

Recent Developments in Quality Management in the Era of Digital Transformation – A Review

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Abstract:

The purpose of the current exploratory research is to trace the growth and evolution of the Quality Management as a critical function in organizations and as a discipline of study in academia and research. The methodology adapted is to review some of the classical works and research in the area of Quality Management, which indicates direction of growth and evolution. There are several pioneers who have contributed richly for building and shaping the Quality Management principles, practices and methodologies over several decades. The current study involved the task of summarizing significant trends of Quality Management starting from the crafts man era and going up to the current trend of managing Quality as part of digital transformation. In the digital era there is an increased emphasis on automation of all the activities related to product and process quality management. The use of IoT based automation

starting from data capturing, archiving and the point of self-diagnostic and autonomous way of managing quality issues is common place in today's industries Quality 4.0 era. There are several challenges along the way for which quality professionals must be equipped in terms of knowledge, skills and attitude necessary for quality problem solving using modern techniques. This aspect is also researched in this study. Familiarity with technology platforms such as artificial intelligence, machine learning, image processing, sensors and actuators and such other emerging technologies must form the arsenal for analyzing data and data patterns in the face of data deluge. This requires several inter and multi-disciplinary knowledge exchange forums for grooming future quality professional. This article aims at tracing the metamorphosis of quality management with focus on people development and continuous process improvements in the manufacturing and allied sectors.

Keywords: *Quality management, Quality 4.0, continuous process improvements and digital transformation.*

Introduction

Quality management practices provide organizations the competitive advantage in the

face of fierce competition. Customer's expectation about the quality standards of product or services are rising in the market.

However, the production units are facing new challenges due to the increasing push towards implementing digitalization and also manufacturing as well as process to align with Industry 4.0 requirements (Lee&Youn, 2015; Lee, 2018). Quality professionals are exploring innovative ideas and are required to implement quality management practices leveraging digital technologies. The authors in this paper have used their professional experience and have studied few important works of researchers through literature review, which led to the development of a summery table that helps in visualizing the relationship between quality management practices and industry 4.0 technologies. The ultimate goal is to build percepts, principles and practices leading to continuous improvement in product and process quality levels. The research paper also focuses on the component technologies of the quality 4.0 implementation. Even though there

are several Quality 4.0 frameworks that have been designed by several authors. The implementation of these frameworks requires that quality managers are drawn based on the multidisciplinary training cutting across disciplines of engineering. Thus preparing the talent pool that can handle the component technologies in an integrated manner to equip professionals with knowledge, skills and attitude to solve quality problems of the industry is of paramount importance. The evolution of quality management practices by linking these to the process of industrialization in the manufacturing sector has been studied. The emphasis being on the methods of Data collection about the quality activities of products and services, the analytical tools and technologies used for understanding data patterns and the tools, techniques & methods of quality problem solving thus leading to continuous quality improvement.

History of Industrialization:

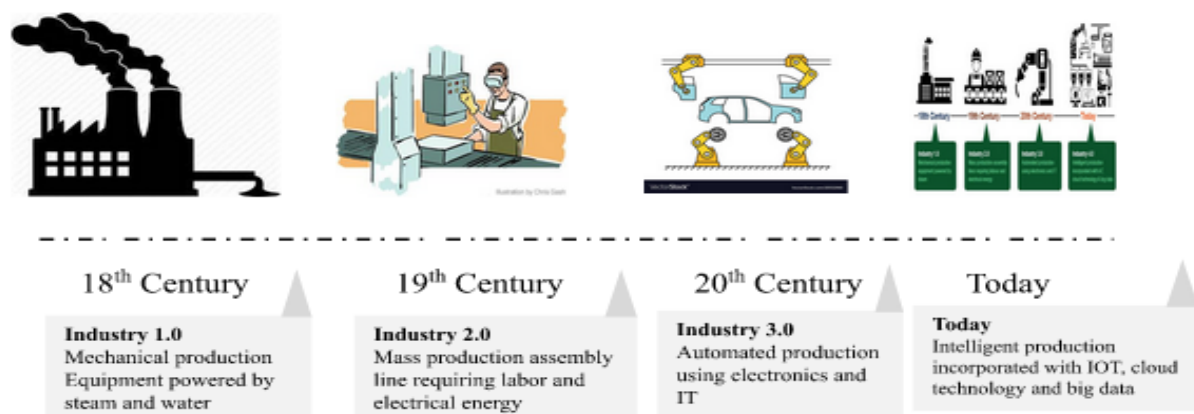


Figure 1. Historical Development of Industrialization

The term Industry 4.0 comes from the Germany. Industry 4.0 was used at the 2011 Hannover Fair. The following year, an industrialist collective known as the Working Group presented the concept to the German government. Since that time, the idea and concepts behind industry 4.0 has caught the imagination of many CEO's, COO's, VP (Quality), Quality leaders and the board level management in various manufacturing sectors all across the world.

These systems for cognitive, interconnected cyber systems in a factory setting have the potential for Continuous Quality Improvements as part of Quality 4.0, which is an element of Industry 4.0. The theme of this paper is on the aspects of Quality 4.0 in the digitally driven factories for transforming the organization based on the technology drivers as well as making out a business case for the implementation of Industry 4.0.

Technological advances over the last decade have brought about a new industrial revolution. This is often referred to as the Fourth Industrial Revolution or "Industry 4.0". This is a revolution driven by the exponential growth of disruptive technologies and the changes they are bringing to the workplace, workforce, and the markets in which businesses serve. A brief description of the features of the industrialization process at various stages of evolution is briefly illustrated in the figure 1.

In keeping with Industrialization the Quality subsystems have also evolved in the manufacturing sector, the most recent evolution is Quality 4.0 version. American Society for quality (ASQ) defines "Quality 4.0" as a term that references the future of quality and organizational excellence within the context of Industry 4.0" (Frank, 2014). Quality professionals can play a vital role in leading their organizations to apply proven quality disciplines to new, digital, and disruptive technologies.

Literature Review

Quality Management (QM) methods are widely used by companies to achieve competitive advantage. Today, it is almost mandatory for all Manufacturing organizations to comply with quality standards in their processes in order to bring the product to market. However, as we approach new manufacturing paradigms, including Industry 4.0, questions arise about how quality control approaches should leverage and adapt emerging technologies in the digital age. Based on the literature review, this study is inspired by the work of the authors in (Carvalho et al., 2020). The aim being to analyze the relationship between various quality management practices and new Industry 4.0 technologies that may improve QM, the authors have referred to empirical and quantitative studies examining the impact of Industry 4.0 on the quality practices. According to one survey (Sample size =1198), 37% exceptional leaders say (Jacob, 2018) "loss of excellence culture" which is the pinnacle roadblock to attain excellence goals is a matter of concern. In fact, many exceptional leaders have long-diagnosed

that instilling a lifestyle of excellence is vital to attain excellence goals and favored outcomes. Naturally, lifestyle tasks are not unusual place throughout the commercial and manufacturing sector, which emphasizes that agencies need to evolve to a greater proactive excellence approach. One vital detail to lifestyle initiatives is early and powerful engagement in new product introduction (NPI). However, maximum of the marketplace lacks early and powerful engagement of excellence processes, insights, and skills inside NPI. Another of the issues is the group's internal conflict to justify deeper involvement.

Further developments in digital technology and the ever-increasing complexity of the global business environment in the age of Industry 4.0 require new quality management systems. Based on a thorough analysis of quality control literature and five concrete examples of predictive quality control using new technologies, this paper proposes (Jacob, 2018) a new concept of predictive quality control. The findings show that predictive maintenance (Lee et al., 2019) with advanced technology using big data analytics, smart sensors, artificial intelligence (AI), and platform development can be deployed in a wide range of industries (Rolls Royce, 2017; McKendrick, 2018; Dong-A Press, 2018). Such predictive quality control systems have the potential to evolve into living ecosystems that can monitor and analyze vast amounts of data, perform cause and effect analysis, and make efficient, real-time decisions.

Evolution of Quality 4.0 and Mapping with Industrialization

The evolution of quality as a serious field of pursuit both the industry and the connected development of theoretical concepts in the academia followed the progression of the process of industrialization. Quality being a support function to production to provide consultancy and service on Quality matters the developments in the field progressed from the minimal technological interventions in the Quality 1.0 to one of using technology to connect the internal and stakeholders in the

Quality 4.0. The Evolution of Quality is presented using symbolic representation below and the Mapping of the Quality movements with industrial revolution and ICT Infrastructure support is shown in Table 2.



The first Quality wave of 1600's.
Do it Yourselfs



The second wave of quality in the 18th century -"Specialization"
"Professional knowledge and inclination."



The third Quality wave 1840-1955
Industrial Revolution "Mass production" Little choice to customers



The fourth quality wave 1945-today
"Total quality management"
"Customer satisfaction"

Table1. Mapping of Quality Movements with Industrial Revolutions Along with the Corresponding Manufacturing Systems and the Supporting ICT Infrastructures

Industry phase	Key descriptors & theme	Quality Phase
Industry 1.0 prior 1760 to 1840. Steam engine and power generation era. Industrial Revolution. Machines allowed faster and easier production, and they made all kinds of new innovations and technologies possible.	Human power harnessed to produce water & steam power. Emphasis on craftsmanship & crude machines. Concept of increasing output through mechanical advantage. Emphasis on speed of work & consistency of work. Transportation & movement of goods frequently occur.	Quality 1.0: Inspection based quality. Quality assurance through inspection. Emphasis on production volume rather than on Quality. Little focus on cost reduction, waste elimination, loss estimation & efficiency. Working conditions not an important factor. Focus on worker productivity improvements.
Industry 2.0 prior 1840 to 1950. Technology Revolution. Superior electrical technology allowed even greater production and creation of more sophisticated machines.	Electrical power generation & industrialization. Performance improvements through application of new mechanisms. Scale of automation increased by varying size factor to suit varying circumstances.	Quality 2.0: Focus on maximizing productivity. Fitness for use and adherence to standards to fix minimum acceptable levels of Quality. Cost implications of poor quality measured based on scrap & rework. Labour output is used to measure productivity.
Industry 3.0 (1950 to 1995). Digital Revolution. Rapid expansion in Industrialization through ICT Revolution. Early days of internet technology with low penetration in organizations.	Computing power access to workers to improve productivity. Use of information & communication technology to drive improvements. Standalone robots to replace manual work.	Quality 3.0: Quality is a business imperative. Meeting customer requirements and increased customer satisfaction emphasized. Gains in productivity through a stabilized process outputs through standardizing work. Introduction of standards such as ISO 9000. Achieving business excellence through organization wide business excellence frameworks. (Malcolm Baldrige & EFQM Models)
Industry 4.0 (Anticipated changes during 1995 to present. Automation Revolution. Convergence of technologies and rapid growth of intelligent and low cost electronics and affordable and accessible computing power.	Implementation of cyber physical systems through automation strategies. End to end automation of systems. Use of humans for decision making where judgment is important. Human interactions cannot be simulated easily.	Quality 4.0: Use of digitization to capture process feedback and adaptive control technologies introduced. Quality shifts its emphasis from process oriented quality to design based quality. Machine becomes intelligent through self-diagnostic protocols and managing their own Productivity & Quality.

Cyber physical systems, Internet of things, Cloud Computing, Cognitive computing.	Machines made to learn through the introduction of artificial intelligence.	Human role and performance is essential in business 7 industries. Emphasis of the use of humans shifts from production to systems design and integration with business systems.
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Digital Transformation for Quality 4.0 - The Journey and the Road Map

The three stages of digital transformation involve digitization, digitalization and then digital transformation.

In the era of Quality 4.0 a host of technologies can help organizations to meet the challenges of capturing data at the sources. Further the relevance and utility of the huge amount of data to the problem on hand is always an important consideration in choosing the method of data capture and the technology tools to be used for data capture. Manufacturing organizations all over the world spend a significant amount of time and energy in choosing the best data collection techniques ideally suited for their processes and environment. There are a number of technology tools and hardware means by which the data required for the problem on hand can be captured at source. Some of the many digital technologies that can be used to help the shop floor personnel in capturing and storing the manufacturing data may include but is not limited to the) sensor integration using IoT (Internet of Things, Line HMI (Human Machine Interface) system integration, PLC (Programmable Logic Controller), integration, RTU (Remote Terminal Units), SCADA (Supervisory Control and Data Acquisition) systems, RFID (Radio Frequency Identification), Barcode technologies, Robots and AGV (Automated Guided Vehicle) integration, CNC and other machine integration.

Digitization of Factory Floor Data and Data Capture Technologies in a Smart Factory

The first digitization process is to digitally capture on-site process data using digital devices such as IoT-based automation, human-machine

interfaces, PLCs, RTUs, SCADA automations, RFID tags and barcodes. The major digital formats include measurement of audio signals, and video images pertaining to Critical to Quality (CTQ) characteristics. Manufacturing sites in many modern manufacturing processes around the world generate large amounts of data. When properly collected and used, these data can provide valuable insights and information about production, quality, and maintenance aspects that are essential to the process of making smarter decisions (Bansal et al., 2004). This can lead to a significant competitive advantage. The benefits of using these digital platforms to collect production data related to process parameters and production status include real-time production insights, advanced dashboards, detailed reports, equipment history records, and overall equipment effectiveness (OEE) (Shi & Zeng, 2016). Key Performance indicators (KPIs) Calculations, Statistical Process Control (SPC) management, alarm and notification configuration, integration with automation and control (PLC based input-output devices) along with other production level integrated systems such as Manufacturing Execution Systems (MES), Product Life Cycle Management (PLCM) and business oriented Enterprise Resource Planning (ERP) Integration systems.

Digitalization of the Quality Management Systems - the Data Analytical Engine

Quality 4.0 certainly includes the digitalization of quality management (Lee, 2015; Marr, 2015). More importantly it is the impact of that digitalization on quality technology, processes and people. Researchers at LNS have identified 11 axes of Quality 4.0, which manufacturing organizations can use to educate, plan, and act (refer to Figure 2).

Using this framework and research, leaders identify how Quality 4.0 can transform existing capabilities and initiatives. The framework also provides a perspective on traditional quality. Quality 4.0 doesn't replace traditional quality methods, but rather builds and improves upon them. Manufacturers should use the framework to interpret their current state and identify what changes are needed to move to the future state. Quality is the responsibility of everyone in the

organization. The Quality 4.0 has dependency on integrating the people, process & technology with focus on continuous quality improvements and sustaining the quality benchmarks achieved with respect to product, process & systems. The 11 axes of quality 4.0 as per LNS research reports include Collaboration, Competency, Leadership, Culture and Compliance related to the people in the organization.

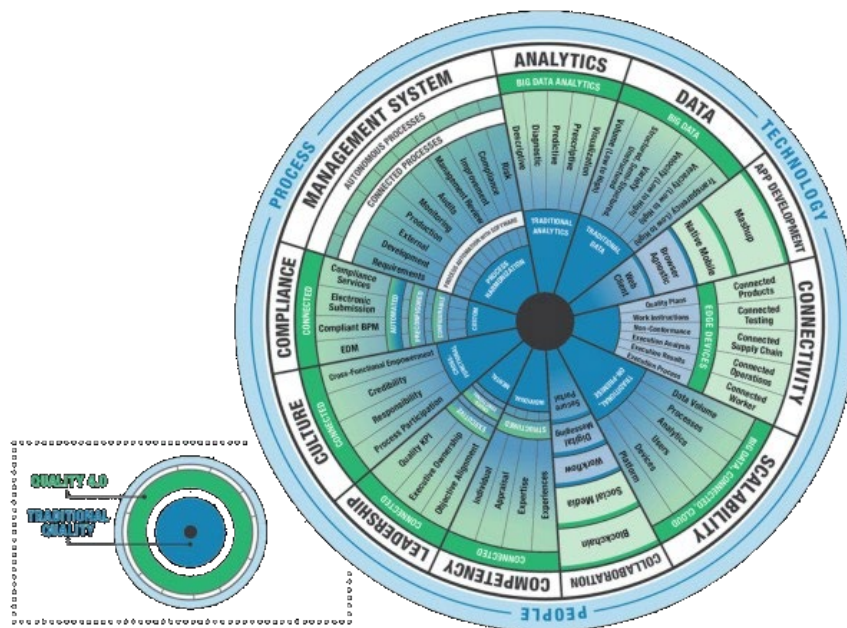


Figure 2. The Eleven Axis of Quality 4.0 as per LNS Research
Source: Jacob (2017)

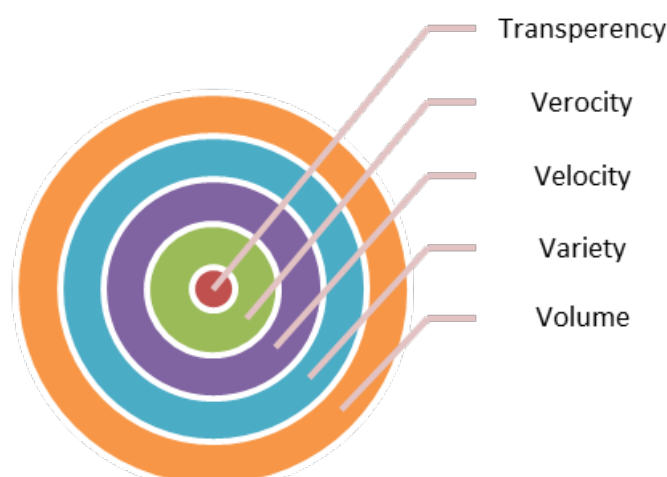


Figure 3. Quality 4.0: Data-Driven Quality Control

The process side of quality 4.0 includes the Quality Management System and the continuous capturing of data from the shop floor and the use of analytics. The Technology dimension includes the App development for the user community for remote monitoring of the factory shop floor. The main issues related to technology that requires constant and continuous attention are the aspects of connectivity and scalability.

Data

Data-driven decisions have been at the heart of quality improvements for decades. Recently the developments in the area industry 4.0 have led to the upgradation of standards to insist on data as a base and re-emphasize the importance of evidence-based decision making. Several important studies in the area of big data identify five important dimensions about data. These are Volume (Low to High), Variety (Semi Structured, Structured, and Unstructured), Velocity, (Low to High), Veracity (Low to High) and transparency (Low to high).

Volume

Continuous Quality Improvement in the manufacturing shop floor is based on sensing through traditional measuring instruments such as Vernier Calipers, Screw gauges and such other measuring instruments for dimensional Quality, material characterization for material quality, various 2D & 3D imaging techniques using profile projector and such other techniques for form quality and surface measuring equipment's for surface finish quality assessments etc. In addition, there are quality records built on data regarding inspection gathered from various conventional and even customized gauges of a wide ranging variety depending on the type of the products and the range of the measurements required. A typical manufacturing shop floor traditionally builds a large volume of transactional records related to the product and process quality decisions. These relate to actions such as corrective actions and preventive actions (CAPA) and also there is a huge Log and records of Quality events that occur on a day to day basis

as shop floor quality records. In the era of Quality 4.0 many of the analog instruments have been replaced with digital instruments and a high degree of connectivity among elements of the digitized factory. In the digitized factory, the volume of data from connected devices is many orders greater, requiring special approaches such as data lakes. The Volume of data can vary from very low to very high depending on the nature and type of manufacturing processes.

Variety

Data scientist recognize that in the digital world that there are three types of data: structured, unstructured, and semi-structured. In the context of digitized factory structured data are in the form of transactional data related to measurements during and after production and consequent actions by way of corrective actions and preventive actions. These also could be the Quality events that occur in the manufacturing shop floors on an ongoing basis. In addition, there are unstructured data which is unorganized (e.g. semantics data, data from sensors and connected devices). Semi-structured data is unstructured and has had structure applied to it (e.g. metadata tags).

Velocity

This refers to the rate at which manufacturing shop floors gathers data on quality related parameters. This rate can be varying from low to high depending on the speed of data streaming. The conventional shop floors with the use of CAPAs for solving quality issues can be considered as low velocity stream of data, at the next level data that is part of statistical process control (SPC) data can be considered as high velocity. In the digitized factory with a plethora of connected devices the streaming data is at even higher velocity.

Veracity

In the conventional systems there was emphasis on accuracy and precision of the instruments and probes used in the shop floors operations. The veracity of the data in the conventional system has low data accuracy. Quality system data in the traditional systems is often low

veracity due to fragmented systems and lack of automation. In the automated environment the possibilities of attaining high accuracy and greater degree of precision in the Quality system data has increased. Veracity can vary from low to high.

Transparency

In the current scenario there is increased emphasis at every level of decision making for the level of transparency in decision making. In this regard Quality databases created on the foundation of common data model at the transaction level can help quality professionals and leaders in building transparency in the systems. Visibility across the various tiers of supply chain and facility for each other's to exchange data and operating on a common data model will help in this regard. Further combining structured system data like inventory transactions and financial transactions with structured operational system data like alarms, process parameters, and quality events, along with unstructured internal and external data like customer, supplier, Web, and machine data provides high veracity and transparency (IBM Corporation, 2014). Depending on the design of the systems the data and information transparency can range from low to high.

Analytics

The next layer in the model is the analytics on the data gathered in the execution of the Quality function in the manufacturing shop floors. Conventionally decisions in the quality area for problem solving involved analysis through cross functional teams using the popular tools such as the seven QC tools for operational issues and the deployment of the seven management and planning tools for problems which require the use of deeper insights and the application of engineering and managerial intellect. These traditional methods of analysis have their own inherent limitations on being mostly a post mortem exercise leading to a reactive style of management in generating ideas on the CAPA's to address the Quality issues many times at a peripheral level without getting into the root of the problem and the connected issues. The advent of analytics has led to the concepts which

emphasize on getting the maximum information from every piece of data gathered from the system. According to a leading survey it has been found that 37% of the market cited inadequate indicators as a major obstacle to achieving quality goals. This study shows that real-time indicators are not well accepted by most market participants. The four areas of analytics are descriptive analysis, diagnostic analysis, predictive analytics and prescriptive analytics (You, 2017).

Manufacturing organization striving to implement Quality 4.0 should build their own analytics strategy based on the assessment of their needs for solving Quality issues intelligently. These analytics strategy must be developed concurrently with a data strategy. If there is poor quality of data, the power of analytics cannot lead to deeper or better insights into data. Data quality issues and errors must be addressed before the application of analytics on the data.

Connectivity

The third element of the model is connectivity. In a broader sense, "connectivity" is the link between business information technology (IT) and operational technology (OT), and business technology includes enterprise quality management systems (EQMS) and enterprise resource planning (ERP). Includes, Product Lifecycle Management (PLM) and OT. Technology used in laboratories, manufacturing and service. In order to leverage information in the connected factory, the Quality management functions must work closely with the Information technology domain. Quality execution must be seamlessly linked to operations technology. There is a gap between management and execution. This is because the connection between IT and OT is broken. This may be due to the lack of standardization of the digital environment leading to various protocols. This gap poses challenges for design transfer and continuous improvement. Quality professionals and quality leaders need to work together with data, processes, and people to enable effective data-driven two-way communication between the IT and OT layers and avoids disruptions.

In the traditional quality systems, the connectivity between people, process and technology was achieved through aspects like Quality plan, detailed work instructions, Records of nonconformance, execution process, and execution analysis and execution results. In the era of Quality 4.0 these are achieved through the edge devices to connect Products, Testing, Supply chain, Operations and workers. These systems, requires tight coupling of Operations

technology with Information technology yielding better Quality of products and services.

The era of Industry 4.0 is transforming connectivity with a proliferation of low-cost connectivity sensors that provide near real-time feedback from connected people, products, edge devices and processes. Figure illustrates the connections.

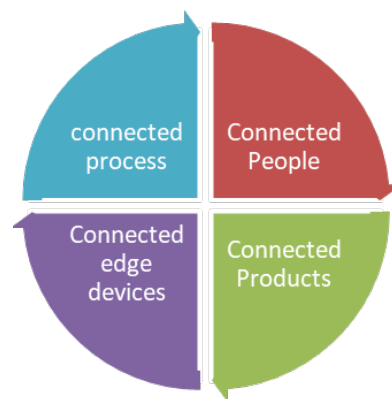


Figure 4. Connectivity: Business Information Technology (IT) and Operational Technology (OT)

Connected People

This type of connection is established using a personal smart device or a smart wearable device that recognizes the worker. Connected worker initiatives are usually aimed at improving efficiency and security

Connected Products

Product IDs such as RFID tags and barcodes can be used to track products at all stages of their lifecycle and provide feedback on overall lifecycle performance.

Connected Edge Devices

Device-level connectivity allows discovered devices to connect efficiently. This approach helps avoid overloading the central OT system by streaming large amounts of sensor data. In this way, edge devices often perform analysis on the device, make predictive / normative decisions (shut down the machine and send for

repairs), and send the data to the central OT system (BOSCH, 2018).

Connected Processes

Process-level connections provide feedback from connected people, products, and devices within the process. Key applications for these concepts are connected products; connected laboratories, connected supply chain, connected operations, and connected Workers.

Collaboration

Collaborations could happen within and across companies and even with customers for co creation of products. The advent of social media has directly weighed on the Quality aspects of products and processes. Customers and client can use this for expressing their dissatisfactions. As a result, manufacturers are using social listening to protect their brands, gain new insights, and begin to drive innovation (Lee & Lim, 2018). Social media also has applications to improve competence and quality culture. Some

technology vendors leverage collective intelligence and insights across the enterprise and, in some cases, the industry. Social allows manufacturers to create virtual excellence centers with much wider participation. Another technology that drives this joint agenda is block chain technology. Block chain is another innovative technology with future quality potential, especially in the areas of auditing and traceability. This is essentially a secure and public distributed ledger. Each block contains a time stamp and is a record associated with the associated block and date. Block chain was born as a financial technology, but industrial companies are now experimenting with it. Third-party groups also use block chain to track finished productions, processing and sales history to ensure sustainable Quality.

In order to understand the impact, the block chain could have on the Quality function, it is necessary to visualize the challenges in the manufacturing supply chains. The Quality characteristics and attributes that are checked and tested at the lower tiers of supply chain need not be again validated at the next layer. This leads to achieving overall cost efficiency and economics in the entire supply chain. Building blocks can connect these tests to provide visibility into quality tests throughout the chain. Traceability is another challenge, especially in recall scenarios. The block chain has the potential to track all instances and answer important questions such as: “Who touched the products along the supply and demand chains, and where is it now?”

The aspects of collaboration, a powerful fuel for innovation and quality improvement, have been radically transformed by connectivity, data and analytics (Lee, 2015). Quality experts and quality leaders develop secure, reproducible data sharing strategies that help them work together to achieve goals such as enhanced capabilities, enhanced monitoring, increased security, traceability and auditability. This dimension includes building of a secure portal, digital messaging systems, automated work flows, social media and block chains. All of these aiming at higher levels of collaboration between the people, process and technology in an automated factory system.

App Development

In the App economy and Gig economy, the Apps rule the world, the quality function can take advantage of these Apps for remote monitoring and control of the manufacturing shop floors. Apps can help in democratization of the automation. It can also go far beyond a simple web-based user interface (WBUI). They play an important role in providing, participating in, and accepting information. Apps become a powerful element of collaboration, capabilities, and efficiency as we progress in presenting relevant content to users in relation to where they are and the world around them. The advances here are first building web clients, then developing data exchanges with browser-independent data management systems, deploying native mobiles, and finally mashups.

Scalability

Through the cloud, manufacturers can purchase Software as a Service (SaaS) and easily add features, users, data, analytics, and devices without having to buy, install, or manage software on-premises. The cloud also provides Infrastructure as a Service (IaaS) by providing globally accessible and highly available (high uptime) solutions. Some vendors offer Platform as a Service (PaaS) as a solution that provides a partner's extended ecosystem in addition to the core software, all connected to enhance the core software.

Data scalability is also important, especially for connected devices. Data lake technology is designed to support a rich dataset that is unique to connected devices and big data. These non-traditional databases allow you to store and correlate different types of data. Scalability is very important when industrializing a solution. Recommendations for manufacturers considering implementing when assessing the current scalability of internal systems and deploying either traditional quality or quality 4.0 where traditional systems were on-premises, Quality 4.0 are global. Considering reach and data complexity, quality management systems with features that includes volume of data, processes, analytics, user communities, devices and platforms with expert systems are to be

conceived. In the automated Quality 4.0 systems, scalability of quality functionalities is achieved through big data, connectedness and cloud technologies.

Management System

This dimension is related to the Enterprise Quality Management System (EQMS). EQMS can be seen as a hub for quality control activities, automating workflows, connecting quality processes, improving data accuracy, providing centralized analytics, ensuring compliance, and facilitating collaboration within a common app to provide a scalable solution. This EQMS is considered as a hub because quality touches every part of the value chain and also indicates how it's managed in every step of the transformation processes. Many manufacturing organizations have instituted EQMS in bits and pieces and are yet to integrate all the activities in the quality function and some of the legacy systems are yet to be integrated into the Enterprise wide Quality Management Systems (EQMS). Further from a supply chain stand point many of the OEM's may have implemented EQMS for managing the quality activities however they are yet to bring all their suppliers and customers into these platforms. Consistency is important for improving global outcomes and capabilities. Manufacturers harmonize processes, automate those processes with software, connect automated processes to other systems and operations, and continuously improve system autonomy using collective analysis and insights. This approach shifts the focus of high-value employees from execution mechanisms to innovation and improvement. In traditional quality management systems, components of this dimension start with requirements, then develop, next considering external influences, setting up productions or operations, then establishing monitoring systems, conducting quality audits as per standards, conducting Management review, implementing improvement ideas, checking compliance to quality standards and evaluating risks. All these aspects in the EQMS of Quality 4.0 implementation are achieved through a system of connected and autonomous processes.

Compliance

Compliance activities include conforming to regulatory, industry, customer, and internal requirements. In the sector of Pharmacy & Life science, manufacturers have huge requirements for compliance. Compliance activities are important to quality teams throughout the industry. Quality often plays a leading role in ensuring process, product, and service compliance. Leveraging technology to reduce the cost and hassle of complying with regulations is a way to address the burden of compliance. Technologies that support compliance have evolved across platforms and process areas. The first step in development was to significantly expand the configurable and eliminate the need for tuning. Nowadays, technology vendors are investing in building robust pre-configurations for common processes (CAPA, 8 Dimensions (8D), nonconformities, etc.). Technology providers have the tools to automate process of validation and reduce the effort required to perform a performance qualification (PQ).

Quality 4.0 offers even more options for automating compliance. Platforms that enable social collaboration provide a mechanism for sharing successful and unsuccessful approaches to compliance across groups, locations, and regions. Organizations can use the analytics application to alert to potential non-compliances and take action to prevent it. As emphasized earlier, an integrated approach to the simultaneous development of IT / OT data models and / or collaboration technologies such as block chain can provide a data-driven approach that automates auditability.

The progression in this dimension is from customer compliance as in the traditional quality management systems, then configurable systems, next stage is Pre configurable systems, graduating to automated compliance with sub systems such as EDM (Electronic Data Management), Compliant Business Process Management (BPM), Facility for Electronic submission to compliance agencies and a slew of Compliance services are implemented. All these leads to seamless connected world between the

people, process and technology within the factory systems at one level. Supply chain partners, collaborators, customers and the external agencies such as the appropriate compliance authorities at another level. All these depending on the business segment and the geography in which the factory and their units operates.

Culture

The building of a Quality culture and initiatives in this regards have been the central aspect of manufacturing organizations since the second industrial revolutions, several training interventions and educational sessions including motivational talks are regular feature to imbibe the quality culture among the associates in the manufacturing organizations. Many organizations have taken several initiatives to develop a culture of quality, since quality often owns process execution with insufficient participation and ownership from other functions.

The biggest mental roadblock for instituting quality culture at every level in the organization is that the strongly held myth in the minds of people that Quality is more a policing activity more viewed as a requirement for monitoring and controlling. The Quantity emphasis of the operations and the execution activities that face the pressure of outputs in a given period of time based on set targets is also a major issue. Quality among many operation level personnel is viewed as a hurdle rather than a vehicle for improvement and performance. According to the LNS survey only 13% of cross-functional teams clearly understand how quality contributes to organization's strategic success (McMillian, 2016).

Leadership: Leadership element will continue to determine the success in the quality initiatives of organization even in the quality 4.0 technology dominated world view of the organizations and its members. Over a period of time the quality function has an image and credibility gap with the rest of the organization. This can be attributed to the view helped by the rest of the organization that the quality department does work akin to that of the police

in the society that monitors adherence to the rules and the discipline of behaviors in public life. Quality department is seen as a police within the organization and the quality leadership is viewed that they are working with an unclear alignment to corporate goals and corporate success. Performance-based quality can have a substantial impact on R&D, manufacturing, service, and finance. Quality ownership should shift from quality-only to cross-functional to executive. In this regards it is necessary that Quality leaders should lead quality across the organization, with increasingly broad ownership through cross-functional executives and top management to broaden the focus on quality and enable effective corporate-wide quality. KPIs play an important role in this effort. Quality 4.0 has already drawn interest from cross-functional leaders. As mentioned previously, leaders outside quality see the potential of Quality 4.0's to improve quality, and they are building initiatives around improving quality with Industry 4.0 technologies. In many ways, this is a positive shift and one that quality leadership should support, reinforce, and lead, to improve outcomes. The evolution in this dimension was minimal leadership in the early stage quality systems, which then led to cross functional leadership, maturing to executive styles of leadership involving KPI's for Quality, executive ownership and ensuring objective alignment with business or corporate leadership teams.

Competency

Competency is an important dimension and has been so through every stage of progress in the industrialized world across all the four industrial revolutions (IBM, 2011). Simply stated, Competence is the capacity of a person to carry out a task effectively and efficiently. Efforts to increase competency levels of individual through intrinsic motivation and individual's own effort and strongly supported by culture of development and improvements through organizational support financial or otherwise are an ongoing transformational leadership impacts in many successful organizations. However several organizations struggle to build a team of competent individuals to manage the change and transitions due to the requirements of customers

or clients or any other influences from factors in the external environments. A culture of sharing & gaining is part of many organizations is desirable in these days of tough competition. Organizations at the lower end of the maturity scale rely on individuals to share knowledge among them. Organizations that are more mature deploy a structured approach that includes facilities like an organizational Learning Management Systems (LMS) or a separate department for learning and development to continuously assess and train the associates in the areas of competencies based on current and future requirements. These trainings are based

on current and future requirements. Scaling up competency development through the institution of Centers of practices and Centers of excellence in specific focused areas of technology and business domains are also common place in many organizations. Quality leaders looking to improve upon the structured approach of traditional quality can use several Quality 4.0 approaches like experiential learning platforms, development of expertise and also performance appraisal triggers and management of learning and development (Shin & Jun, 2015; Susto et al., 2015).



Figure 5. Quality 4.0 Traits for Manufacturing

Digital Transformation

Quality professionals and Quality leaders are very familiar and conversant with the traditional tools of Quality management such as the seven QC tools and the seven management planning tools, PDCA Cycle of Deming, Juran's trilogy and host of other concepts & ideas that were part of the Quality professional's tool kit across all the Quality revolution. In the era of Quality 4.0, the new and emerging technology areas that need to be learnt by quality professionals and quality leaders are as shown in Figure 6.

The Quality 4.0 implementation based on the digital maturity levels of the company and the

relevant tools of Quality 4.0 described below should be used to solve the quality issues implementing and deploying these systems to enable digital transformation. According to ASQ these tools and principles as used in Quality 4.0 are briefly highlighted.

- **Data science:** Merge heterogeneous datasets to make predictions (7), perform classifications, find patterns in large datasets, reduce large observation sets to the most important predictors, and use sound traditional techniques. Techniques (such as visualization, inference and simulation) to generate viable models and solutions.

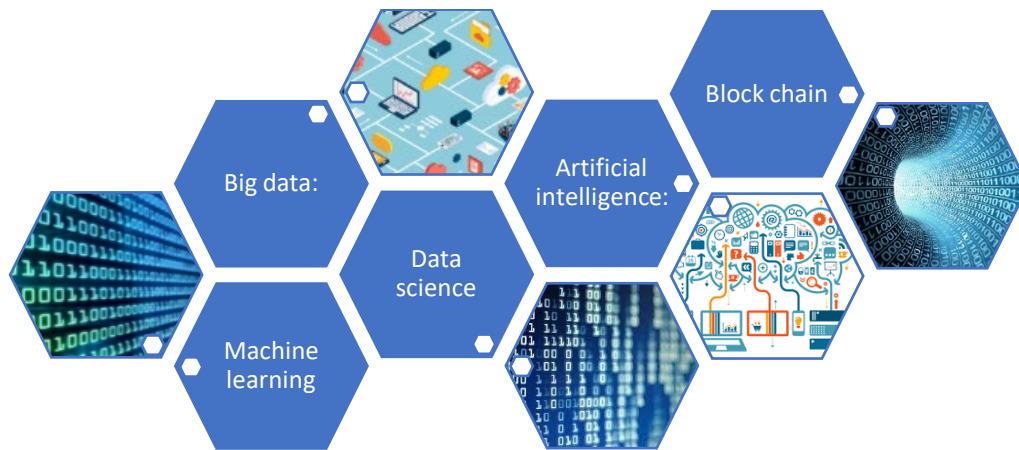


Figure 6. Modern Tools of Quality 4.0

- Big data: infrastructure:-(such as Map Reduce, Hadoop, Hive, and NoSQL databases), easier access to data sources, tools for managing and analyzing large data sets without having to use supercomputers.
- Enabling technologies: - affordable sensors and actuators, cloud computing, open-source software, augmented reality (AR), mixed reality, virtual reality (VR), data streaming (such as Kafka and Storm), 5G networks, IPv6, IoT.
- Artificial intelligence: - Computer vision, voice processing, chat bots, personal assistants, navigation, robotics, complex decision making.
- Machine learning: - Text analytics, recommender system, email spam filter, fraud detection, object grouping, predictions etc.
- Deep learning: - image classification, complex pattern recognition, time series prediction, text generation, audio and art creation, fictitious video creation from real video, heuristic-based image adjustment (for example, frowning) Make someone smile with a photo).
- Block chain: - Improve transaction transparency and testability (assets and information) and monitor conditions to prevent transactions if quality goals are not met.

Thus it can be seen that implementing Quality 4.0 requires the understanding of host of technologies and developing people knowledge and skills in a gamut of technology tools and building a “Can do” attitude to leverage these technology platforms to solve quality problems and issues at all the tiers of the globally dispersed manufacturing plants and across the supply chain involving all supply chain partners including logistic providers and several third party agencies.

Conclusions and Scope for Further Developments

This paper has traced the evolution of Quality functioning through the evolution of the industrialization process. The 11 dimensions involved in the implementation of Quality 4.0 have been deliberated in detail. On implementing these dimensions, it is necessary to check the unique value propositions to the organizations.

Value propositions for Quality 4.0 initiatives fall into six major categories, weighted by importance. These are augment human intelligence, increase the speed and quality of decision making, improve transparency, traceability, and auditability, anticipate changes,

reveal biases, and adapt to new circumstances and knowledge.

Quality professionals must develop deep skills in the emerging areas and then only will be in the best position to propose and lead digital transformation initiatives. In the age of data-driven decision making, providing leadership for organizational learning and establishing processes for continuous improvement are of utmost importance. It is also necessary for Quality professionals to understand how decision-making affects people and their life relationships, also their communities, their well-being, health and their role in the society in general.

Organizations at different levels of maturity have to implement digital transformation strategies to reap the immense benefits of implementing Quality 4.0. Technology resources are important requirements for fulfilling the goals in the Quality 4.0 journey.

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Conflict of interests

No conflict of interest.

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