

Guide to Quality 4.0

Glossary of Terms

Digital Transformation

A convergence of technological trends such as the Internet of Things (IoT), Industrial Internet of Things (IIoT), mobility, cloud and big data analytics providing a multi-faceted approach to digitizing business processes and operations to speed time-to-market, increase understanding and tap into additional revenue opportunities beyond a company's core offering.

Industrial Internet of Things (IIoT)

Building on the basic premise of the Internet of Things (IoT) in the consumer space, IIoT refers to smart connected operations used within a production facility to create products and services.

Industry 4.0

The fourth industrial revolution brought about by recent rapid technological advances in connectivity, mobility, analytics, scalability and data that transform manufacturing efficiency, supply chain performance, product innovation, and enable new business models. Specific examples of Industry 4.0 technology include cloud, big data, machine learning (ML) and artificial intelligence (AI) and more.

Quality 4.0

Quality 4.0 is a reference to Industry 4.0. In basic terms, Quality 4.0 is the digitalization of quality, management systems and compliance. It does not focus exclusively on the technology itself, but rather on the improvements in culture, collaboration, competency and leadership made possible by that technology.

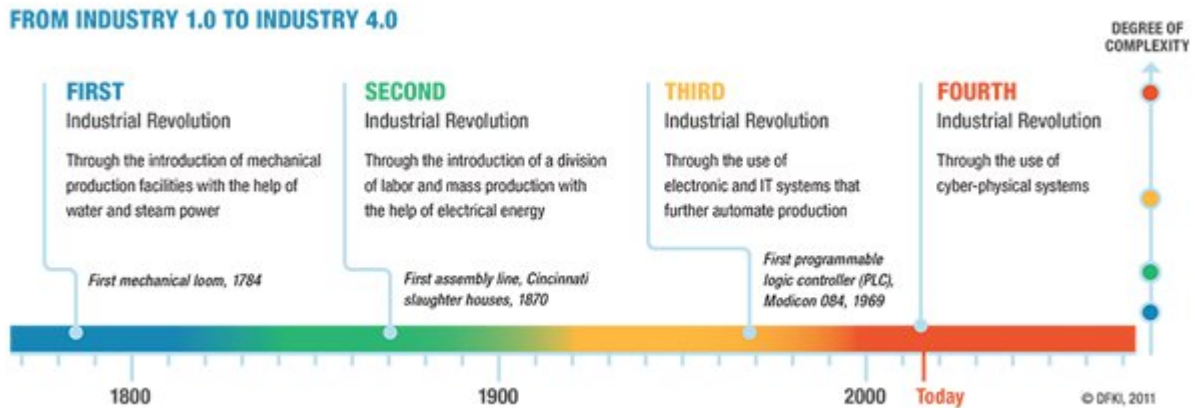


The technology at our disposal is exceeded only by the number of ways it can be applied to improve communication, understanding, planning and productivity. In fact, the last decade has seen such rapid advances in areas like connectivity, mobility, analytics, scalability and data that it has sparked a fourth industrial revolution, known as Industry 4.0. IT and operations teams are chomping at the bit to implement these new technologies to help them operate better, smarter and faster. But what does this mean for quality and the teams responsible for it?

If your company is like over 50 percent of other manufacturers, it already has a plan in place to implement or further optimize its digital systems through automation, connectivity and advanced analytics. And of the top potential uses for connected digital systems, known as the Industrial Internet of Things (IIoT), quality improvement and monitoring are among the most promising. Ironically, the function reporting the lowest intention of actually using IIoT to monitor and improve quality was quality itself.

Quality 4.0, which aligns quality management with Industry 4.0, should be a high priority for quality leaders, and yet many of today's quality-centered initiatives are being led by other groups, such as IT, operations, engineering, or sales and marketing, as quality teams remain occupied with solving yesterday's quality problems, mainly caused by fragmented systems and minimal cross-functional ownership of quality. To help quality leaders and their teams keep pace with the

current Digital Transformation and lead the Quality 4.0 charge, this article highlights the key takeaways including an overview of the basic concepts and actionable recommendations for adopting a new approach to quality.



A timeline depicting each of the industrial revolutions. The fourth industrial revolution, or Industry 4.0, promises unprecedented levels of operational and quality excellence.

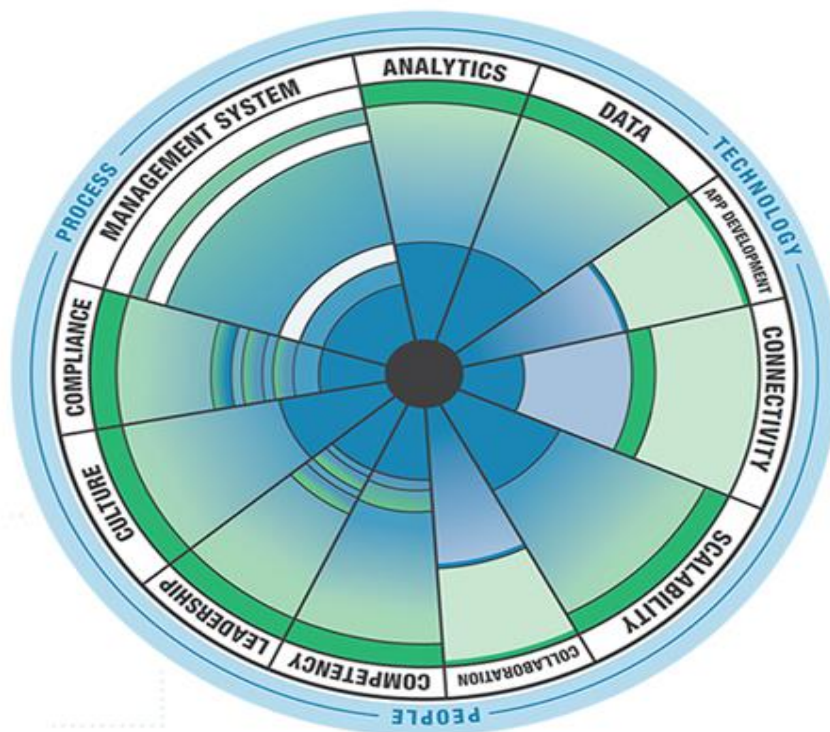
11 Axes of Quality 4.0

Quality experts have identified 11 components or “axes” of Quality 4.0. Some of these concepts are very familiar (e.g., Compliance, Management Systems), but some reflect the changing nature of technology brought about by Industry 4.0 and might be new to you or your company’s quality division (e.g., App Development, Connectivity, Scalability). Understanding these axes will help you take the first step in adopting a Quality 4.0 approach.

Data – Data has always driven quality, and many updated regulations and standards highlight the importance of data-driven decision making. But most of the market lags in its adoption of real-time metrics, with only a small percentage of typical companies using real-time visibility of quality metrics in customer service, supplier performance, engineering and manufacturing. Companies must seek ways to combine data from various systems to ensure accuracy and transparency.

Analytics – A moderate percent of the market identifies poor metrics as the primary barrier to accomplishing quality objectives. Traditional quality metrics typically describe what happened, why it happened and what might happen next, but they fail to prescribe what actions to take, an insight only available with the help of Big Data, ML and AI. Companies are well-served to develop an analytics strategy after or concurrently with a data strategy, otherwise the insights will be of little value.

Connectivity – Connecting business information technology (IT) (e.g., EQMS, ERP, PLM, etc.) with operational technology (OT) (e.g., technology used in laboratories, manufacturing and service) is a longstanding challenge – of those that have invested in an EQMS, only a small percentage are connected to manufacturing operations. Industry 4.0 enables greater connectivity with inexpensive sensors that connect and provide feedback from people, products and processes. Leaders should work to bridge the IT/OT divide, not only with technology, but by enabling data, processes and people to work together.



Quality 4.0 is equal parts technology, people and process, as shown in this image of the 11 axes of Quality 4.0.

Collaboration – Moderate percentage of the market has adopted an EQMS, forcing quality to execute its (often collaborative) processes with the help of email, automated workflows, portals and even paper documents. Tech trends such as social listening and blockchain have transformed collaboration in recent years, and leaders should look to leverage the transformative powers of connectivity, data and analytics.

App Development – Apps are becoming more versatile, customizable and mobile. Recently, companies have created “mashup” apps that combine content from multiple sources into a single interface, a meaningful trend for quality with its involvement in all facets of operations and management. Leaders should consider the full potential of interactive apps available today, including wearables, augmented reality and virtual reality.

Scalability – A moderate percentage of companies cite fragmented data sources and systems as a top challenge in achieving quality objectives. Without global scale, traditional quality and Quality 4.0 alike are unable to reconcile processes, best practices, competencies and lessons learned throughout the company. Cloud computing is of particular importance to scalability, along with data lake technologies. Start by assessing the current scalability – or the ability to support data volume, users, devices and analytics on a global scale – of your in-house system.

Management Systems – Moderate percentage of the market has adopted an EQMS and of those, 41 percent have adopted a standalone, unintegrated solution. Due to fragmented core processes, companies often find it unrealistic to adopt quality technology. But harmonizing and automating processes and systems can allow quality staff to shift their focus from simply executing quality to innovating and improving it.

Compliance – A large number of companies have reported that ensuring compliance was their top strategic objective for quality management, followed by reducing the total cost of quality. Quality 4.0 provides many opportunities to automate compliance. Today’s tech providers deliver highly configurable, automated and connected EQMS solutions, and even offer tools to automate validation. Companies should assess their current compliance systems and strategies to identify where improvements can be made.

Culture – At times, quality can seem to exist in a vacuum, despite its corporate-wide reach and importance. In fact, only a small percent of cross-functional

teams clearly understand how quality contributes to strategic success. The improved connectivity, visibility, insights and collaboration offered by Quality 4.0 make a culture of quality attainable.

Leadership – Despite a widespread interest in quality improvement and the tendency to include quality as a corporate value, only a small number of companies say that quality is a priority for top management. To address this issue, quality teams must realign their objectives to clearly link to the organization's strategic objectives, and quality leaders should advocate and lead quality across the organization, including at the executive level, to encourage buy-in and instill ownership.

Competency – Quality 4.0 can also facilitate a movement toward improved baseline competency of workers and better scaling of specialized knowledge. Technologies such as social media, ML and AI, mashup apps, wearables and VR should be leveraged to improve training and knowledge sharing.

3 Ways to Get Started

#1 Assess where you stand on each of the 11 axes of Quality 4.0

#2 Identify the potential uses of analytics, apps, data, connectivity and other technologies to influence performance across the enterprise

#3 Determine if your company has a Digital Transformation strategy and align your quality objectives with it.

Where Quality and Technology Meet

Industry 4.0 and its technologies provide new ways for people, machines and data to connect, and makes powerful technology an accessible commodity. With that said, one of the main assertions is that Quality 4.0 is not about technology, but about the people who use the technology and their processes; the other is that Quality 4.0 does not replace traditional quality, but builds and improves on it. For quality, these technologies are most significant because they allow for a meaningful transformation of culture, leadership, collaboration and compliance.

Like the first, second and third industrial revolutions before it, Industry 4.0 represents major changes in the way products are manufactured. But it also

signals an important shift in quality processes, systems and methods of collaboration from isolated to integrated. With the technology and connectivity available today, quality teams are poised to solve the long-standing quality challenges that have prevented them from innovating and improving quality.

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