

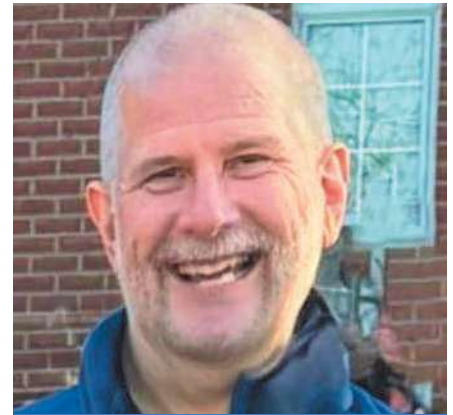
Quality 4.0: Don't Feel Overwhelmed—Feel Motivated!

Thoughts from a QMS Software Industry Veteran

By John Cachat

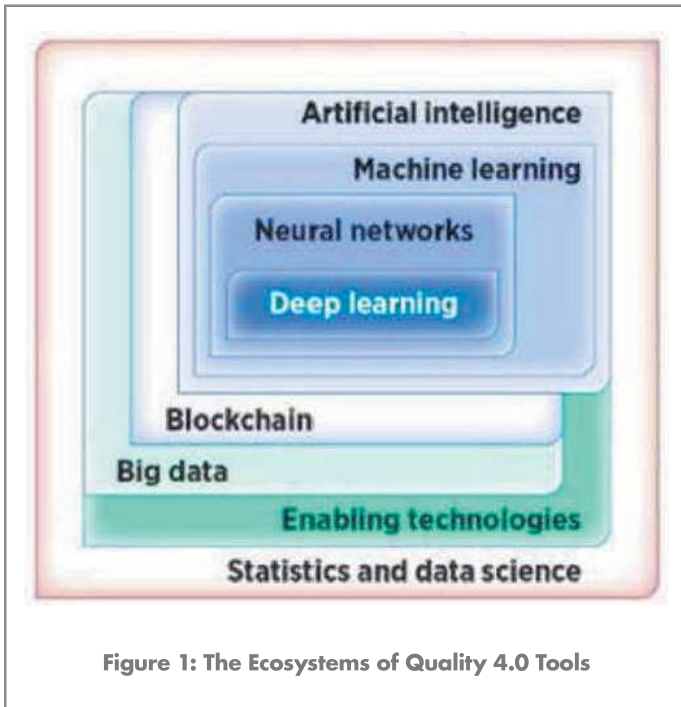
Thirty years ago, I was asked to chair the ASQ Quality Management Division Technical Committee on Quality Information Systems (QIS). QIS, a single, integrated software that regulated quality management processes, was a new thing back then. Just as it took time for QIS to be accepted, Quality 4.0 (referenced throughout as Q4.0) has its critics. To some, it is just noise; others believe it is a competitive advantage. Thoughts on this subject vary widely, regardless of company size, among executives, managers, and engineers across all markets.

Quality 4.0 is a term used to describe the application of Industry 4.0 technologies (McKinsey & Company, 2022) and practices in the field of quality management. Industry 4.0, also known as the fourth industrial revolution, involves the integration of advanced technologies, such as the Internet of Things (IoT), Artificial Intelligence (AI), and big data analytics, into processes.



John M. Cachat

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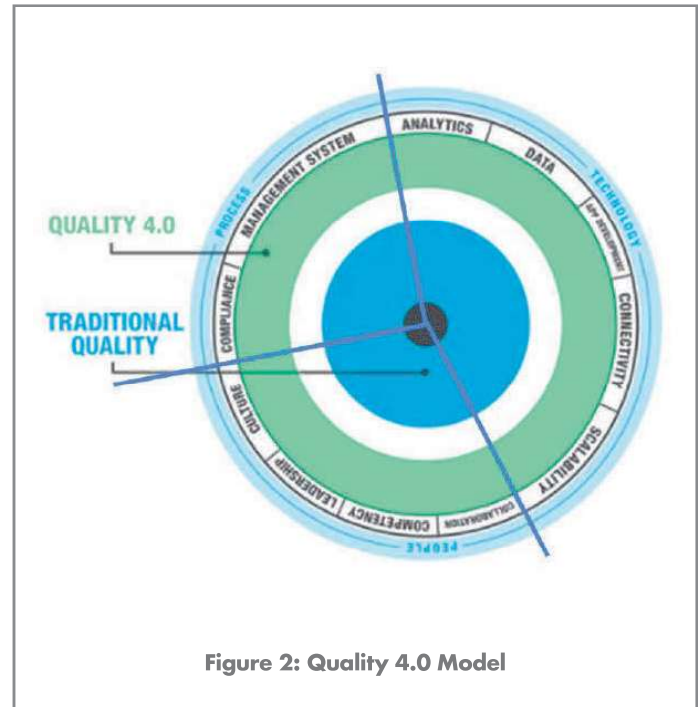


In the context of quality management, Q4.0 seeks to use these technologies to improve the efficiency and effectiveness of quality processes, reduce the risk of product defects and recalls, and enhance customer satisfaction. Q4.0 reinforces the priority on people who are looking to improve their processes with technology.

Overall, Q4.0 is an approach to quality management that leverages the latest advances in technology when the people and processes issues are ready to be automated. The business goal is the same as QIS was back in the day: improve the quality of products and services with the latest technologies to reduce costs and improve efficiency.

So, what does “The (Technical) Ecosystem of Quality 4.0 Tools” mean to you? The Ecosystem of Quality 4.0 Tools is shown in Figure 1.

Let’s look at another model, shown in Figure 2.



People, Processes, Technology

As a young and enthusiastic founder of a QMS software company in 1988, I was focused on:

- Technology – “I have the software you need.”
- Processes – “I have all the processes you need.”
- People – “Tell your people to use it!”

As a veteran in the QMS software industry, I am telling you now that, back then, I was wrong. It should be people, processes, and then technology.

People: Culture, Leadership, Competency, and Collaboration

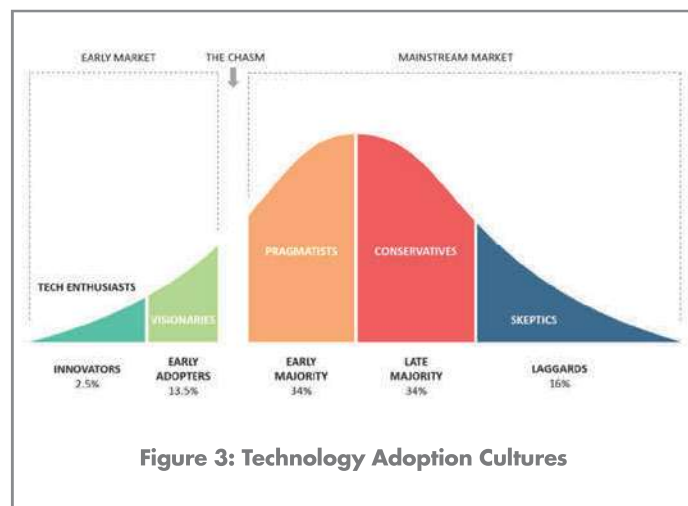
In retrospect, as a General Motors co-op student at a stamping plant, I saw two examples where people delayed technology

improvements. One was the deployment of the first robotic welding line. Delay after delay after delay, I finally asked the maintenance people why it was taking so long. The answer was, "We do not want it to work." The second example was in-line inspection technology that would automatically shut down the line if dimensional problems were identified. Production simply turned off the in-line inspection technology to keep the line running. Frustrated, management "solved" the problem by installing a red flasher to indicate if the in-line inspection technology was turned off. What did the people do? They put a box over the light and continued to make parts. Back in the day, "overcontrol" was a person adjusting process variables with a screwdriver. Now, if we choose to accept it, artificial intelligence (AI) can make these adjustments automatically.

Culture

Thirty-six percent of companies cite a lack of quality culture as their top challenge. You need to understand where your company fits on the curve of Technology Adoption Cultures shown in Figure 3¹. Some companies are early adopters, some are followers, and others are laggards.

While you personally may be an early adopter, you might be working in a laggard culture. Don't get frustrated.



Adapted from: Rogers, 1962.

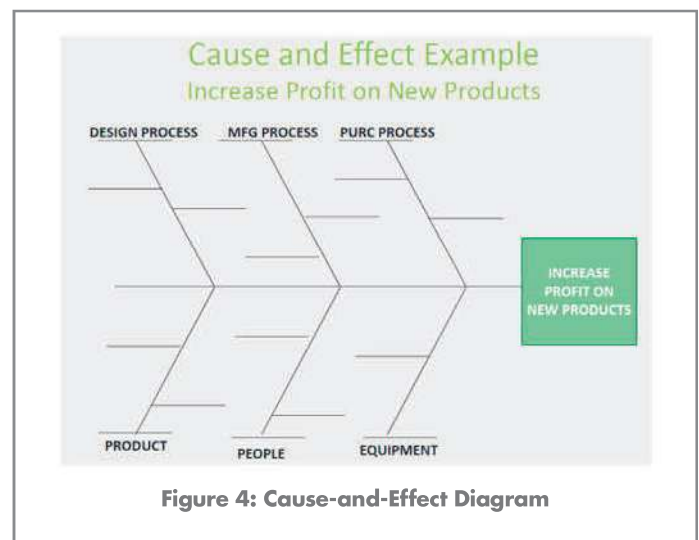
Leadership

Only 26% say that the quality function has a clear and compelling role in delivering corporate strategy. Quality professionals must understand and sell (yes, sell to their organization) how they can help exceed company goals. The best way is to take each corporate objective and engage in a fishbone cause-and-effect conversation, as shown in Figure 4.

Another issue is that of information technology (IT) leadership. Far too many quality improvement efforts are stalled by IT leadership for several reasons. This includes the paradigm in which decisions are driven by technology, hopefully improving the processes, and be used by the people. These are common scenarios that are road blockers to Q4.0:

- Use this app; we already have it.
- We bought this app for you; hope it works!
- We can't move from emailing/uploading spreadsheets across the supply chain until we have a cybersecurity infrastructure: we do not know when that will be done.

The IT department needs to be focused on the users (people) who are motivated to help improve business processes using technology.



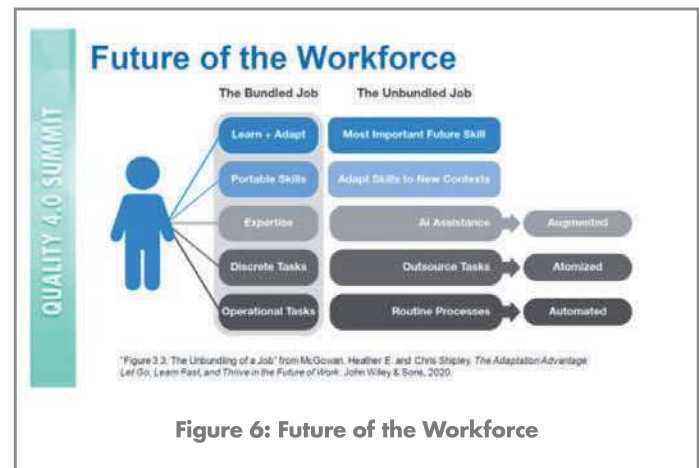
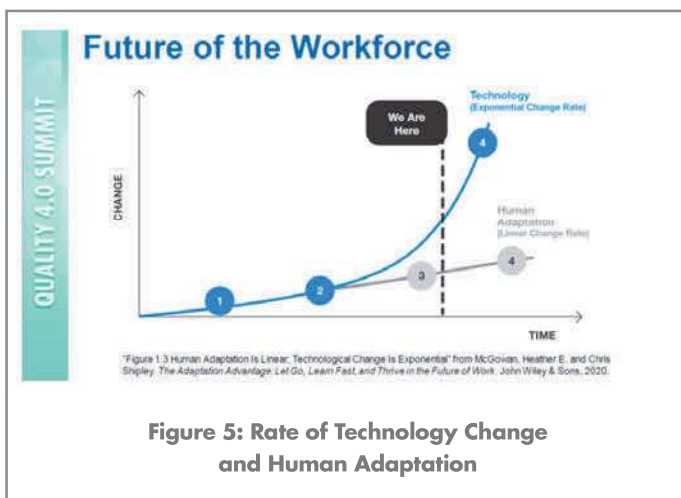
Competency

Quality management and most leadership professionals know the importance of training management systems in enabling effective and efficient employee competency improvements. When it comes to Q4.0, we need to understand that the ability of people to adapt is significantly slower than the exponential change rate of technology, as shown in Figure 5.

So don't confuse people with a bunch of technology jargon. That would be like explaining all the hardware, software, sensors, and more of the new machining center to a computer numerical control (CNC) operator. The operators really don't care about all these details; they just want to make good parts.

Today, the quality professional's role has transformed from old-school tried-and-true job descriptions to a process-centric role as shown in Figure 6.

The common phrase "I don't like change" must be addressed. Any time someone says this phrase to me, I challenge them to turn off their cell phone for 24 hours. What most people mean is, "I do not like change that is not beneficial to me." I can agree with that. The ADKAR model (Awareness, Desire, Knowledge, Ability, Reinforcement) for change management provides more insight into facilitating individual change, (Prosci Adkar Model, 2024).



Collaboration

Collaboration is not sending emails to everyone. OK, I got that off my chest. (Though I do recommend every company review and document the email process as part of a Q4.0 plan.)

Quality professionals know that "quality processes" are often a cross-functional concern that involves various departments, such as production, engineering, supply chain/purchasing, regulatory affairs, customer service, and legal. Q4.0 collaboration can be split into two groups:

Internal collaboration is inside the organization, between departments by providing a common platform for communication and data sharing. In Q4.0, this means a common platform that has been reviewed by the people who verified their processes are at least supported by the technology.

External collaboration is outside the organization to include customers, suppliers, and partners that allow for the same results from communication and data sharing. The goal is to lower overall costs by rapid defect reduction across the global supply chain.

Cybersecurity, ITAR compliance, and HIPPA rules are just a few examples of the technical challenges encompassed with Q4.0 and collaboration. There is a lot to learn for technology decision-

makers. For example, a Tier 2 supplier has a raw material plant in Canada, raw material processing in the UK, and an assembly in Mexico. This scenario represents a very complex solution where it is difficult to define who is authorized to even view the information.

Process: Management System and Compliance

- You can only improve what you can control.
- You can only control what you can measure.
- You can only measure what you can define, i.e., the process.

Management System

Historically, the first thing companies computerized was accounting. The financial reports took too long, and the results were flawed. Then the accountants told management, “We have too much inventory,” so we automated production scheduling and reporting. Then we did purchasing to help get parts only when the parts were needed. Companies created electronic data interchange (EDI) to make it easier to transfer information between customers and suppliers. Then companies wanted to get faster engineering, so they introduced computer-aided design (CAD), then product data management (PDM), and now product lifecycle management (PLM). Then marketing and sales technology was added with customer relationship management (CRM).

Q4.0 represents a clear and present opportunity for quality professionals to sit at the executive table. This is accomplished by analyzing the current processes, starting with where we are using spreadsheets. We show how robust database tools, integrated with the existing software platform, under a secure single sign-on (SSO) environment, will enable the company to meet its goals.

Compliance

Compliance to, versus delivering corporate strategy, has the same challenge as it does in education: do we teach to learn

or teach to pass the test? Leadership drives this decision. Both are OK, but focusing only on compliance, or passing the audit, does not support a Q4.0 mindset. It will create processes that are focused on the bare minimum to pass the audit, and it will frustrate your people. You may want to consider compliance audits/maturity assessments to help people understand the scope of compliance and its role in meeting business objectives.

Technology: Data, Analytics, Connectivity, Scalability, and App Development

To help demonstrate this section, I will use a common quality process that can be adopted across a wide range of industries: the production part approval process (PPAP) shown in Figure 7. The caveat is that you cannot successfully go from 1.0 to 4.0.

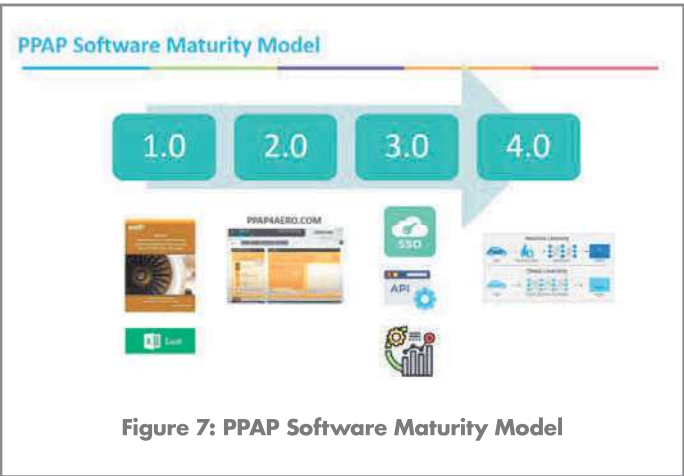


Figure 7: PPAP Software Maturity Model

PPAP MATURITY LEVEL	SUMMARY
1.0	Spreadsheets and written procedures
2.0	Database-driven technology designed by people
3.0	Connectivity in existing enterprise software tools
4.0	Analytics, ML, AI, and more

Most PPAPs are poorly executed on both the customer and supplier side of the supply chain (PPAP 1.0). Some automotive OEMs have recently started to require a database tool to replace standalone, non-integrated spreadsheets (PPAP 2.0). Why? Ask any auditor the easiest place to uncover findings, and they will say, "I look at the PPAP documents, especially if the process flow, PFMEA, and control plan are synchronized."

Technological advances (PPAP 4.0), such as advanced analytics and artificial intelligence, will help organizations achieve real-time visibility of vital quality metrics. Imagine asking the computer questions like, "Are there any other part numbers being impacted for the same reason?" or "What are the top 10 highest total cost suppliers, including purchase price and all appraisal and failure costs?" or "Is the failure rate (during validation trials vs. production) consistent with FMEA expectations?"

Talk—don't type. Gone are the days of waiting for someone to modify a report to get the answer to your question, which, of course, as soon as you see the answer, you then have an immediate follow-up question. You just keep asking the computer.

Data

"In God, we trust, all others bring data."
W. Edwards Deming

Data-driven decisions are the best. However, for most companies, there is still a significant lag in the quality-related business processes of data collection,

transaction processing, analysis, and decision making.

Quality professionals possess more analytical expertise than most employees. Sharing these talents will provide better insights into all processes and products that enable better decision making. As we get access to more and more data, we must verify that the data are being reviewed statistically and pragmatically.

Analytics

Analytics is often where quality professionals get stuck. Thirty-seven percent (37%) of companies say poor metrics are a major roadblock to accomplishing quality objectives. There are several reasons that this might happen, including that the metric does not have a defined cause and effect with corporate goals, and, most likely, there is no automatic way of tracking the metric. This causes numerous employees to waste time creating what they think management may want to see, only to get blocked by follow-up questions by management that they can't answer.

This halts the process since their only response is that they will have to come back to that.

There are five major things all quality professionals, and really any top executive, want to know:

1. What happened? (This is usually the easiest question to answer!)
2. Why did it happen?
3. What action should be taken?
4. Will it happen again in other areas?
5. Was the action effective?

Quality professionals know that creating engineering changes in production will cost more and impact profits. Quality professionals know if suppliers charge strictly based on price, the total cost, including appraisal and failure costs, is higher. Wouldn't it be great if these analytics were database-driven (not on spreadsheets) and enabled follow-up questions? See Figure 8.



Figure 8: Increase on Profit on New Products

Analytics is the best way to sell your company on how you as a quality professional can provide clear and compelling roles in delivering the corporate strategy. Remember the cause-and-effect relationships that make metrics go up or down.

Connectivity

A key element of Q4.0 is the swift, effective collation of data from various sources to empower informed and swift decision making.

Let's keep this simple by starting with some basic enterprise software connections, including:

- Customer, Supplier, Employee, and Product files: One master shared by all with either one- or two-way updates.
- Single Sign-On (SSO): Anyone in the company's secure technical framework should only have to enter a login once. Logging into systems outside the company's secure technical framework is always a risk. SSO should make it easier for the IT Department to maintain a secure network.
- Transactional events (between enterprise resource planning [ERP], PLM, manufacturing execution system (MES), quality management system [QMS], CRM, etc.): Provide information to the people who need it, when they need it. For example, purchasing wants to know if someone is an approved supplier; everyone wants to know if the PPAP is approved; manufacturing engineering wants to know how the actual product non-conformance transactions compare to the occurrence, detection, and severity estimates made during FMEA risk review; manufacturing wants to know how engineering changes in PLM impact delivery and cost?
- Analytics across multiple data sources (ERP, PLM, MES, QMS, CRM, etc.): If we understand the people and their processes, we gain tremendous insight as to why they are spending non-value-added labor to compile data from multiple sources to perform value-added labor of data insights and action.

Using the PPAP example, it can be very powerful if suppliers receive a key product characteristic (KPC) list as part of the PPAP request. Theoretically, the customer's design failure mode and effects analysis (DFMEA) have this information. From the supplier quality engineer viewpoint, it would eliminate the same part at

three different suppliers. The objective is to create uniform KPCs across all suppliers.

Scalability

This refers to an organization's ability to perform well under an increased or decreased workload, or a dynamic demand environment. From a technology viewpoint, a computer system that scales in a dynamic demand environment will be able to provide the correct level of performance as the demand varies. Cloud hosting is the fastest path to support dynamic demand with the "pay for only what you need pricing model." What about people and processes? If an application is thrown over the proverbial wall onto the people without understanding their processes, then the technical scalability issue is a moot point.

App Development

The nontechnical discussion about app development is more about culture and leadership. I have always found it interesting to review why people use spreadsheets. Common responses include:

- I am trying to get a list of....
- I combine these four files into one spreadsheet.
- I do a complicated, special analysis that is not currently documented.
- I do not want to tell you because it is embarrassing.

Not being able to go from 1.0 to 4.0 makes sense. The process of going from 1.0 to 4.0 is a series of baby steps that focus on building blocks from the previous step. It's not perfect, but it's better. I learned from a tremendous group of users that "if it is too complicated, we are going back to spreadsheets." The point is that you must help your people understand their processes before any app development or app purchasing is started.

There are some very exciting and innovative technology tools coming soon. Outputs from artificial intelligence and machine learning systems can be used to develop new competencies. Virtual reality (VR) systems can be used with improved training delivery—short, focused, on demand, and with verbal requests.

What Would a Quality 4.0 Implementation Plan Look Like?

The specific details of the plan would depend on the organization's goals, resources, current level of quality management maturity, and technology adoption culture. Some common steps that organizations may follow when developing a Q4.0 implementation plan include:

1. **Conducting a Baseline Assessment:** The first step in a Q4.0 implementation plan is to conduct a comprehensive assessment of the organization's current quality management practices, processes, and systems. Such assessment can help identify areas for improvement and guide the development of a roadmap for Q4.0 adoption.
2. **Developing a Vision and Strategy:** Once the baseline assessment is complete, the organization must develop a clear vision and strategy for Q4.0 adoption. This should include defining specific business goals, identifying the technologies and practices that will be leveraged, and determining the resources and budget required for implementation.
3. **Building the Necessary Data Governance:** Q4.0 adoption requires a robust data governance framework to ensure data is accurate, consistent, and accessible. This may involve developing data quality standards, establishing data ownership and stewardship, and implementing data security and privacy measures.
4. **Building the Necessary Technical Infrastructure:** The next step is to build the necessary infrastructure to support Q4.0 implementation. This may involve investing in new equipment and software, establishing data analytics capabilities, and developing a framework for IoT connectivity and data sharing.
5. **Managing Projects:** With the necessary vision and strategy in place, and taking baby steps in following a project plan approach, a company will progressively move the infrastructure and data governance framework, thereby allowing the organization to implement Q4.0. It is very important to confirm that Q4.0 is going to address critical customer satisfaction and financial issues. Deep knowledge of QMS processes and the ability to interpret between quality and IT are critical skills needed by the Q4.0 project manager.
6. **Continuing to Improve:** The company must be prepared to continuously optimize its quality management systems and processes. This may involve using data analytics to identify and address quality issues, implement changes to improve product quality, and integrate feedback from customers and other stakeholders. When the CEO or owner asks, "Why do I need this?" it is best to compare the investment to upgrading the machines in the shop or upgrading the PLM software in engineering. All these actions have the same goal—reduce costs with improved quality.

Quality 4.0 Key Takeaways

- Q4.0 will remove the perception of the quality department as being little more than the "quality police," "the people that always shut down production," or "the ones who hold up shipping."
- Q4.0 provides a clear and present opportunity for quality professionals to clearly align their objectives and practices with the company's strategic business goals by improving the ability to communicate value in reducing bottom-line costs (warranty, reduced returns, scrap, rework) with analytic-driven business decision making that drives future strategies.
- Quality professionals possess more analytical expertise than most other employees. Sharing these talents will provide better insights into all processes and products in an enterprise that enables consistently better data-based decision making.
- Q4.0 will provide better collaboration capability to manage internal cross-departmental quality activities (between departments/plants) and external stakeholders (customers, suppliers, partners).
- Q4.0 is a chance for companies to look closely at why they are facing problems and figure out ways to make things better. They can also think about how using new technology, such as getting clear and helpful information from data, can help them create a quality culture—a true organization-wide culture of quality—more attainable.
- Improving technical software system integration will reduce the time that high-value staff and management spend on non-value-added execution and will allow them to shift focus toward improvement and innovation.

References

1. Rogers, Everett (16 August 2003). Diffusion of Innovations, 5th Edition. Simon and Schuster.
2. No Author, The Prosci Adkar Model, <https://www.prosci.com/methodology/adkar>, accessed: 5/2/2024.