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Emerging Technologies: Empowering people to capture, share and transfer tacit knowledge

Donncadh J. Nagle
TU Dublin

Melanie J. Adams
PRST, TU Dublin

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Authors

Donncadh J. Nagle, Jacobs Engineering & TU Dublin Researcher
Melanie J. Adams, Associate Director Knowledge Management MSD & PRST TU Dublin

Abstract

ICH Q10 was published in 2008, and presented a model for an effective Pharmaceutical Quality System (PQS). However, the industry still has some way to go in embracing and implementing its principles in order to achieve greater product realisation, to establish and maintain a state of control, and to facilitate continual improvement.

ICH Q10 introduced us to two key enablers: Knowledge Management (KM) and Quality Risk Management (QRM).[1] While the pharmaceutical industry has made progress in implementing the principles of QRM since 2008, there has been significantly slower progress in implementing knowledge management practices. However, there may be solutions available to us today that may very well help speed up this implementation. This journal article looks at how emerging technologies may assist pharmaceutical companies to capture, share and transfer tacit knowledge.

The article focuses on the potential that emerging technology has to harness knowledge that is often difficult to capture, namely tacit knowledge. Paper 1 in this series defines Tacit Knowledge and gives examples. Tacit knowledge is typically acquired through experience, and it is intuitively understood. As this type of knowledge and skill is challenging to articulate in pharmaceutical policies and procedures, it can be difficult to transfer this information to other individuals. However, recent advances in technology may well hold the key to unlocking this illusive and invaluable source of knowledge within our industry. This article explores the benefits of using mixed reality technology (AR/VR) to assist pharmaceutical companies capture, share and transfer knowledge with a focus on KM as applied to technology transfer.

Introduction

ICH Q10 defines Knowledge Management as:

> *'a systematic approach to acquire, analyse, store and disseminate information'*[1]

Recent research into knowledge management has recognised that knowledge transfer is very important to enable technology transfer.[2]

In the 14 years since ICH Q10 was released the emergence of new technologies that are reshaping the competitive landscape across the pharmaceutical industry has occurred. The industrial internet of things (IIoT), Industry 5.0 and digitalisation are all transforming the way pharmaceutical businesses and facilities operate. This rapid advancement of digital technologies in the world today is arguably the most rapid

advancement of any innovation in our history. One has to ponder: why isn't Pharma taking advantage of this technological revolution and using it for the betterment of KM?

Tacit Knowledge

Tacit knowledge is defined in the introductory paper of this journal issue, and is knowledge gained through experience, However, one must question: do we actually understand what tacit knowledge is? Do we understand the power and value of tacit knowledge?

Tacit knowledge can be defined as skills, ideas and experiences that people have but are not codified and may not necessarily be easily expressed [3]. Individuals do not all learn in the same way so tacit knowledge can be considered innately human. Although tacit knowledge is difficult to articulate, its importance cannot be overlooked, and techniques should be employed to surface and transfer appropriate tacit knowledge.[2]

In 2021 the International Society of Pharmaceutical Engineers (ISPE) released a Good Practice Guide on Knowledge Management in the Pharmaceutical Industry. The guide proposes that a systematic knowledge management program that manages tacit knowledge is a powerful tool to help maximise knowledge awareness and to minimise knowledge loss that can threaten business continuity.[3] This article explores ways emerging technology could be used as one solution to capture and manage tacit knowledge.

Emerging Technology – Introducing Mixed Reality Technology

Emerging technologies are quickly playing a greater role in how the Pharmaceutical and Life Sciences Industry collects, stores and interprets its data and knowledge. Mixed reality technologies and platforms are becoming more widespread in the application of displaying and interrogating this data and knowledge.

The Microsoft HoloLens2, is one of these mixed reality technology solutions, and is a digital headset that uses augmented reality and holographic imagery that offers a unique user experience. Referred to as mixed reality, this technology offers a blend of physical and digital worlds, unlocking natural and intuitive 3D human, computer, and environmental interactions.[4] Figure 1, prepared by Microsoft illustrates how this interaction works.

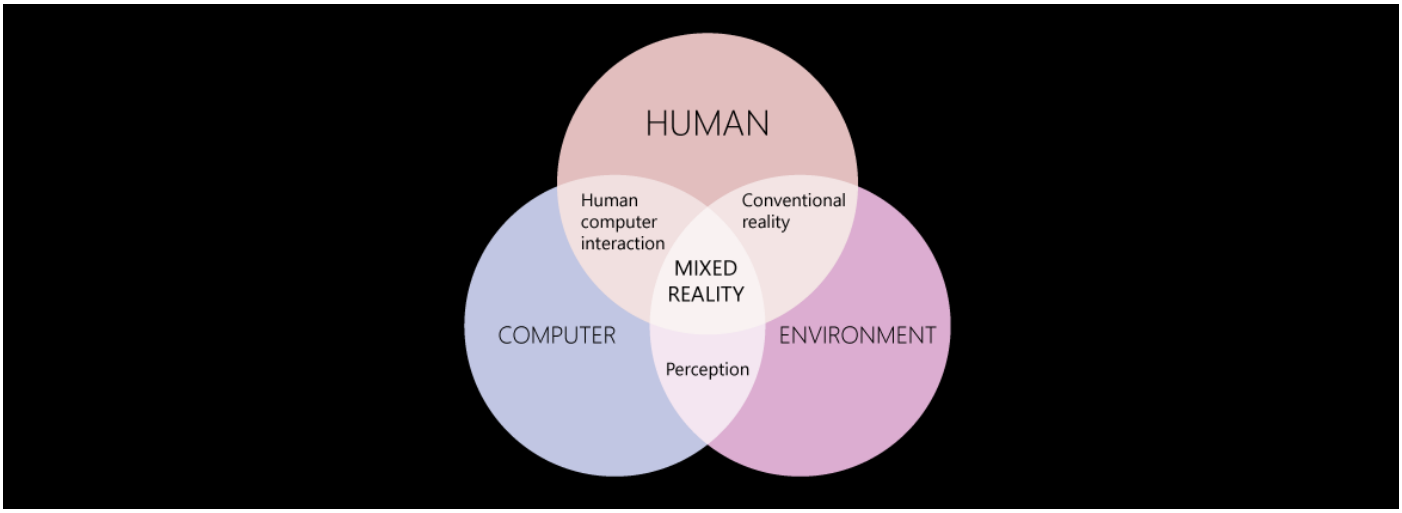

Figure 1: The interactions between computers, humans, and environments *Image Source: Microsoft Corporation*

A recent research study by one of the authors of this paper carried out technical and industry based trials supported by KENX USA, TU Dublin and BioPharmaChem Ireland (BPCI) using a Microsoft HoloLens2 mixed reality headset. The study looked at three areas of interest within the Pharma industry; namely:

- Remote Equipment Qualifications
- Remote Audits & Inspections
- Remote Factory Acceptance Testing (FAT)

The results highlighted the potential that emerging technologies such as mixed reality technology have in helping the pharmaceutical industry capture, share and transfer data and knowledge.[5] With this technology personnel can 'learn by doing' using the augmented reality and holographic images, the research study demonstrated how this type of technology could be used to integrate tacit knowledge into 'On the Job Training (OJTs)' as well as troubleshooting across pharmaceutical facilities.

Not only can the use of emerging technologies by validation and technology transfer teams facilitate the improvement of tacit knowledge capture and sharing (linked to speed to competency), it is also proven to achieve significant cost savings (communication, travel, time). Therefore, the implementation of technological solutions like mixed reality can be invaluable to the industry.

Mixed reality headsets help make knowledge transfer more effective. The multimedia/holographic imagery enables the user to understand immediately what the end result should look like and therefore decrease variability, confusion and risk. This is a great example of what the pharmaceutical industry is seeking to achieve when it comes to knowledge management during technology transfer.

Figure 2 below illustrates a Microsoft HoloLens2 in use within Pharmaceutical plant by the author.

Figure 2: Microsoft HoloLens2 in use within a pharmaceutical plant. *Image Source: Microsoft Corporation & D.Nagle, Author*

Competence learning using Mixed Reality Technology

As with the use of all technical solutions, competence in using Mixed Reality Technology is paramount. The 'Conscious Competence Learning Model' to support this was first described by management trainer Martin Broadwell in 1969.[7] This model describes 4 stages of competence developed over time, in relation to performance, namely:

1. Unconscious incompetence: The lack of awareness stage
2. Conscious incompetence: Awareness stage
3. Conscious competence: Step-by-step stage
4. Unconscious competence: Skilled stage

This model is illustrated in Figure 3

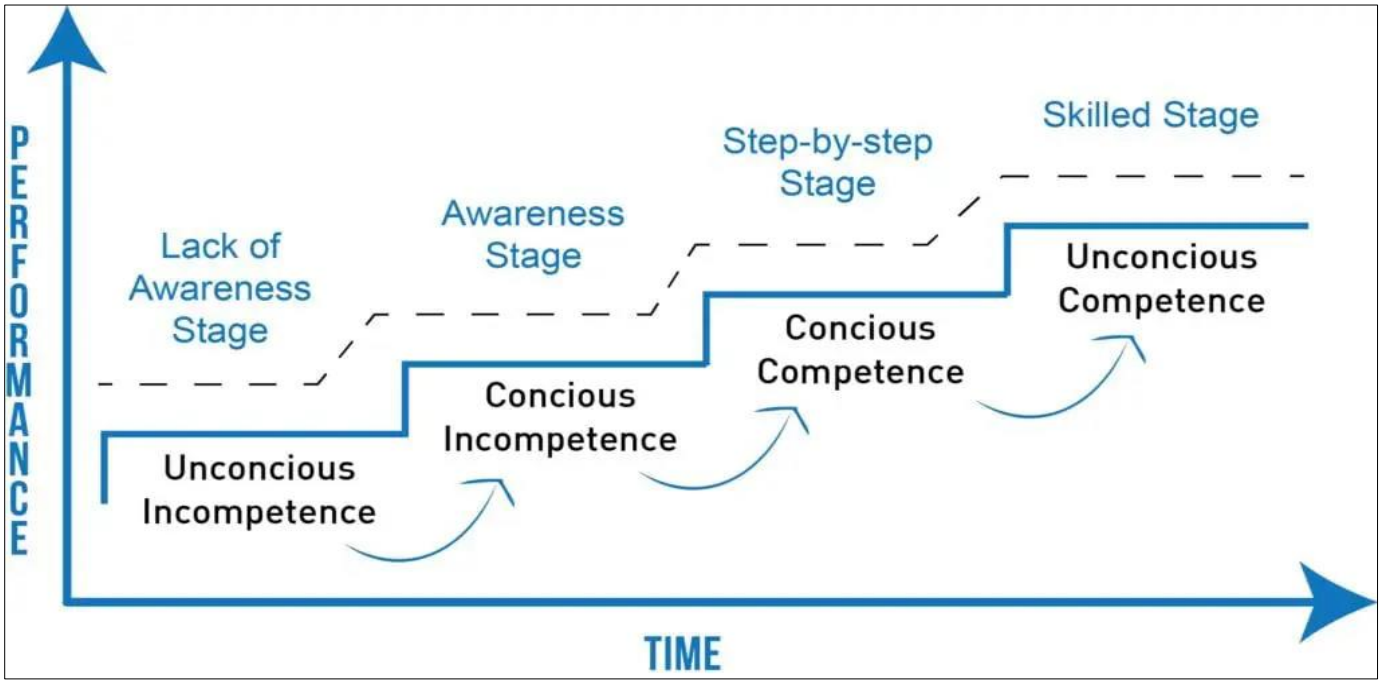

Figure 3. 'Conscious Competence Learning Model'

Knowledge that is captured or lost in Technology Transfer is fundamental to validation and commercial manufacturing. Lost information results in missed opportunities and high risk. The authors explore the Conscious Competence model and relate it to how emerging technology could be used to capture tacit knowledge. This is important to understand as the use of tacit knowledge can accelerate a trainee through the stages of competence:

- At the beginning of a Technology Transfer of a new product from A – B, technicians may be described as having **Conscious Incompetence**

- Subject matter experts then train the receiving site technicians which results in them entering the **Conscious Competence** state. This happens through on-the-job training and troubleshooting.

- Then, when technicians reach the **Unconscious Competence** they can '*hit-the-ground running*'. These are the technicians that are desirable on teams at Technology Transfer. They have reached the tacit knowledge stage, however, often this group of people generally don't know that they are the ones with the Tacit knowledge, the much sought-after knowledge!

- **Unconscious Competence** has its risks. It's like knowing the '*tricks-of-the-trade'* or '*rules-of-thumbs'* that are not written down: the intricacies' of doing a job. However, the fact that these steps are rarely known or recorded, may lead to higher risk to processes through variability in results, observations or defects.

It is the authors' belief that using emerging technologies such as mixed reality headsets (e.g. Microsoft HoloLens2) can help pharmaceutical companies deliver effective training programmes that will allow the users to understand the intricacies of the job they are training for and/or the function they need to prepare for. Using mixed reality headsets with the 'Unconscious Competence' subject matter expert should reduce the reliance on tacit knowledge while also capturing this tacit knowledge in recorded training sequence/video. This is invaluable information and can be saved and reused multiple times.

The standard operating procedures (SOPs) used in the pharmaceutical industry still have variability due to the interpretation of text and how limiting text is for "*painting-pictures*". There is a need to reduce this variability. Emerging technology could help reduce this variability and create more effective learning/communication experience.

Research has shown that an unintentionally perpetuated fallacy within the industry which managers and quality leaders often state unequivocally is that personnel must "always have the document in front of them". While this is certainly a well-intended statement, it belies the misguided belief that having documents in front of workers helps to ensure a consistent and error-free process. Unfortunately, that belief is based on an overly simplistic model of how work is performed, and it does not drive improved outcomes." [10]

Conclusion

Tacit knowledge is powerful, but the pharmaceutical industry must identify the key people who have this valuable knowledge, and mechanisms to capture and share this knowledge. A Pharmaceutical Regulatory Science Team (PRST) research study in TU Dublin has shown that video media such as that used in mixed reality headsets allows a trainee to understand WHAT is happening and WHY it's happening.

The authors suggest that the next evolution of Technology Transfer and Validation in the Pharmaceutical industry needs to include emerging technologies and the understanding of the power, requirement and value of our people's tacit knowledge. If this is achieved, a more engaged workforce will result, and this will help improve business performance, increase efficiencies, and build better, more robust processes.

Digital transformation is happening and for the pharmaceutical and life-science sector it will not be just a transformation of technology. It will also require a transformation of policies, processes, and cultures to drive their organisations to a new level of competitiveness. Emerging technologies and the understanding of the power, requirement and value of our people's tacit knowledge will have a key role in driving the industry forward. Without these working together, opportunities to innovate and continuously improve will be lost.

Recommendation

Fourteen years after ICH Q10 was first released, the industry is now starting to realise that people and technology working together are critical to the success of pharmaceutical companies. ISPE's Industry 5.0 has now a strong refocuses on 'people' and this is a welcome development. Co-operation between people and emerging technologies combines human intelligence and digitalisation. It is important that this connection is understood better and that learning and development and educational programs are designed to advance this and take advantage of the tacit knowledge that exists. Further research into this area would be of significant benefit to the pharmaceutical industry.

It is important to highlight that digitalisation and regulation should go *hand-in-hand*. Implementation of these new technologies will require assessment on a case-by-case basis. However, a platform approach could be adopted. Further research to identify the requirements in the regulatory space should be undertaken – as digital transformation of the pharmaceutical manufacturing landscape cannot take place without an understanding of what the key regulation requirement are.

Finally, training effectiveness for pharmaceutical staff who use emerging technologies within GMP facilities such as mixed reality should also be assessed. Establishing methods to measure "Training Effectiveness" using this technology should be undertaken.

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About the Authors

	**Donncadh J. Nagle** is a pharmaceutical industry professional based in Ireland. Currently a CQV Manager with Jacobs Engineering and Assistant Lecturer with TU Dublin. Donncadh is an experienced Validation Engineer with over fifteen years of experience in all areas of validation including; Process/Product Validation, Equipment/Automation Qualification, Facilities Qualification, Computer System Validation, Test Method Validation, and Cleaning Validation. Through strategic thinking, he has success in steering and managing complex validation projects within the medical device and pharmaceutical industries. PhD Researcher with the PRST team in TU Dublin. Current Chair of the BPCI Validation group, Ireland and a published author with KENX USA and IVT/JVT, USA.
	**Melanie J Adams** is a member of the PRST in TU Dublin and an Associate Director in a Knowledge Management (KM) Center of Excellence. She is an industry leader with over 17 years' experience; including SOD Manufacturing Operations, Quality Control, Technical Transfer and the deployment of Knowledge Management strategies in SOD and Bio-Pharma Sites in Wyeth, Pfizer and MSD Pharmaceutical Organizations. Adams was also a member of the ISPE KM Good Practice Guide Team, leveraging her practical experience deploying KM within industry when writing the guide.