markus and Conner (2013) called such a culture "interdependent." Hofstede, Hofstede and Minkov (2010) clarify that for their definition of "collectivist," there is no political overtones. Rather, it means "power of the group" (p. 91). Children in Africa grow-up in an extended family comprised of aunts, uncles, grandparents, and cousins. As a result, these children come to view society as a "we" group. This "we" mentality transfers to the school and workplace (Hofstede, Hofstede & Minkov, 2010).

Opposite to a "we" viewpoint is viewing society through an "I" lens. Children that grow-up in an "I" culture are said to be "individualists" (Hofstede, Hofstede, & Minkov, 2010). In individualist family, there may be some siblings, but the extended family rarely lives in the same house. Instead of an interdependence in the school environment, individualist youth are expected to move out of the parents' home when

their education is finished Hofstede, Hofstede and Minkov (2010) say, “neither practically not psychologically is the healthy person in this type of society supposed to be dependent on a group” (p. 91).

The purpose of advancing education is therefore seen differently between the collectivist and individualist societies. The individualist societies see education to teach the student how to stand on their own feet, and cope with unforeseen situations (Hofstede, Hofstede, & Minkov, 2010). In the collectivist society, education is understood to teach children how to be effective with other people. Hofstede, Hofstede and Minkov (2010) say “the purpose of learning is less to know how to do than to know how to learn” (p. 118-119). This corresponds to the creative inquiry movements of “connection and development, integration and judgment” (Fourman et al., 2017, p. 7).

Per Hofstede, Hofstede and Minkov (2010), the individualist versus collectivist society comes to the workplace. These researchers say that management in the individualist society is promoting or not, an individual based on their merit. It is the “I” that gets the raise or bonus pay. Whereas, in the collectivist society, management is one of supervising groups. It is the “we” that collectively gets the raise. This mentality corresponds to the creative inquiry movements of “innovation and evaluation” (Fourman et al., 2017, p. 7)

It is important to also look at the United States scores that were high in the global skills words and themes. The global skills being “adjustment, empathy, integration, recognition and respect” (Fourman et al., 2017, p. 6). Especially, higher scores in empathy and recognition. The author has talked about the lower scores of the Sub-Saharan culture in this genre. In reverse, it is the independence of the American culture

that may have fostered the high scores. However, from the outside looking in, this may seem counter-intuitive. The author of this research suggests that Senge (2006) may have some insight on why this is true. Perhaps, the biotechnology information is accelerating to such a point that those who were previously known for their independence, now realize we need to be interdependent. Senge goes on to say that our technology is leading us to an "age of interdependence" (p. 69). Per Senge (2006), looking at ill-structured problems, such as global health outcomes, requires looking at the whole problem and how the parts of the problem affect the outcome. Senge (2006) says:

> Complexity can easily undermine confidence and responsibility – as in the frequent refrain, "It's all too complex for me," or "There's nothing I can do. It's the system." Systems thinking is the antidote to this sense of helplessness that many feel as we enter the "age of independence." Systems thinking is a discipline for seeing the "structures" that underlie complex situations, and for discerning high from low leverage change. That is, by seeing wholes we learn how to foster health (p. 69).

Waks (2006) agrees with this when he says:

> In today's "knowledge society," knowledge professionals and high-skilled production workers use complex background knowledge from their educations and their out-of-school experiences, in unpredictable ways. They combine it with flows of real-time data and information, and knowledge modules such as on-line software tutorials, to respond to ill-structured problems and make decisions under conditions of uncertainty (p.290).

These two researchers, tie together the concept confirmed with the data from this research that culture and problem-solving knowledge play a joint part in solution-based outcomes.

Senge's (2006) systems thinking corresponds to the distributed cognition of workers and learners commented on this research literature review. Distributed cognition being the "system" of cognition and knowledge being distributed among individuals, and tools for problem-solving (Hollan, Hutchins, & Kirsh, 2000).

This discussion on global skills transitions into the creative inquiry movements because they are tools for fostering solution-based outcomes. The creative inquiry movements are tools to solve problems which is at the heart of pragmatic instrumentalism. A key piece of pragmatic instrumentalism is to connect with a problem, develop and invent the problem solution, integrate the solution, and use evaluation techniques to judge the solution's usefulness.

The number of comments of creative inquiry movements were very similar in number between the American and Sub-Saharan student entries. The themes of "connection and development" (Fourman et al., 2017, P. 7) were higher with the American students. There were several words and themes in this cluster (Fourman et al., 2017, p. 7):

- Connection
- Development
- Useful in the working of problems
- Usable in the fit of a product
- Capabilities of human beings
- Task of development

- Building concrete prototypes
- Refining the idea
- Bringing together all the elements
- Necessary for production or implementation

Of these themes, three stood out as being somewhat higher with the American students than the Sub-Saharan students (Fourman et al., 2017, p. 7):

- Useful in the working of problems
- Usable in the fit of a product, and
- Capabilities of human beings

However, the question needs to be asked why the African students scored lower than the American students. Again, Hofstede, Hofstede and Minkov (2010) have the suggested answer. This research has discussed the interdependence of the Sub-Saharan culture in the home, school and work environments. To complete the interdependence picture, Hofstede, Hofstede and Minkov (2010) examine the collectivist viewpoint in internet usage. These researchers call the "use of modern information and communication technologies, ICT" (Hofstede, Hofstede & Minkov, 2010, p. 123). Hofstede, Hofstede and Minkov (2010) continue by saying that ICT tools are more readily accepted in individualist societies. Whereas, in collectivist societies, people have more chance to speak to relatives that usually live near. Yet, ICT is connecting the world together. This reinforces the purpose for this research pertaining to a technical, on-line, yet interactive regulatory science curricula.

Per Waks (2006):

> The driving forces of the growth of digital networks included the rapid technical advances and price declines in computer chips, satellites and fiber-optic cables which facilitated growth in television, telephony, FAX, and the Internet, turning the global information grid into a seamlessly integrated resource (p. 281).

Thus, the outcomes for the global skills and creative inquiry movements show that the African students want to learn "how to do," and the American students want to learn "how to learn" (Hofstede, Hofstede & Minkov, 2010).

This makes sense. Senge (2006) calls a cluster of people working together for a common goal, an aligned team. The frequent themes of the American students align with a team of human beings working together to solve a problem. Senge (2006) goes on to say that when a team is aligned and working for solution-based outcomes, "there is a commonality of purpose, a shared vision, and understanding of how to complement on another's efforts" (p. 217). Teams are increasingly becoming the decision makers in companies today. Teams are solving ill-structured problems and putting their decisions into actions (Senge, 2006). This corresponds to the higher answers in the "connection and development" (Fourman et al., 2017, p. 7) cluster. Thus, using creative inquiry movements in teams as tools for problem-solving can set the tone for the bigger organization.

For further confirmation that this is the correct conclusion, Senge (2006) has three dimensions for team effectiveness. These dimensions correspond to Dewey's (2015) pragmatic instrumentalism. Dewey's (2015) first premise is problem-recognition. This corresponds to Senge's (2006) first team dimension when he says, "First, there is the

need to think insightfully about complex issues" (p. 219). Dewey's (2015) second pragmatic premise is to gather possible solutions and evaluate their potentials. Similarly, Senge (2006) says, "Second there is a need for innovative coordinated action" (p. 219). Dewey's (2015) third premise for pragmatic instrumentalism is evaluation of the solution's utility, both with society and outcomes. Dewey's (2015) society is the people impacted by the outcome. This could be the team members, as well. Per Senge (2006), "Third, there is the role of the team members on each team" (p. 219).

Communication is important within the teams for maximum effectiveness. This brings to bear the concept of using the best words to express ideas and designs to fellow team members. As the data in this research showed, the words used to convey an idea may not be commonly understood. This is where the global skills come to the forefront. Peat (1987), explained that team dialogue can foster solution-based outcomes. Senge (2006) agreed when he says, "in dialogue, a "kind of sensitivity" develops that goes beyond what is familiar, what we normally recognize as thinking. This sensitivity is "a fine net" capable of gathering in the subtle meanings in the flow of thinking" (p. 225). Using the global skills of "adjustment, empathy, integration, recognition and respect" (Fourman et al., 2017, p. 6) can foster constructive team dialogue that will beget solution-based outcomes. Thus, we leave this part of the discussion with the understanding that global skills and creative inquiry movements are important for a collaborative and global biotechnology environment.

The discussion will now transition to the regulatory intelligence survey responses. Again, the BIRS Master's students from both the United States and Africa filled out the survey. Again, the delivery of the workshop was identical in both places. Each question

contained a yes or no response area, as well as, an open-comment field directly under each question. The African students answered yes to the questions more frequently than did the American students. The no response answers were greater with the American students. The yes questions represented engagement. It could be questioned that the author's presence in the classroom during the survey answer time might have biased the answers more toward a "yes." However, the author delivered the survey the same in both the United States and Africa. The fact that the African students answered yes more is suggested due to their view of learning.

Per Magnus (1996), the students from Sub-Saharan Africa come from predominantly oral societies. This is important in instructional delivery. Especially in Sub-Saharan Africa because English is a second language. Per Magnus (1996):

> A common characteristic of countries in oral traditional societies is that they are multilingual, often with a spoken rather than a written language/culture. Nigeria, for example, ...has more than 100 spoken languages, for which a written tradition exists for about a dozen or so" (p. 22).

Thus, The Sub-Saharan African students "are more likely to prefer the spoken over the written word" (Magnus, 1996, p. 22). Magnus (1996) continues by recommending interactive learning techniques, role-playing and simulations for the Sub-Saharan students. This is confirmation that the *BIRS Experience* is an appropriate instructional approach.

Both audiences seemed to be open to regulatory intelligence as a new way to gather drug and device development information. The workshop started out with the definition of regulatory intelligence being the same as in the glossary of this dissertation.

That being Aslam's (2015) definition of "Processing targeted information and data from multiple sources, analyzing the data in its relevant context and generating a meaningful output to the regulatory strategy. This process is driven by business needs and linked to decisions and actions" (p. 4).

The workshop students then were presented with why regulatory intelligence is important and how it can be implemented for enhancing solution-based outcomes. The concept of looking at a desired drug or device product with the end-in-mind was introduced to reverse engineer the biotechnology steps to achieve the desired state. Or, taking apart the drug or device, figuratively, to see how it works and what can be done for improvements.

The workshop is taught in three steps. The first step is looking at marketplace of the product's intended disease state. This can be done by key learnings from approved drugs or devices already on the market:

- Disease state competitor approval timelines
- Safety data of approved drugs
- Clinical study designs
- Summary basis of approvals
- Advisory committee opinions
- Pediatric studies
- Clinical overview of trials in development

The second step of this type of reverse engineering was to look at drug labeling, especially the following parts:

- Indication and usage

- Mechanism of action
- Drug dose
- Clinical studies

Another item to investigate in this step was advertising and promotion of products already on the market.

The third step was to research the following areas in the intended disease state:

- Post-marketing requirements and commitments
- Quality requirements
- Discontinued and withdrawn drugs in the disease state
- World-wide guidance documents
- World-wide conferences on disease state

Although analysis was carried-out on the global skills and creative inquiry movements, it is note-worthy to look at comments pertaining to reverse engineering. No American students mentioned reverse engineering. African comments about reverse engineering follow:

- "The strategy of reverse engineering could be the source of making innovation improvements for the future" (from regulatory intelligence survey question number one).
- "I will try to design/redesign existing quality practices by using the concept of reverse engineering" (from regulatory intelligence survey question number two).
- "Clinical practices can be implemented differently by again using the concept of reverse engineering" (from regulatory intelligence survey question three).

While reverse engineering was not a global skill or creative inquiry searched on, the concept is still pertinent by providing regulatory intelligence survey context. As this researcher has used engineering and design educational strategies for examination, the process of reverse engineering aligns with this pattern. Per Reverse Engineering (2017), the reverse engineering process is the following (p. 3-4):

Step 1 – Prediction:

- What is the purpose of this product?
- How does it work?
- What market was it designed to appeal to?
- List some of the design objectives for the product.
- List some of the constraints that may have influenced the design.

Step 2 – Observation:

- How do you think it works?
- How does it meet design objectives (overall)?
- Why is it designed the way it is?

Step 3 – Disassemble:

- How does it work?
- How is it made?
- How many parts?
- How many moving parts?
- Any surprises?

Step 4 – Analyze:

- Carefully examine and analyze subsystems (i.e., structural, mechanical, and electrical) and develop annotated sketches that include measurements and notes on components, system design, safety, and controls.

Step 5 – Test:

- Carefully reassemble the product.
- Operate the device and record observations about its performance in terms of functionality (operational and ergonomic) and project durability.

Step 6 – Documentation:

- Inferred design goals.
- Inferred constraints.
- Design (functionality, form (geometry), and materials).
- Schematic diagrams.
- Lists (materials, components, critical components, flaws, successes, etc.).
- Identify any refinements that might enhance the product's usefulness.
- Upgrades and changes (Engineering, 2017, p. 3-4).

This list corresponds to Dewey's (2015) and the regulatory science philosophy of technology of pragmatic instrumentalism. Table 5.1 shows the comparison between the process of reverse engineering and pragmatic instrumentalism.

Table 5.1

Reverse Engineering Process compared to Pragmatic Instrumentalism

Reverse Engineering Process	Pragmatic Instrumentalism
• Prediction • Observation	Define problem
• Disassemble • Analyze	Work to solve the problem
• Test • Documentation	Evaluate solutions usefulness

Regarding the global skills words and themes regulatory intelligence survey comments of interest is the outcomes for "adjustment," specifically, the outcome for "working with those from multiple cultural backgrounds" (Fourman et al., 2017, p. 6). For this, the African student comment total was approximately double that of the United States students. "Recognition" in the "requirements" cluster was also of importance to the African students as their comments total was appropriately double that of the Americans. Again, the reader is to remember for this research, "requirements" denotes the need for policies and procedures necessary for solution-based outcomes.

It is suggested that African students put "working with those from multiple cultural backgrounds" (Fourman et al., 2017, p. 6) as a high comment count is due to the challenge global regulatory science professionals face to solve a problem – "whether business know-how or cultural know-how is more crucial for the success of the operation" (Hofstede, Hofstede & Minkov, 2010, p. 406). This ties into the African student higher response for recognition as well. Before this is tied together, it is again important to note that the "recognition" cluster deals with the policies and procedures necessary for solution-based outcomes. For a developing country, the solutions could

impact many elements of society. Hofstede, Hofstede and Minkov (2010) confirm this when they say:

> Economic development has ecological costs, which economists tend to ignore. The Western democracies' standard of living implies a degree of environmental pollution and depletion of resources that precludes extending this standard of living to the entire world population. Whoever seeks development for everybody should find a new way of handling our ecosystem: sustaining the rich countries' quality of life but drastically reducing its ecological cost. The concept of economic growth may in this respect already be obsolete; another measure for the quality and survival power of economic and ecological systems will have to be found (p. 414-415).

Similarly, the culture of an organization that makes drug products cannot "be taken for granted" (Hofstede, Hofstede & Minkov, 2010, p. 415). The author of this research suggests this to be the reason why the American students scored higher with "empathy." Perhaps different from a developing country's pharmaceutical organization:

> Personnel selection, nomination, and promotion procedures have to take into account arguments other than suitability for the job. Key persons may be moved before they have learned their jobs; often objectives are unclear, and where they are clear, means-ends relations are nebulous...differences in nationality within these organizations again effect both the process and the content of the organization's work (p. 415-416).

As stated previously, in this research, advancing technologies are being used to deliver global instructional content globally to the subjects in this study. The subjects are

connected via "the use of modern information and communication technologies (ICT)" (Hofstede, Hofstede & Minkov, 2010, p. 123). The influence of this technology could be the bridge between the traditionally independent versus interdependent cultures. The author suggests; therefore, the creative inquiry movement comment numbers were very similar between the American and African students. Hofstede, Hofstede and Minkov (2010) agree with this when they say, "The internet and email hold strong appeal and are frequently used to link individuals" (p. 124).

Peters (2006) calls this the global "information economy" (p. 303). Peters (2006) further "hypothesizes a new kind of information capitalism predicted on the shift from knowledge to information" (p. 303). His key points regarding the global "information economy" follow (p. 303):

- Transformation of society from industrial to service to information economy.
- Transformation from analog to digital processing technologies.
- Transformation from analog to digital processing technologies.
- Transformation from knowledge to knowledge management, and from knowledge management to the articulation of fragmentary flow of information.
- Exponential growth of knowledge and emergence of the knowledge industry.
- Transformation from late capitalism to ad hoc transnational management capitalism and bricolage entrepreneurialism in postindustrial nations (Peters, 2006, p. 303).

Entrepreneurship denotes innovation. However, what this research would like to look at more closely from the previous bullet is the word "bricolage." Per the Oxford

Living Dictionary (2017), "bricolage" is defined as "something constructed or created from a diverse range of things." This is innovation and can be applied to the regulatory science profession.

This desire for innovation is validated by the responses to the world café questions collected from the 2017 First Annual Summit of Academic Excellence in Quality Assurance and Regulatory Science. The question responses for the global skills and creative inquiry movements themes follow (Fourman et al., 2017, p. 6-7):

Global skills themes:

- Integration of other's ideas.
- Working with those from multiple cultural backgrounds.
- Understanding diverse frames of reference pertaining to problems.

Creative inquiry movements themes:

- Connection and development is important in the working of problems and in the production and implementation of problem solutions.
- Evaluation procedures that control the generation of designs and provide effective utilization of knowledge.
- Invention in the respect of awareness of what is happening in different organizations.
- Similarly, invention with respect to knowing what is happening with the external world of users.

By looking at the question responses, both global skills and creative inquiry movements, it is evident that innovation is imperative going forward in the regulatory science discipline. The next section will look at the recommendations for achieving these

global skills and creative inquiry movements in instruction that begets the tools for solution-based outcomes.

5.2 Recommendations

This research impacts regulatory science instruction, negotiations and subsequent global health outcomes. The following is therefore recommended enhancements for a regulatory science global curriculum (Guang & Trotter, 2012). Develop the following:

- Leadership course that stresses the global skills of adjustment, empathy, integration, and respect.
- Course that recognizes the global guidances and regulations used to ensure a quality culture.
- Critical thinking course using connection and development, invention, integration, evaluation and judgment as a template for problem solving.
- Courses that use technologies for real-world case studies and interactive simulations that connect the Sub-Saharan and United States students together to solve the problem.
- Course that involves networking in the geographical areas impacted by regulatory science development.
- Course for current global pharmaceutical trends in safety and risk mitigation.
- Innovation and entrepreneurial course where students become conversant with global pharmaceutical business topics.
- Clinical strategies course pertaining to novel drugs, dosage forms, and delivery systems.

- Assignment rubrics that balance academic structure with regulatory professional judgment.

While the *BIRS Experience* was developed and delivered to be a global interactive instructional simulation, there are other strategies. Besides a curriculum taught with a focus on the key points previously mentioned, workshops like the regulatory intelligence one need to continue. Other topics for the workshops can include quality, leadership, business acumen, good clinical practices, supply chain management, statistics, good manufacturing practices, international submission processes, good laboratory practices, regulatory informatics, and development and approval of drugs, biologics, diagnostics and devices. Topics can also be informed from annual summits to collect world café responses such as in this research.

However, this is not all. As the literature suggests, cultural awareness impacts how global business is handled. Since there are African subjects in this research, not only a business, but also a health outcomes mindset is imperative (Guang & Trotter, 2012). Confirming this, Guang and Trotter (2012) recommend the following for establishing a regulatory science international community:

- Develop international empathy to enhance regulatory science development opportunities.
- Respect cultural dialogue contrasts with the regulators.
- Understand that cultural differences are not right or wrong.
- Realize that a regulatory science solution may not be transferable to every geographical area.

- Involve colleagues from the geographical area to participate in decision making related to regulatory science strategies.

To achieve these points, the author of this research suggests a concept called the Regulatory Toolkit. The premise of this tool is to help the developer of a health-related product to achieve regulatory approval from the respective Ministry of Health (MoH). Even though the country MoH, such as the American FDA, or the European EMA regulate the development, manufacturing and quality for drug products, the process of achieving official approval can be overwhelming to the applicant. Moreover, consulting may be cost prohibitive to drug start-ups. In addition, electronic systems have created unique challenges for developing, implementing and successfully maintaining an effective quality management system in a global environment. To provide the required information more easily and effectively, the author suggests developing a web-based approval guidance tool called the Regulatory Toolkit. The toolkit will provide the global (FDA and EMA) information for drug manufacturing and quality to researchers in an academic and industrial settings who do not have access to regulatory intelligence experts. It will be updated by graduate students from the Purdue University Polytechnic Institute BIRS Center. It will also provide both quality assurance and quality control information. Medicine quality is imperative to patient outcomes. Lack of quality can lead to lack of confidence in the healthcare system, drug ineffectiveness, adverse reactions, hospitalization, and even death. When medicines do not meet the standards for purity, strength, and quality in the labeling, they are classified as adulterated, misbranded or counterfeit.

The Regulatory Toolkit can be the instrument to take raw data and turn it into active and related analysis. This data analysis and integration into company practice and procedures produces regulatory intelligence which enhances commercialization approvals. The toolkit can also provide robust information as it pertains to the quality required for pharmaceutical manufacturing.

This recommendation for a regulatory toolkit simplifies the process of applying for MoH approval. For example, when an applicant is concerned about the extent of the quality section required for manufacturing, they can submit a query and the answer will take them to pertinent global guidances. The author suggests that such a toolkit approach is using technology to its fullest regarding global health solutions.

However, an evaluation mechanism needs to be in place if the regulatory toolkit is to meet the pragmatic instrumentalism criteria. It is suggested to design an evaluation method that is a mix of qualitative and quantitative measures that informs continuously and provides objective measurement of the extent to which the toolkit achieves its stated objectives. Formative evaluation needs to be conducted to provide feedback and strategies for product monitoring and improvement, and information needed to identify possible gaps in the toolkit's implementation. With evaluation, minor adjustments can be made and identify features contributing to, or inhibiting, program success.

The author of this research also suggests development and validation of instruments to measure the effectiveness of regulatory science education programs in developing student competencies in core areas such as scientific comprehension, regulations, quality, clinical practices, communication, strategy, ethics, critical thinking, and manufacturing

5.3 Chapter Summary

Per Fourman et al. (2017):

> This research has examined the need for global skill development in the regulatory science discipline. The skills are valued by both the Biotechnology Innovation and Regulator Science (BIRS) Center at Purdue University Polytechnic Institute, as well as other workforce development groups such as BioCrossroads (2012), and the global real-world business developers (Economic Intelligence, 2005). Additionally, from previous course survey data, this researcher gleaned that more global interaction instruction was sought by the regulatory science students. An interactive regulatory science classroom activity called the BIRS Experience was developed and analyzed to see if it could be a gap-filler for global skill instruction. The subjects in the research were both American and Sub-Saharan Africa students who took the same course and submitted the same assignments (p. 9).

Suggestions on why the American and African students had different global skill and creative inquiry movement outcomes has been addressed.

Another set of data was questions asked after the delivery of a regulatory intelligence workshop to both American and African students. Again, the outcomes were analyzed for global skills and creative inquiry movements. Once again, the outcomes were different from the American and African students. This research suggests that cultures from the different regions influenced the answers, but also the expanding technologies that has connected global regulatory science communities.

Lastly, the answers from a world café exercise from a quality and regulatory science summit were analyzed. Information was obtained from the questions with the intention to forecast what is needed for the regulatory science professional of the future. It was clear that global skills, as well as a framework for solving ill-structured problems is needed for the regulatory science professional discipline. It is suggested that the creative inquiry movements be used for the problem-solving framework. More research is required after implementation of the proposed key points in this research of regulatory science education and workshop delivery moving forward.

APPENDIX

Purdue IRB Protocol #1602017223

Purdue IRB Protocol #: 1602017223 - Expires on: 26-JUN-2018

CONTINUING REVIEW or CLOSURE

Purdue University, Institutional Review Board, v20160525

INSTRUCTIONS

1. Amendments to the study must be submitted separately from the request for Continuing Review. The only amendments permitted using this form are those minor changes requested by the IRB.
2. Additional pages may be added as necessary. Please indicate in the appropriate sections/questions on this form when attachments have been provided.
3. **CITI Education for studies NOT closing**: All Principal Investigators, Co-Investigators and Key Personnel CITI certifications must be current. Studies cannot be approved until all of the aforementioned investigators have their current CITI certifications for Human Subjects Research.
4. **Attachments for studies still open to enrollment:** Attach the current consent form (clean copy) in pdf and all recruitment materials.
5. **For studies conducted with collaborative institutions**, provide a copy of the collaborative institution's current IRB approval, or indicate that IRB oversight has been deferred to Purdue University. See Section VI Required Attachments.

INVESTIGATOR INFORMATION

1. Principal Investigator contact information:

Name and Title	Department	Campus Address	Phone	Email	CITI Training Expiration Date
Kari Clase, Professor	TLI	YONG 367	4-4649	kclase@purdue.edu	09/20/2008

2. Co-Investigators and/or Key Personnel contact information:

Name and Title	Department/ Institution	Email	Directly Interacting with Subjects? Y/N	Accessing Identifiable Information? Y/N	CITI Training Expiration Date
Jan Fourman, Research Assistant	TLI	jfourman@purdue.edu	☐Yes ■No	☐Yes ■No	01/20/2021
Chandrani Mishra, Postdoc	BIRS Center	mishrac@purdue.edu	☐Yes ■No	☐Yes ■No	02/20/2001
Lauren Terruso, Operations Manager	BIRS Center	lterruso@purdue.edu	☐Yes ■No	☐Yes ■No	06/20/2001

3. Consultant(s) contact information:

Name and Title	Department/ Institution	Phone	Email	Directly Interacting with Subjects? Y/N	Accessing Identifiable Information? Y/N
				☐Yes ☐No	☐Yes ☐No
				☐Yes ☐No	☐Yes ☐No

CONFLICT OF INTEREST

4. Do the investigators or personnel have a significant financial interest in this study that has not previously been disclosed for this study?

☒ NO - If no, skip to question 6.
☐ YES - If yes, proceed to question 5.

5. Has a Significant Financial Interest Disclosure Form been filed?

☐ NO - If no, refer to Financial Conflict of Interest: Policy and Procedures.
☐ YES - If yes, proceed to question 6 below.

6. Do the investigators or personnel have any other known conflict of interest in this study for this study which have not been previously disclosed?

☒ NO
☐ YES - If yes, please explain the conflict:

STUDY INFORMATION

7. Study Title: Biotechnology Innovation and Regulatory Science Program Evaluation

IRB Study number: 1602017223

IRB Approval Expiration Date (see stamped consent form): 06/12/2017

8. Funding Source: Has funding for this study changed since the last IRB review?

☒ NO

☐ YES
If yes, select all that apply:

- ☐ Federal Funding
  Identify the Sponsor and grant/award number:
- ☐ Other External Funding
  Identify the Sponsor and grant/award number:
- ☐ Departmental Funding
- ☐ Self-Funded

SECTION I: STUDY ACTIVITY SINCE EXPIRATION DATE

Has IRB approval expired on this study?
■ NO, go to Section II
☐ YES, identify the study activities have been undertaken on the study since expiration of IRB approval?

Check all that apply. Dates are in the format of mm/yyyy.

☐ Subjects Recruited
Date range: _____ to _____
☐ Subjects Enrolled
Date range: _____ to _____
☐ Data collected about subjects (directly or indirectly)
Date range: _____ to _____
☐ Identifiable data about subjects used in data analysis
Date range: _____ to _____
☐ Identifiable data about subjects was secured and has not been accessed

Has the data been stored in a locked room?
☐ NO,

☐ YES, identify

Location of the Data: _____

Date: _____ to _____

Other: Please describe:

Date range: _____ to _____

I affirm that no activity was undertaken after expiration of IRB approval ☐ YES

☐ NO

SECTION II: STUDY STATUS GOING FORWARD, AFTER IRB REVIEW

(Check one and follow the related instructions)

■ **Open to Enrollment** – Check one of the following and **Attach copies of last IRB approved consent document(s) and recruitment material(s)**. To modify these documents, a separate Amendment must be uploaded.

■ Enrollment of new subjects or review of records/specimens continues. **Skip to Section III.**

OR

☐ No subjects have been enrolled to date. **Please explain below** why no subjects have been enrolled, **then skip to Section IV.**

☐ **Closed to Enrollment** – Check which of the following conditions apply, **then skip** to **Section III**

☐ No new subjects are being enrolled but they are still receiving research-related intervention or interaction.

OR

☐ No new subjects are being enrolled. Subjects they have completed research-related interventions; but long-term follow-up procedures continue. Long-term follow-up includes:

- Research interactions that involve no more than minimal risk to subjects, or
- Collection of follow-up data from procedures or intervention that would be done as part of routine clinical care. Research interventions which would not be performed for clinical purposes are considered research-related interventions and are not considered follow-up.

☐ **Data Analysis Only** – If the following conditions are met, **skip to Section III.**

- Subjects have completed research-related intervention or interaction and long-term follow-up has been completed, **AND**
- Remaining research activities are limited to only data analysis that may require access to identifiable records and/or specimens whether identified directly or via code with existing code key.

☐ **Study Closed** – Check all that apply, **then go to Section III:**

1. ☐ No further interventions/interactions with subjects, no follow-ups, nor access to personally identifiable information for research purposes are occurring.
2. ☐ All data analysis involving the research site(s) under this study is complete. **OR**

   ☐ Data have been de-identified. No direct identifiers or code key(s) (if data are coded) exist that would allow for the potential identification of subjects.
3. ☐ Grant funds associated with the study are no longer being accessed. **OR**

   ☐ An associated grant remains active, the human subject research activities have ended and a Memorandum of Understanding with the Office of Research Administration has been executed.

   Any questions related to grant funds should be directed to vprregulatory@purdue.edu.

SECTION III: SUBJECT SUMMARY

☐ Check here if the study utilizes accessing existing records about or specimens from people. Provide the number of records/specimens that have been reviewed or collected in the Subject Summary Table.

☐ Check here if the IRB has approved a waiver of consent for the study.

When this form asks for the number of subjects, document the number of individuals enrolled or the number of records that have been reviewed in the Subject Summary Table.

2. **Subject Summary Table**

Subject Summary Table		On-Site*
Since last IRB review	Total number of subjects **enrolled** (include those consented for screening), or whose records/samples have been accessed	50
	Total number of subjects who **failed screening** (e.g. found ineligible to participate) after they were consented	0
	Total number of subjects who **withdrew** from the study	0
Since beginning of study	Total number of subjects **enrolled (include those consented for screening), or whose records/samples have been accessed**	50
	Total number of subjects who **failed screening** (e.g. found ineligible to participate) after they were consented	0
	Total number of subjects who **withdrew** from the study	0
	Total number of subjects who have **completed** the study	50
	Total number of subjects who have **yet to complete** the study	50

* On-Site refers to the study site(s) for which the study was approved by the Purdue IRB. For multi-site trials, do not include subject summary information for study sites over which the Purdue PI did not have oversight.

2. **Withdrawal**. If any subjects have withdrawn from the study since the last IRB review, state the reason(s) for subject withdrawal(s).

3. **Ethnic/Racial Reporting Required for Federally-Sponsored and VA Studies**

Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino				0
Not Hispanic or Latino				0
Unknown (Individuals Not Reporting Ethnicity)				0
Ethnic Category Total of All Subjects	0	0	0	0

Racial Categories				
American Indian/Alaska Native				0
Asian				0
Native Hawaiian or Other Pacific Islander				0
Black or African American				0
White				0
More Than One Race				0
Unknown or Not Reported				0
Racial Categories Total of All Subjects	0	0	0	0

SECTION IV: STUDY EVENTS

1. Since the last IRB approval, did any unanticipated problems involving risks to subjects or others, adverse events, protocol deviations, subject complaints or noncompliance occur that required prompted reporting to the IRB?

☒ NO

☐ YES – Provide a summary of these events either in the space provided or as an attachment, and the date(s) these events were reported to the IRB.

2. Since the last IRB approval, did any protocol-related adverse events, protocol deviations or subject complaints occur that did not require prompt reporting to the IRB?

☒ NO

☐ YES – Provide a summary of these events either in the space provided or as an attachment. For convenience a **Tracking Log for Events Not Requiring Prompt Reporting to the IRB** is available on the Forms page of the HRPP website

3. Is there a data safety monitoring plan for this study? ■ YES NO

Did this study have a data safety monitoring board?

☒ NO

☐ YES – Please upload the most recent monitoring report to COEUS if it has not already been provided to the IRB.

4. Have changes to risks to subjects presented by this study been identified (whether by type, frequency, duration and/or severity) since the last IRB approval?

☒ NO

☐ YES – Please explain:

SECTION V: SUMMARY

1. **Study Progress:** Describe the progress of the research, including any preliminary observations and information about study results or trends:

Fifty students have been interviewed at their final semester of their BIRS Master's program and data has been collected. In addition, currently enrolled students, and those entering in the future will be interviewed in their final semester. Alumni will be contacted beyond graduation.

2. **Literature Summary:** Summarize the recent literature that has been published or presented by the investigator or others relevant to this study since the last IRB approval. Include in the summary if there has been a demonstrated significant impact on the well-being of subjects?

N/A

3. Have there been any external reviews of this study (ie, by a study sponsor, federal agency, regulatory body, or other IRB) since the last IRB review?

☒ NO

☐ YES – Please identify when the review was conducted, by whom, and a summary of any findings. Attach the report(s) if available.

4. Has the risk/benefit ratio of this study been altered since the inception of the study?

☒ NO

☐ YES – Please explain:

SECTION VI: REQUIRED ATTACHMENTS

Please check the appropriate boxes as they apply to the study. **Consent/Assent Documents and Recruitment Materials** (**Required** for studies in **Open to Enrollment** status):

	#	Description
☐ Assent form; number of assents forms attached:	0	
■ Consent form; number of consents forms attached:	2	one online; one written
☐ Parent permission form; number of permission forms attached:	0	
■ Study information sheet; number of information sheets attached	0	Recruitment materials, information sheet, and cons
■ Recruitment materials (please list):	0	Recruitment materials, information sheet, and consent forms are all the same document and distributed to students at the same time.

Submit clean (without the IRB stamp) copies with the submission in COEUS.

Other Study-Specific Documents

☐ HIPAA Authorization; (**Required** for **Open to Enrollment** studies if applicable)

☐ IRB Approvals from other institutions, if Purdue has not deferred IRB review (please list):

Purdue IRB Protocol #1702018747

PU
Protocol #: 1702018747
Investigator: CLASE, KARI L

Expiration Date:
Last Approval Date:

Purdue University
Protocol Summary

Protocol Number: 1702018747
Sequence Number: 1
Status: Pending/In Progress
Expiration Date:
Last Approval Date:
Investigator: CLASE, KARI L

Protocol Details

Type: Request for Non-Exempt Approval
Description:
Application Date: 02/03/2017
Reference Num 1:
Reference Num 2:
FDA Application No:
Title: Global On-Line, Interactive and Simulated Learning Techniques Via BIRS

Organizations

Type	Organization	Address
Performing Organization	Purdue University	Purdue University 155 S GRANT STREET WEST LAFAYETTE IN - 479072114 USA

PU
Protocol #: 1702018747
Investigator: CLASE, KARI L

Expiration Date:
Last Approval Date:

Investigators

Person Name	Units		Affiliate	Training Flag
CLASE, KARI L	41906000	Tech, Leadership, an	Faculty	N
FOURMAN, JANET L	41906000	Tech, Leadership, an	Key Personnel	N
TERRUSO, LAUREN A	42703000	Bindley Biosci Ctr	Non Key Personnel	N

Areas of Research

Code	Description
000001	All Research Areas

Actions

Description	Comments	Action Date
Submitted to IRB	Submit to IRB	12/12/2017
Submitted to IRB	Submit to IRB	02/03/2017
Protocol Created	Protocol Created	02/03/2017

Subjects

Subject	Count
IRB Approved Max. Participants	50

Protocol Notes

Comment	By	Time
Protocol rejected: Please complete a cover sheet and re-submit. Also note you no longer have to submit through coeus, you can simply log onto	BRAUN10	12/12/2017 15:13:50

PU
Protocol #: 1702018747
Investigator: CLASE, KARI L

Expiration Date:
Last Approval Date:

Protocol Notes

Comment	By	Time
www.irb.purdue.edu and upload your documents through our IRB portal - Thank you, HRPP		
Protocol rejected: PI cannot have 2 protocols with same title. Please edit the title and submit again.	OZTURKE	02/15/2017 12:13:02
20170213 email rerouting sent to PI and all investigators.	OZTURKE	02/13/2017 11:27:34

Roles

Protocol Aggregator

User Id	User Name	Unit Name
LTERRUSO	TERRUSO, LAUREN A	Bindley Biosci Ctr

Protocol Approver

User Id	User Name	Unit Name
DECKER26	DECKER, SCHELLY	Vp For Research
BRAUN10	BRAUN, DANA M	Vp For Research
RATHINAR	ATHINARAYANAN, RAGU	Tech, Leadership, an
JRIDDICK	RIDDICK, JENNIFER, C	Vp For Research
GRIMESL	GRIMES, LYNN, A	Polytech-Adm
KGASCHO	GASCHO, KIMBERLEY E	College Of La-Admin
ACARLSON	CARLSON, AMY S	Sponsored Prog Svcs
EEPARKS	ALDRIDGE, ERIN E	Inactive Users
KCLASE	CLASE, KARI L	Tech, Leadership, an
MLSPRING	SPRINGER, MITCHELL L	Org Leadership/Supv
MARTI652	MARTIN, AMBER L	Ofc of VP Stu Life
KKBURNS	MUMMERT-BURNS, KIMBERLEY K	Inactive Users
TRAMIRE	RAMIREZ, THOMAS D	External Users
SMIT2553	SMITH, JALEN K	Purdue University West Lafayette

PU
Protocol #: 1702018747
Investigator: CLASE, KARI L

Expiration Date:
Last Approval Date:

User Id	User Name	Unit Name
NHATHAW	HATHAWAY, NANCY	Inactive Users
OZTURKE	OZTURK, EMINE	WL Educational Studi
RAHMAN5	RAHMAN, MUNAZZAH	Engineering Educ
HRPPIRB	ADMIN, HRPP IRB	Vp For Research

Others

Name	Value
AREA	
COMPENSATION AMOUNT	
COUNTY	
LAST RENEWAL REPORT DATE	
PROGRAM AREA	
PROJECT END DATE	
PROJECT START DATE	
REVIEWING_IRB	
X_DEFERRING_INSTITUSTION	
X_DEFERRING_INSTITUSTION_02	
X_DEFERRING_INSTITUSTION_03	
X_DEFERRING_INSTITUSTION_04	
X_DEFERRING_INSTITUSTION_05	
X_DEFERRING_INSTITUSTION_06	
XX_STUDY METHODS	
XX_STUDY METHODS 02	
XX_STUDY METHODS 03	
XX_STUDY METHODS 04	
XX_STUDY METHODS 05	
XX_STUDY METHODS 06	

Questionnaire

Questionnaire Name:	IRB: Non-Exempt Request	**Principal Investigator:**	CLASE, KARI L
Protocol Number:	1702018747	**Title:**	Global On-Line, Interactive and Simulated Learning Techniques Via BIRS

Complete and submit this questionnaire when requesting approval for a non-exempt study. use this questionnaire for studies to be reviewed by either expedited or full board review. Incomplete questionnaires will be returned to the investigator without review. Select "Yes" to proceed.

Yes

[1] Do you request Full Review or Expedited Review?

Expedited

[2] Co-Investigators must be CITI Certified, or an equivalent. If Co-Investigators are from another institution, please upload the accepted human subjects research training completion report for their institution to the Attachments Screen before submission to IRB. Click Yes to continue.

Yes

[3] Where will the project be conducted?

Purdue West Lafayette Campus

[4] Which vulnerable subject populations does this project involve? Select all that apply.

None

[5] What is the maximum number of subjects to be enrolled in this protocol? This number shoud be consistent with sound principles of research design.

50

[6] does this project propose to use an Investigational New Drug (IND) or an Approved Drug for an Unapproved Use?

No

[7] Does this project propose to use and Investigational Medical Device or an Approved Medical Device for an Unapproved Use?

No

[8] Does the proposed project require Radiation Safety Approval?

No

[9] Does the proposed project expose subjects to Radiation or Radioisotopes?

No

[10] Which of the following does the project propose to employ? Select all that apply.

None of these

[10b] Please complete and upload your Non-Exempt Application to the Attachments screen before submission to IRB. Please note that your narrative needs to describe any of the above items answered in the affirmative. This form can be found on the website under the Forms Page. Select Yes to continue.

Yes

[11] Do you, or any other personnel listed on this protocol, have any financial interests and/or potential or real conflicts of interest related to this study?

No

[A] Did you find that you were unable to add certain personnel to the Investigators/Study Personnel tab? If so, please list the missing study personnel below along with their role, email address and phone numbers. If you have entered all personnel successfully on this protocol, please enter N/A.

N/A

Purdue IRB Protocol #1705019228

PURDUE
UNIVERSITY

HUMAN RESEARCH PROTECTION PROGRAM
INSTITUTIONAL REVIEW BOARDS

To:	CLASE, KARI LFOURMAN, JANET LTERRUSO, LAUREN A
From:	DICLEMENTI, JEANNIE D, Chair Social Science IRB
Date:	02/01/2018
Committee Action:(2) (4)	Determined Exempt, Category (2) (4)
IRB Action Date:	01 / 23 / 2018
IRB Protocol #:	1705019228
Study Title:	Outcomes of Summit in Academic Excellence in Quality Assurance and Regulatory Science

The Institutional Review Board (IRB) has reviewed the above-referenced study application and has determined that it meets the criteria for exemption under 45 CFR 46.101(b).

Before making changes to the study procedures, please submit an Amendment to ensure that the regulatory status of the study has not changed. Changes in key research personnel should also be submitted to the IRB through an amendment.

General

- To recruit from Purdue University classrooms, the instructor and all others associated with conduct of the course (e.g., teaching assistants) must not be present during announcement of the research opportunity or any recruitment activity. This may be accomplished by announcing, in advance, that class will either start later than usual or end earlier than usual so this activity may occur. It should be emphasized that attendance at the announcement and recruitment are voluntary and the student's attendance and enrollment decision will not be shared with those administering the course.
- If students earn extra credit towards their course grade through participation in a research project conducted by someone other than the course instructor(s), such as in the example above, the students participation should only be shared with the course instructor(s) at the end of the semester. Additionally, instructors who allow extra credit to be earned through participation in research must also provide an opportunity for students to earn comparable extra credit through a non-research activity requiring an amount of time and effort comparable to the research option.
- When conducting human subjects research at a non-Purdue college/university, investigators are urged to contact that institution's IRB to determine requirements for conducting research at that institution.
- When human subjects research will be conducted in schools or places of business, investigators must obtain written permission from an appropriate authority within the organization. If the written permission was not submitted with the study application at the time of IRB review (e.g., the school would not issue the letter without proof of IRB approval, etc.), the investigator must submit the

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written permission to the IRB prior to engaging in the research activities (e.g., recruitment, study procedures, etc.). Submit this documentation as an FYI through Coeus. This is an institutional requirement.

Categories 2 and 3

- Surveys and questionnaires should indicate
  - only participants 18 years of age and over are eligible to participate in the research; and
  - that participation is voluntary; and
  - that any questions may be skipped; and
  - include the investigator's name and contact information.
- Investigators should explain to participants the amount of time required to participate. Additionally, they should explain to participants how confidentiality will be maintained or if it will not be maintained.
- When conducting focus group research, investigators cannot guarantee that all participants in the focus group will maintain the confidentiality of other group participants. The investigator should make participants aware of this potential for breach of confidentiality.

Category 6

- Surveys and data collection instruments should note that participation is voluntary.
- Surveys and data collection instruments should note that participants may skip any questions.
- When taste testing foods which are highly allergenic (e.g., peanuts, milk, etc.) investigators should disclose the possibility of a reaction to potential subjects.

You are required to retain a copy of this letter for your records. We appreciate your commitment towards ensuring the ethical conduct of human subjects research and wish you luck with your study.

Exemption Granted on 23-JAN-2018

The following questions will be verbally read for discussion to the world café participants

- What will a quality and regulatory professional (scientists, pharmacists, those in healthcare industry) look like in 2027?
- How do you (as a leader in your organization, as a student, as a faculty member) plan to prepare for the changes you have heard about at the symposium?
- How are emerging technologies, including both scientific and technological advances, impacting the new biotechnology?
- Given the regulatory challenges for emerging technologies, what are your recommendations to help universities bring the innovation to industry and ultimately the patient?

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