Digital Transformation of Quality in the Life Science Industry

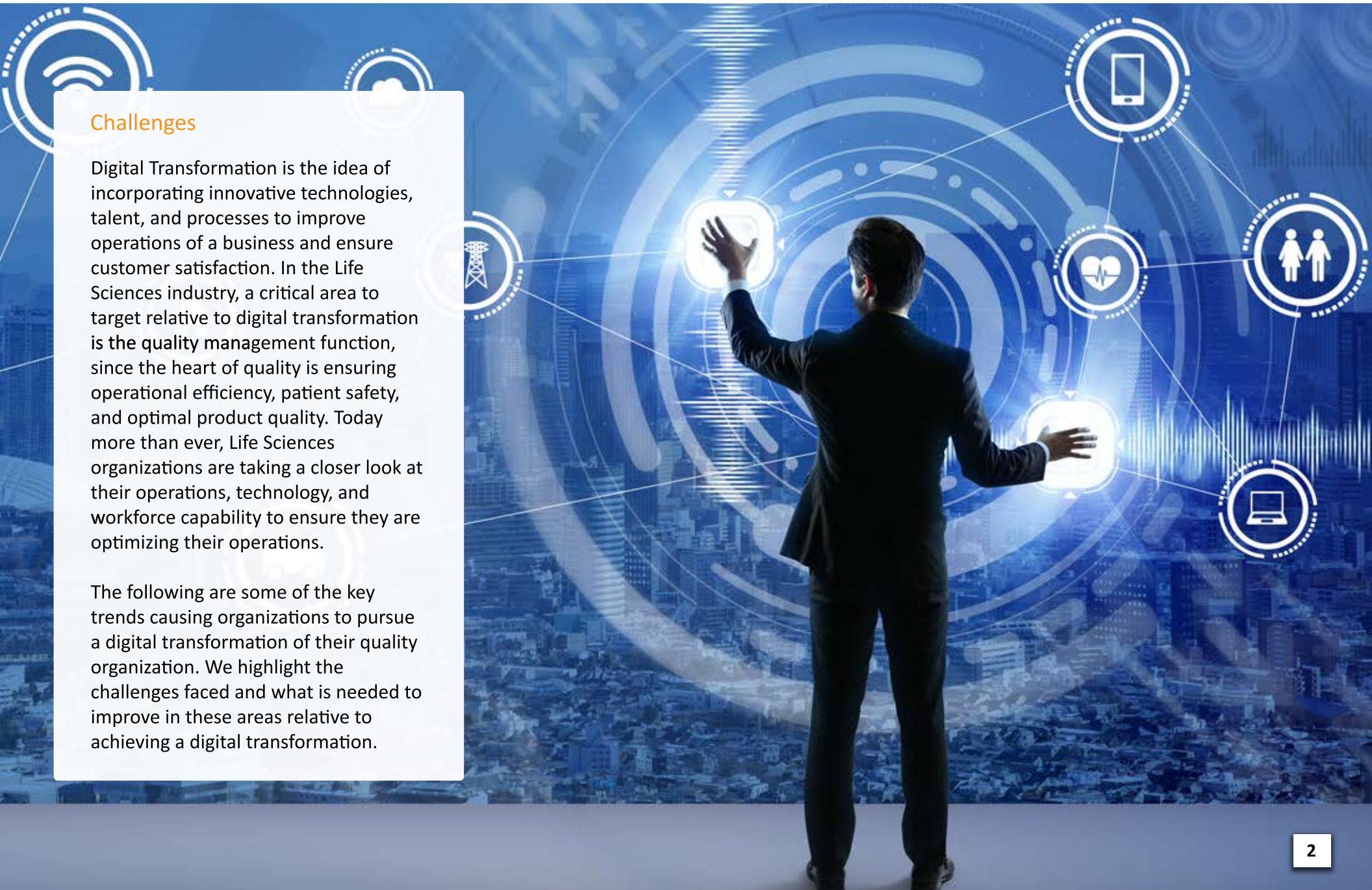
Introduction

The life sciences industry has been a slow adopter of technologies and solutions owing to cost of quality associated with the adoption. Challenges associated with the implementation of technologies as well as a lack of clarity and direction related to the use of these emerging technologies have been front and center with organizations. With the latest guidance from the regulatory authorities (such as the FDA), there is a scope for organizations to realize additional flexibility as well as efficiencies in the overall quality process. This linked with the emergence of cloud based Quality Management Systems (QMS) has provided the necessary opportunities for organizations to recognize and capitalize on the shift to Digital Quality as well as other areas of the business.

Given this new opportunity, Life Sciences organizations need to consider how to approach moving forward. In this eBook, we discuss several important areas effecting Life Sciences organizations and their quality function. We begin by reviewing several of the key challenges shifting quality towards a Digital Transformation. We then review Quality 4.0 and Digitization and what organizations need to consider as they move towards this future state of quality. And finally, we discuss 6 key imperatives in order to achieve a digital transformation of the quality function.

Topics

4 Challenges Shifting Quality Towards a Digital Transformation



Challenges

Digital Transformation is the idea of incorporating innovative technologies, talent, and processes to improve operations of a business and ensure customer satisfaction. In the Life Sciences industry, a critical area to target relative to digital transformation is the quality management function, since the heart of quality is ensuring operational efficiency, patient safety, and optimal product quality. Today more than ever, Life Sciences organizations are taking a closer look at their operations, technology, and workforce capability to ensure they are optimizing their operations.

The following are some of the key trends causing organizations to pursue a digital transformation of their quality organization. We highlight the challenges faced and what is needed to improve in these areas relative to achieving a digital transformation.

Challenge #1: Data Quality

Data is the heart and center of any organization. Availability of the right data or the lack thereof results in good or poor decisions being made. There are several areas where quality organizations are faced with data quality challenges thus leading to a need for digital transformation.

One key challenge organizations face is data silos across the organization. Various data silos exist depending on the process area, application being used, organizational group, and the data being collected. A few examples are business quality data, IT quality data, product quality data, and supplier quality data. Not all data is being collected using the same method and this incongruent data is being used together in the decision process. Many times, this leads to flawed decisions. Additionally, organizations are leveraging multiple systems serving each one of their processes. For example, some businesses are automating parts of their processes, but not across the entire enterprise. This is also causing major inconsistencies relative to the data.

Challenge #2: Technology Advancements

Technology solutions are providing organizations with the capability to do more in less time. Organizations are leveraging various technologies across the organization like EQMS in an effort to bring all the quality data across the company together. Technologies like IoT, machine learning, AI, and the cloud are being leveraged to optimize processes.

Organizations need to look at technology solutions not just from an internal quality angle, but also from the company's business partners and the customer perspective. They need to be able to make informed decisions based on the data and to communicate specific aspects of that data accurately to suppliers, vendors, and customers. Communication of the data across the quality ecosystem enabled through technology is critical to the transformation process of the Quality organization.

Challenge #3: Strategy Execution

While strategy is typically set at the higher levels of the organization, the execution is more the responsibility of the feet on the ground. This leads to silos across the various groups and departments. The execution is also, many times, not connected back to the strategy that it's meant to fulfill. For example, there are organizations that are investing in many new "shiny object" projects and programs. Spending a tremendous amount of effort and resources but failing in the end to tie back to the quality strategy, data strategy, or digitization strategy. Companies are now looking to tie their strategy to the execution in order to ensure they have cohesive results. A digital transformation strategy is required to assist them in getting there.

Challenge #4: Skillset required

Another key element that is compelling organizations to embrace digital transformation is the skill set needed for the future. Many organizations are considering what skills they will need beyond those with a quality background. They are looking at acquiring people who understand data - like data scientists and analytics specialists. The quality group, in some organizations, is looking to have an IT bend of mind to understand the technology and make sure that it is leveraged to the maximum – helping them drive efficiencies across the organization.

Quality 4.0 & Digitization
Key Consideration for the Life Sciences Industry

The advances in technology in the past decade have resulted in a new industrial revolution. This is frequently referred to as the fourth industrial revolution or "Industry 4.0." The revolution is being driven by the exponential growth of disruptive technologies and the changes that those technologies are bringing to business and the markets that organizations serve.

Quality 4.0 is a term that refers to the future state of quality and organizational excellence. This is within the framework of Industry 4.0. This new Quality of the future requires leading the organization to apply proven quality best practices along with new digital disruptive technologies. We discuss here some areas to consider as an organization moves towards Quality 4.0.

The Shift from Traditional Quality to Quality 4.0

With Quality 4.0 organizations need to deliver quality at a much faster pace based on what the business and the customers want and need. The shift is from the traditional quality approach to Quality 4.0 which is the intersection of traditional quality, analytics and data governance and the adoption of new technologies.

Business Benefits

For digitalization to be effective, organizations need to be able to define the business benefits. The quality leaders need to sit down with the business stakeholders and have a focused conversation on ensuring that everyone is clear on the desired outcome. Once the quality organization is confident that they understand the business needs, they can setup the right processes for them to get those benefits. It might not happen overnight, but if the quality group is reviewing it and tweaking, changing, and updating based on those expectations, the organization will reach its quality objectives.

Start with a Pilot

When moving to Quality 4.0, a use case is a good start. The quality organization's first use case should be simple. It should not be something as drastic as changing the way that the company does its entire CAPA or nonconformance process. Instead, for example, the quality team could start with a Robotic Process Automation (RPA) to identify and report CAPAs. With this process, the quality team can collect, through systems, all data and then report on that data. Organizations can use this as a simple use case. As the business starts looking at this current use case, it will highlight and focus the organization on other opportunities where there are process steps that can be improved. Through this iterative process, a pilot becomes a project, and the project becomes a program.

Digitization is an "Opportunity"

Digitization is not just limited to quality. It should work in tandem with the organization's goals and vision as well as follow a similar roadmap. The Quality team should work together with IT to use the technology to drive optimization and efficiencies across the Enterprise and not just the quality aspect.

Leverage Experience Outside your Organization

Life Sciences organizations need to look at what is happening outside of the business. There are many industry groups and conversations that can be had with people outside the business. For example, the processing of CAPAs discussed earlier came from an idea of using RPA to process loan applications. However, the RPA process could be easily modified into the CAPA realm because the data was similar in the way that it was captured and used in the process. So, by looking at what other industries, peers, are doing, it can help with the building of use cases for digitization.

Focus on the Culture of Quality, Leadership, and Processes

From a culture of quality perspective, organizations should focus on leadership and the processes that are enterprise wide. Performing digitalization for one process in one location might be a good pilot, however, the focus should be on what can be done across the enterprise. By having buy-in from both IT and business together, the speed of digitization is greater.

Define the Real Value: Improved Quality, Efficiency, and Cost

To identify the return on investment there is a need to define the real value that the organization is receiving. The focus should to be improved quality, while also considering efficiency of processes, and ultimately cost associated with quality. Value has to be defined in those three parameters at a minimum.

6 Imperatives for the Digital Transformation of your Quality Function
A Digital Quality Framework

Quality management's ultimate goal is the protection and safety of patients along with ensuring product quality and maintaining data integrity. Given the significant regulatory and technology changes that continue to occur, it is essential that organizations optimize their quality function. To that end, there are 6 key imperatives that we believe should be considered.

1. EQMS

An Enterprise Quality Management System (EQMS) is a critical component to any digital quality framework. The objective of EQMS is to manage content and business processes for quality and compliance across the value chain. It is a platform for quality management that integrates with the IT architecture and data model and facilitates cross-functional communication and collaboration.
It is essential that the EQMS is not siloed.

Quality information should be collected as data and leveraged across the organization to make informed decisions.

The EQMS has to also have an interface to other systems whether it is ERP, PLM, supplier quality, vendor management, or other enterprise systems integral to the organization. Those interfaces are critical because that is where data resides, and access to that data is vital for decision making.

EQMS also needs to be mobile. It can't be at one particular location or region or within one area. The EQMS has to provide the ability to look at data wherever, whenever, and however needed.

2. Transition

A second imperative of reaching an optimized digital quality transformation, is that the company and quality organization shift from a “deliverable mindset” to a “data mindset”. Quality organizations have always been recognized as only focused on deliverables (chasing down the elusive “approvals” on deliverables). Although this is an extremely important aspect of the quality organization’s mission, when thinking about transition, about the focus should not be the deliverables but the actual data that is driving a lot of those deliverables. There's a huge amount of efficiencies and improvements that can be identified and focused on by transitioning to a data mindset. The data will actually be available once a centralized data model has been established and implemented. Organizations have to move away from the data residing across multiple silos across the quality organization (i.e. business quality data, IT quality data, product quality data, and supplier quality data) to a centralized data model. This centralized data model provides for additional and better access for not only internal use, but possibly for even customers and vendors.

3. Connected

Systems across the enterprise need to be connected. Silos between systems have to be bridged with the goal of establishing an interoperability of data and not limited to one aspect of data - supplier data, product data, process data, metrics. Everything has to be linked and available seamlessly. The lack of a holistic picture or view of that data will potentially lead to imperfect business decisions.

90% of products in compliance with your EQMS is where organizations should aim to be. This aim has a direct impact on the reduction of cost of poor quality. Based on recent studies, there is at least a 2% to 5% drop in the cost of poor quality once an EQMS implementation has been started and connectivity is established between key systems.

4. Availability

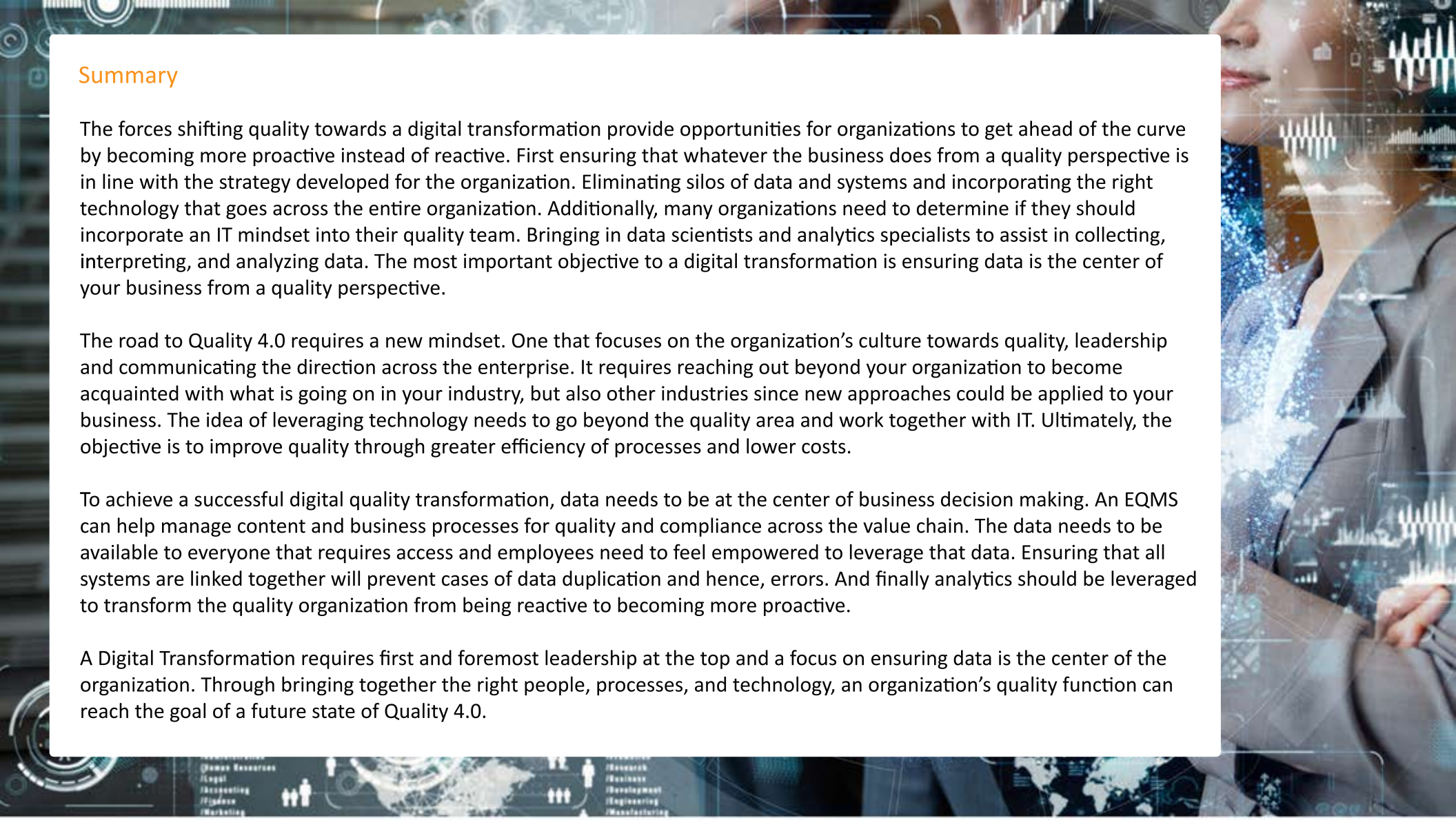
In many companies data is held as though it is an asset only accessible on a need to know basis. That needs to change in order to be successful in any digital quality optimization endeavor. Organizations / systems have to be able to provide data based on a person's role, process area, location, or other criteria. Everyone has to have access to that data. There is a marked jump in efficiencies and process compliance once the data silos are diminished or disintegrated, primarily because people are making assessments with the data they need to have in order to make those critical decisions.

5. Empowered

By providing the availability of the data across the organization, employees and other support staff are empowered. Providing them the technology and tools to make the right decisions or access to data across the organization is helping them make the right decisions. This also leads to optimizing current processes to help drive better decision making and reducing the cost of quality.

6. Analytics

Analytics is an essential part of the framework to gain insights from an organization's data. Analytics is being able to understand at the data structures and locations in an effort to enable organizations transition from a reactive to proactive approach. With a proactive approach, decisions made based on data that is available for processes that can help avoid quality incidents. That can prevent, for example, a CAPA or nonconformance. Being proactive also means, having the ability to spot and analyze trends



Summary

The forces shifting quality towards a digital transformation provide opportunities for organizations to get ahead of the curve by becoming more proactive instead of reactive. First ensuring that whatever the business does from a quality perspective is in line with the strategy developed for the organization. Eliminating silos of data and systems and incorporating the right technology that goes across the entire organization. Additionally, many organizations need to determine if they should incorporate an IT mindset into their quality team. Bringing in data scientists and analytics specialists to assist in collecting, interpreting, and analyzing data. The most important objective to a digital transformation is ensuring data is the center of your business from a quality perspective.

The road to Quality 4.0 requires a new mindset. One that focuses on the organization's culture towards quality, leadership and communicating the direction across the enterprise. It requires reaching out beyond your organization to become acquainted with what is going on in your industry, but also other industries since new approaches could be applied to your business. The idea of leveraging technology needs to go beyond the quality area and work together with IT. Ultimately, the objective is to improve quality through greater efficiency of processes and lower costs.

To achieve a successful digital quality transformation, data needs to be at the center of business decision making. An EQMS can help manage content and business processes for quality and compliance across the value chain. The data needs to be available to everyone that requires access and employees need to feel empowered to leverage that data. Ensuring that all systems are linked together will prevent cases of data duplication and hence, errors. And finally analytics should be leveraged to transform the quality organization from being reactive to becoming more proactive.

A Digital Transformation requires first and foremost leadership at the top and a focus on ensuring data is the center of the organization. Through bringing together the right people, processes, and technology, an organization's quality function can reach the goal of a future state of Quality 4.0.

About Astrix

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For over 25 years, Astrix has been a market-leader in dedicated digital transformation & dedicated staffing services for science-based businesses. Through our proven laboratory informatics, digital quality & compliance, and scientific staffing services we deliver the highly specialized people, processes, and technology to fundamentally transform how science-based businesses operate. Astrix was founded by scientists to solve the unique challenges which science-based businesses face in the laboratory and beyond. We're dedicated to helping our clients speed & improve scientific outcomes to help people everywhere.