

QUALITY 4.0 IMPACT AND STRATEGY HANDBOOK

Getting Digitally Connected
to Transform Quality Management

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TABLE OF CONTENTS

SECTION 1: Executive Summary	<u>3</u>
SECTION 2: Defining Quality 4.0	<u>7</u>
SECTION 3: Understanding the 11 Axes of Quality 4.0	<u>11</u>
SECTION 4: Summary and Recommendations	<u>26</u>



**ACRONYM
QUICK REFERENCE**

VIEW ON BLOG



SECTION 1

Executive Summary

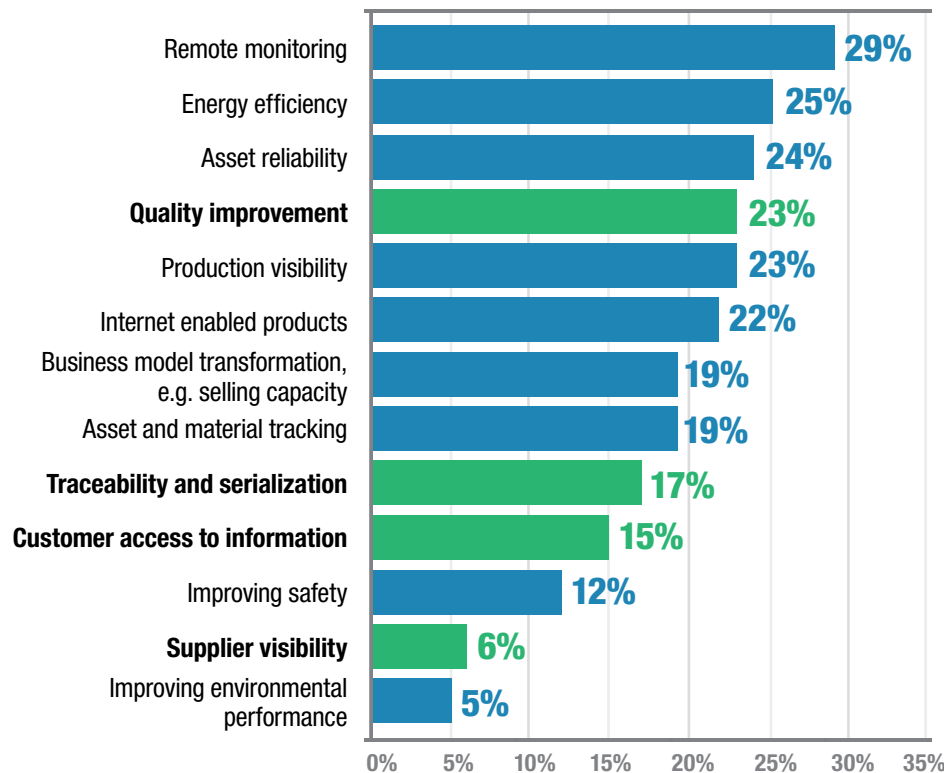
Executive Summary

The most recent decade has seen rapid advances in connectivity, mobility, analytics, scalability, and data, spawning what has been called the fourth industrial revolution, or Industry 4.0. This fourth industrial revolution has digitalized operations and resulted in transformations in manufacturing efficiency, supply chain performance, product innovation, and in some cases enabled entirely new business models.

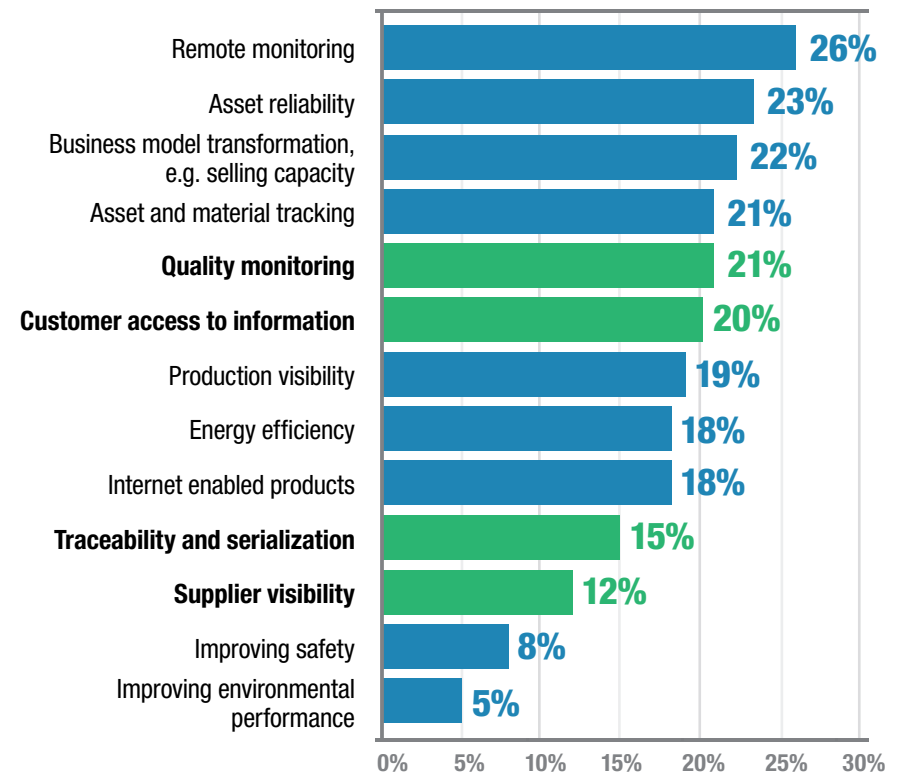
This transformation should be top of mind for quality leaders, as **quality improvement and monitoring are among the top use cases**

for Industry 4.0. Quality 4.0 is closely aligning quality management with Industry 4.0 to enable enterprise efficiencies, performance, innovation and business models. However, much of the market isn't focusing on Quality 4.0, since many quality teams are still trying to solve yesterday's problems: inefficiency caused by fragmented systems, manual metrics calculations, quality teams independently performing quality work with minimal cross-functional ownership, and ineffective supplier communication, among others.

What are the top IIoT use cases your company is pursuing today? (N=252, all respondents)



What are the top IIoT use cases your company will start pursuing in the next year? (N=249, all respondents)



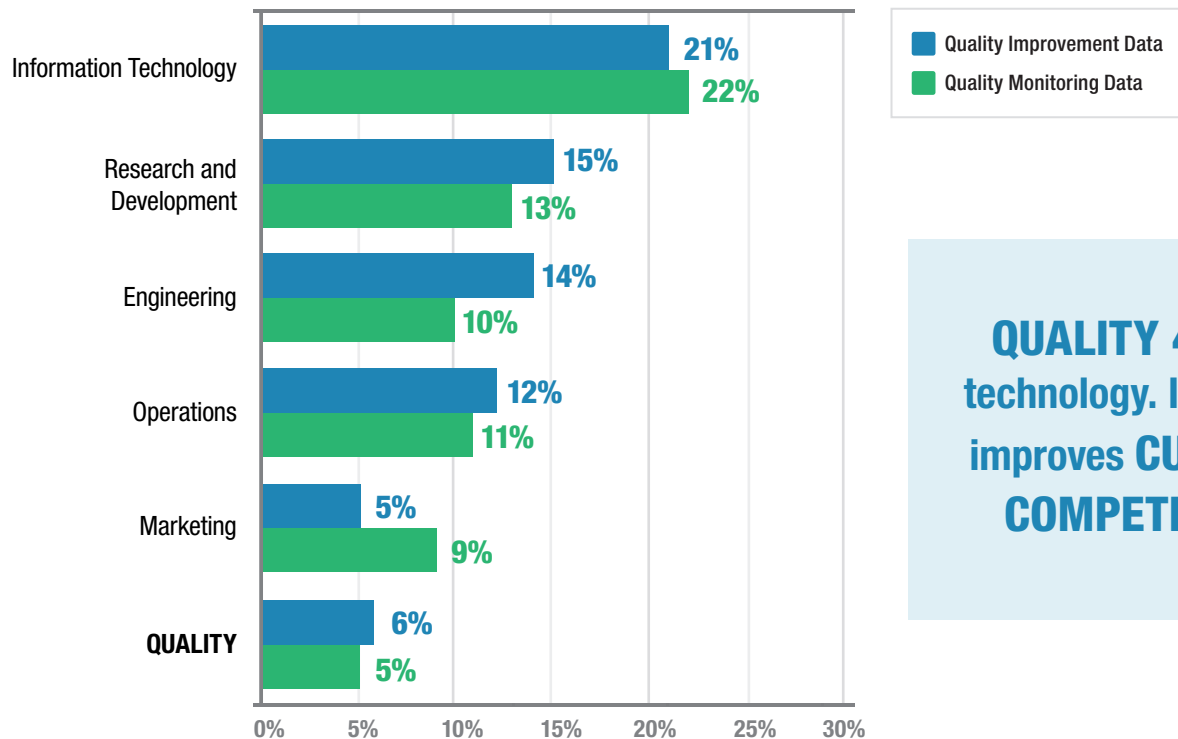
Executive Summary (Cont.)

Interestingly, a vast number of existing quality-centered Industry 4.0 initiatives are not being led by quality, but by IT, operations, engineering, or sales and marketing. Many conversations with quality leaders make it clear that a large portion of them do not possess a clear understanding of Industry 4.0 technologies, their application, and their importance. This lack of understanding is preventing quality from effectively leading the charge on Quality 4.0.

Quality 4.0 isn't really a story about technology. It's about how that technology improves culture, collaboration, competency and leadership. It's also about the digital transformation of management

systems and compliance. Although it's an advanced topic, this also isn't a story about tomorrow, since leading manufacturers are already on their Digital Transformation journey. This eBook provides manufacturers with the tools and insights required to lead the Quality 4.0 transformation. It communicates the technologies, how they transform people and processes, existing concrete accomplishments by peers, and guidance to enable the transition from traditional quality to Quality 4.0. Regardless of who leads the Quality 4.0 transformation, those that apply the technology to greatest effect will be the innovation leaders of tomorrow.

Which roles are planning to use IIoT to monitor and improve quality?



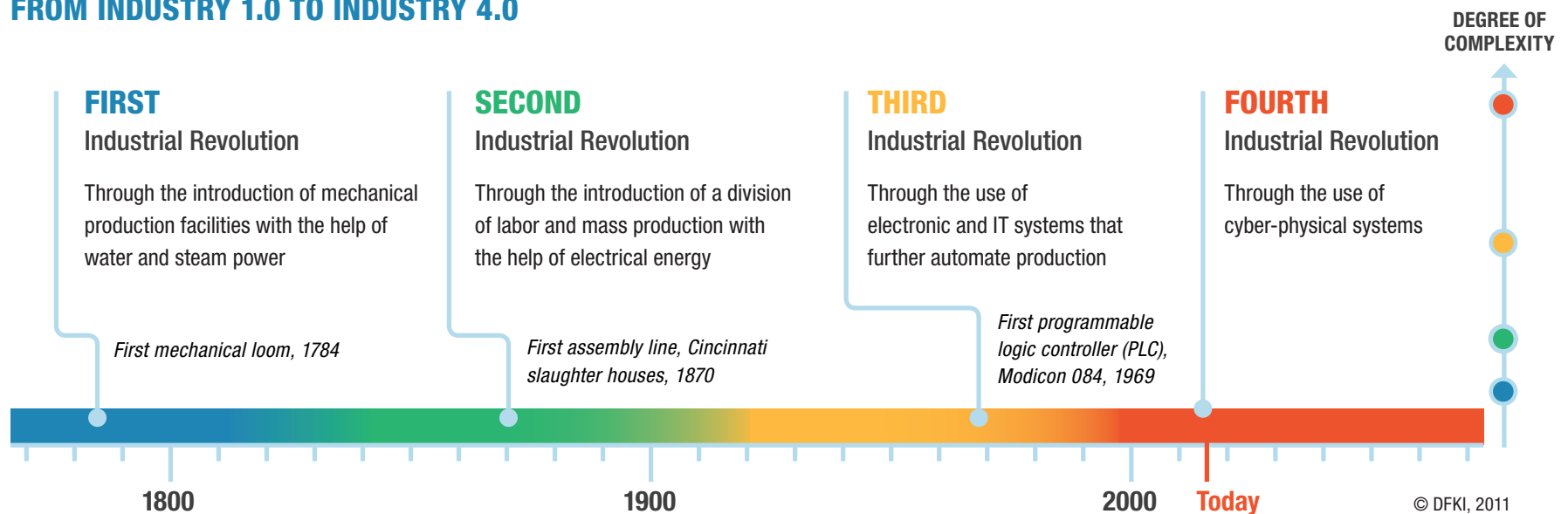
QUALITY 4.0 isn't really a story about technology. It's about how that technology improves **CULTURE, COLLABORATION, COMPETENCY, AND LEADERSHIP.**

Why Quality 4.0?

Quality 4.0 is a reference to Industry 4.0. The First (real) Industrial Revolution embodied three revolutionary changes: machine manufacturing, steam power and the move to city living for people who had previously been agriculturalists. During the Second Industrial Revolution, the production line and mass manufacturing drastically reduced the cost of consumer and industrial products. The Third Industrial Revolution was barely a revolution as electronics and control systems gradually penetrated manufacturing, allowing greater flexibility and more sophisticated products at a significantly lower cost. The Fourth Industrial Revolution is happening around us right now. It extends the digital impact of the third revolution and merges it with the physical

and natural worlds. Several critical technology changes have enabled this, including advances in data, analytics, connectivity, scalability, and collaboration. As the fourth revolution takes hold, it will impact everything that we do. It connects people, machines and data in new ways, it democratizes technologies that were previously only accessible to the specialized few, and ushers in transformative capabilities such as those in material science and 3D Printing. For quality, these technologies are important because they enable transformation of culture, leadership, collaboration, and compliance. Quality 4.0 is truly not about technology, but the users of that technology, and the processes they use to maximize value.

FROM INDUSTRY 1.0 TO INDUSTRY 4.0



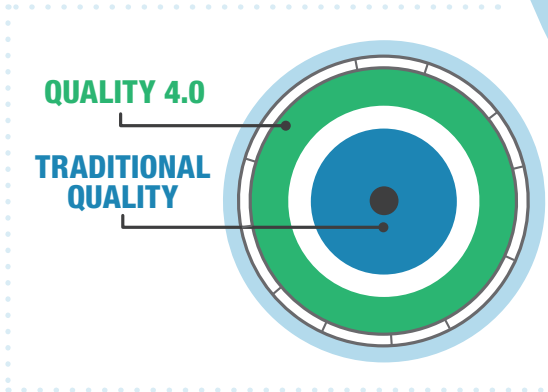
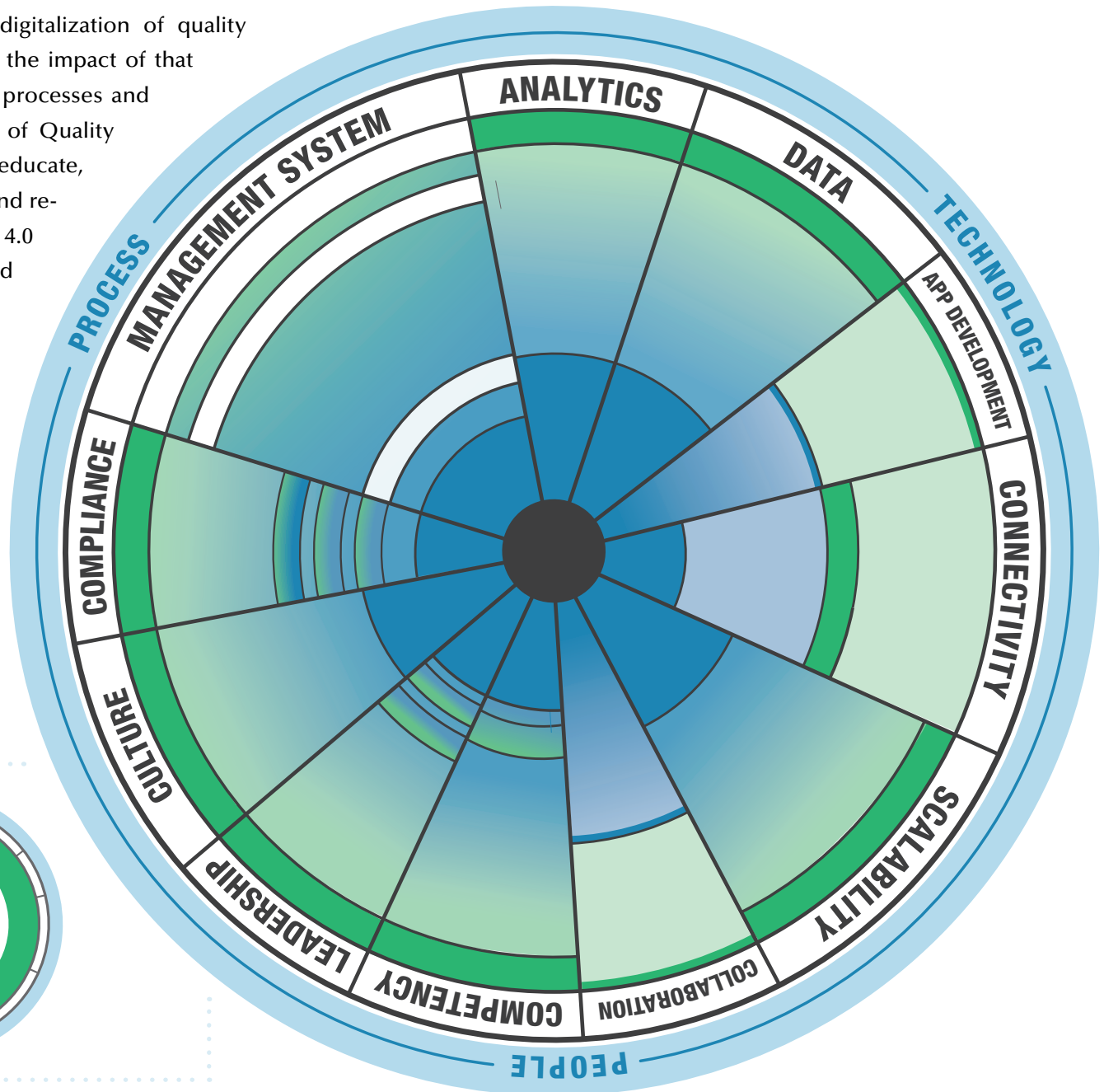


SECTION 2

Defining Quality 4.0

What is Quality 4.0?

Quality 4.0 certainly includes the digitalization of quality management. More importantly it is the impact of that digitalization on quality technology, processes and people. LNS has identified 11 axes of Quality 4.0, which companies can use to educate, plan, and act. 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.



USE CASE 1: Managing Recipe Variation

Let's bring the framework to life with some examples. Brewing beer is a touchy process that must balance the relationships between live cultures, bacteria, time, ambient and equipment temperatures, ingredients, equipment, elevation, and much more. The inherent variation can cause quality issues.

One of the largest craft brewers in the US recently implemented machine learning (ML), artificial intelligence (AI) and historical

process data to solve a batching problem that was causing a major quality issue and the loss of entire batches.

The brewmasters thought the problem was the relationship between pressure and temperature; instead it was an issue with the timing of batch processes determined by natural variances in yeast. They used ML/AI to build a model to alter the recipe and optimize batches on previously unknown relationships. By establishing a new process, the brewer eliminated lost batches associated with this quality issue and recaptured two weeks of extra capacity per lost batch.

TAKEAWAY:

The brewmasters applied Quality 4.0 analytics to traditional data and processes to drive quality improvement and new competencies.

Original Pale Ale ★★★★★

FAVORITE SAVE PRINT

INGREDIENTS FOR 1000 GALLONS

1000 lb. pale malt	200 oz. Amarillo hop pellets
250 lb. honey oats	200 oz. Citra hop pellets
40 lb. honey malt	dry hop after FG
40 oz. hop pellets 8%	
150 oz. Citra hop pellets 12%	

DIRECTIONS

Mash 1000 lb. pale 2-row malt with flaked and honey malts at 152° F for one hour.

Drain, rinse grains, and dissolve 50 lb. pale malt extract syrup into resulting wort.

Top off with reverse osmosis or distilled water to desired boil volume and proceed as above.



Original Pale Ale

<i>10 lbs. pale malt</i>	<i>Mash 3 lb. pale 2-row malt with flaked and honey malts at 152° F for one hour.</i>
<i>2.5 lb. honey oats</i>	
<i>half pound Malt</i>	<i>Drain, rinse grains, and dissolve 50 lb. pale malt extract syrup into resulting wort.</i>
<i>1 ounce. hop pellets</i>	
<i>half-ounce hops 8%</i>	<i>Top off with reverse osmosis or distilled water to desired boil volume and proceed as above.</i>
<i>2 lb. mashed malt</i>	
<i>dry hop after FG</i>	

USE CASE 2: Supplier Quality Management

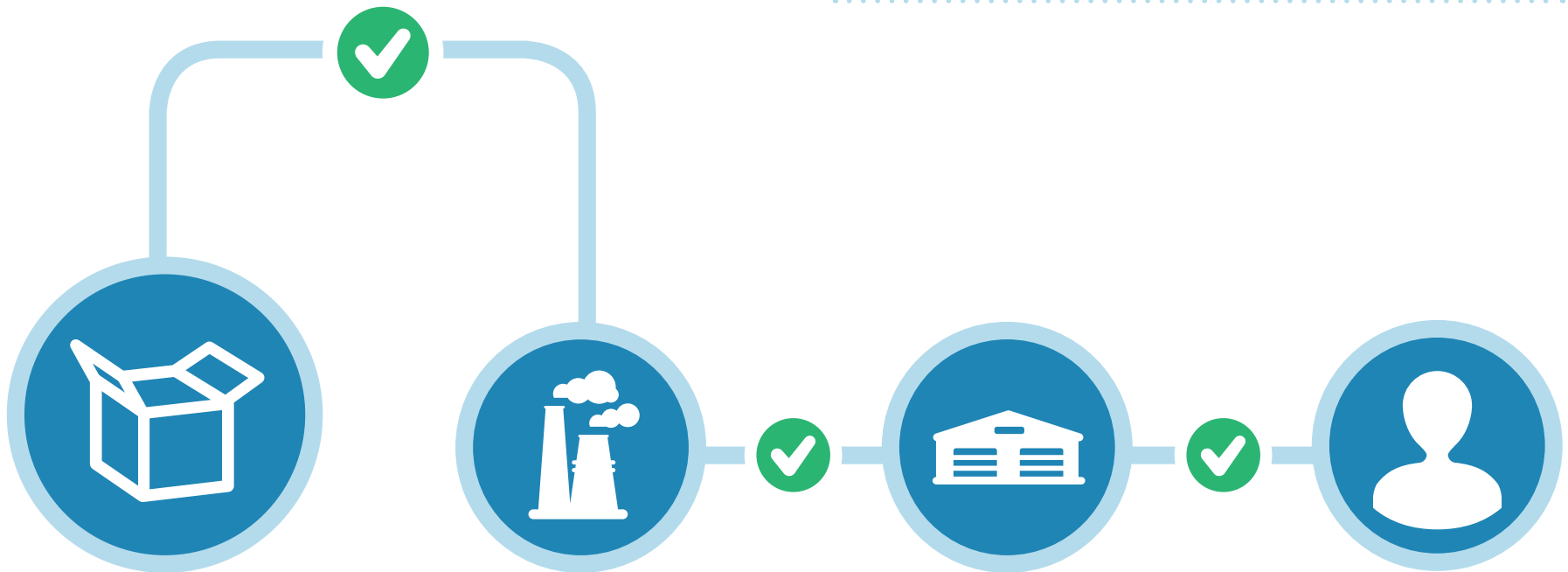
Supplier quality management (SQM) is a leading roadblock to achieving quality objectives. Suppliers continue to grow in importance as their percentage of end products grows, and quality teams have been working diligently to adopt mature SQM processes and technology.

One large contract manufacturer has a Digital Transformation strategy that encompasses manufacturing and it has deployed Cloud, big data and ML/AI to improve tracking of machine performance. Using the new approaches, the manufacturer can predict and remedy machine downtime and product quality issues before they happen. As a result, the company increased up yield and reduced manufacturing cycle time.

The company also expanded this approach to the supply chain to analyze data in its existing enterprise SQM technology and manufacturing execution systems with ML/AI. The ML/AI analyzes incoming inspection data, and in some cases data from final testing performed at supplier facilities. The contract manufacturer can now identify issues with their suppliers' manufacturing processes before suppliers do, which enhances non-conforming material process and impacts supplier risk profiles.

TAKEAWAY:

Quality 4.0 is a journey; there's value in a common data model and analytics, and Quality 4.0 has an impact on management system processes and culture.





SECTION 3

Understanding the 11 Axes of Quality 4.0

Data

Data-driven decisions have been at the heart of quality improvements for decades. Many recently updated standards re-emphasize the importance of evidence-based decision making. However, industry has a long way to go. As shown in the chart, much of the market continues to struggle with evidence while more mature companies have mastered traditional data and are now leveraging big data.

Real time visibility of quality metrics in...	Median adoption by innovation leaders	All others
Customer service	83%	43%
Supplier performance	69%	19%
Engineering	55%	17%
Manufacturing	52%	9%
Across all four areas	65%	22%

Let's break down what data is and how to think about it. Data has five important elements to consider:

VOLUME: Traditional systems have a large quantity of transactional records (e.g. corrective and preventive action (CAPA), quality events, etc.). However, the volume of data from connected devices is many orders greater, requiring special approaches such as data lakes.

VARIETY: Systems gather three types of data: structured, unstructured, and semi-structured. Structured data is highly organized (CAPAs, quality events). Unstructured data 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 is the rate at which a company gathers data. CAPAs are low velocity, while statistical process control (SPC) data is high velocity, and a global fleet of connected devices streaming data is even higher velocity.

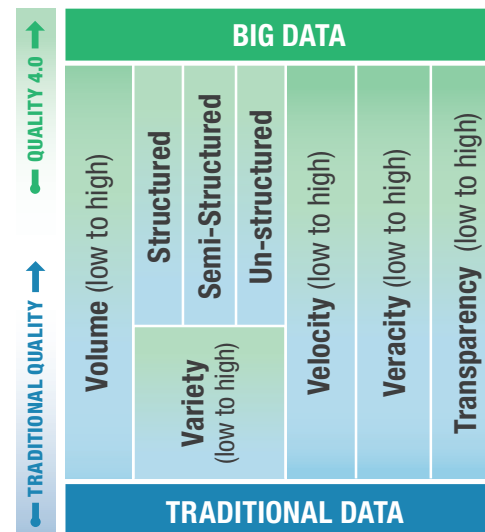
VERACITY: This refers to data accuracy. Quality system data is often low veracity due to fragmented systems and lack of automation.

TRANSPARENCY: Consider for a moment the ease of accessing and working with data no matter where it resides or what application created it. Leaders should work to develop a common data model to combine structured business system data like inventory transactions and financial transactions with structured operational system data like alarms, process pa-

In God we trust; all others bring data.

—W. Edwards Deming

rameters, and quality events, with unstructured internal and external data like customer, supplier, Web, and machine data to provide high veracity and transparency.



Analytics

Analytics unlock the insights captured within data. Today, analytics are often a stumbling block for quality – 37% of the market identifies poor metrics as a top roadblock to accomplishing quality objectives. As shown earlier, there is insufficient adoption of real-time metrics by most of the market.

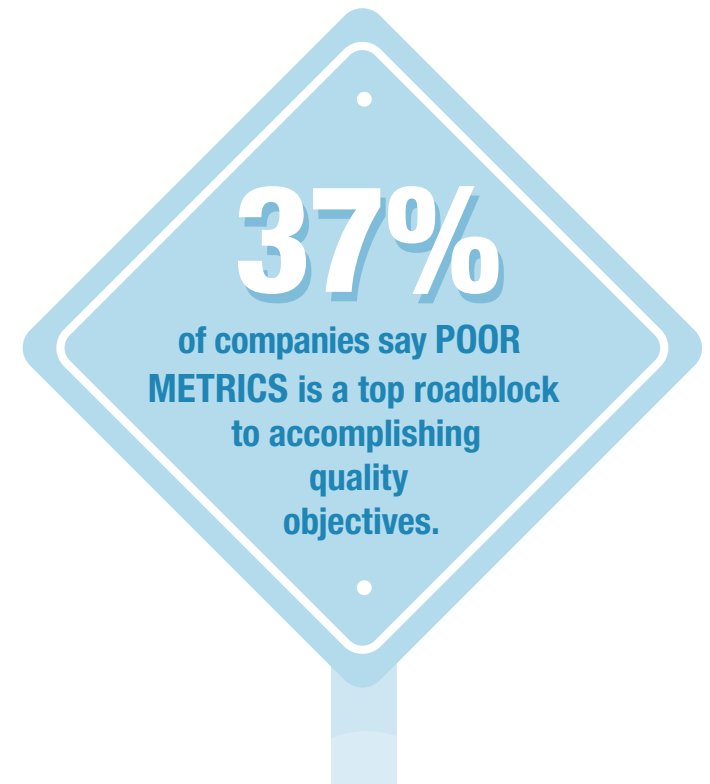
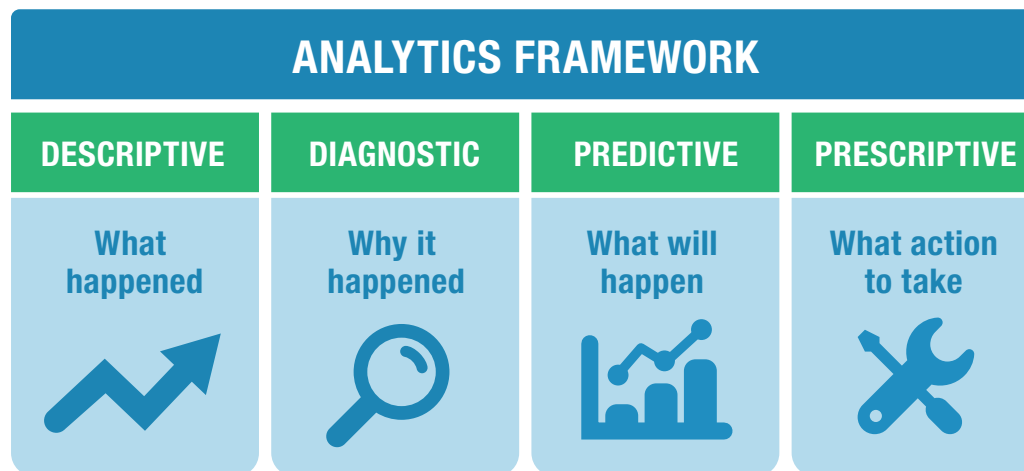
Analytics fall into four categories, maturing from left to right. Descriptive are the most traditional metrics to monitor known or suspected correlations. Quality generates descriptive metrics (number of open quality events), diagnostic metrics (quality process cycle times to identify bottlenecks), and predictive metrics such as trend analysis (application of trend rules to SPC data).

Companies can apply Big Data analytics, or ML/AI to traditional data or Big Data to determine correlations based on patterns in the data, which result in new insights. These insights are often much more specific than traditional analytics, such as predicting the failure of each specific machine. ML can identify, diagnose, and eventually predict a pattern that will result in a negative outcome such as prod-

uct or process failure. Prescriptive analytics are more advanced; they predict failure and specify what should be done to address or change the outcome, and usually include some level of autonomous behavior. Descriptive, Diagnostic and Predictive analytics are performed in traditional quality with traditional data, but new insights are realized with ML/AI. Prescriptive analytics are exclusively in the ML/AI domain.

Visualization has evolved right along with data, and enables more effective human interpretation. Traditional visualizations include reports, charts, and dashboards, where big data visualizations include mashup apps, which will be discussed in detail later.

Companies striving toward Quality 4.0 should build their analytics strategy *after or concurrently with a data strategy*. Powerful analytics applied to low veracity data yields poor veracity insights.



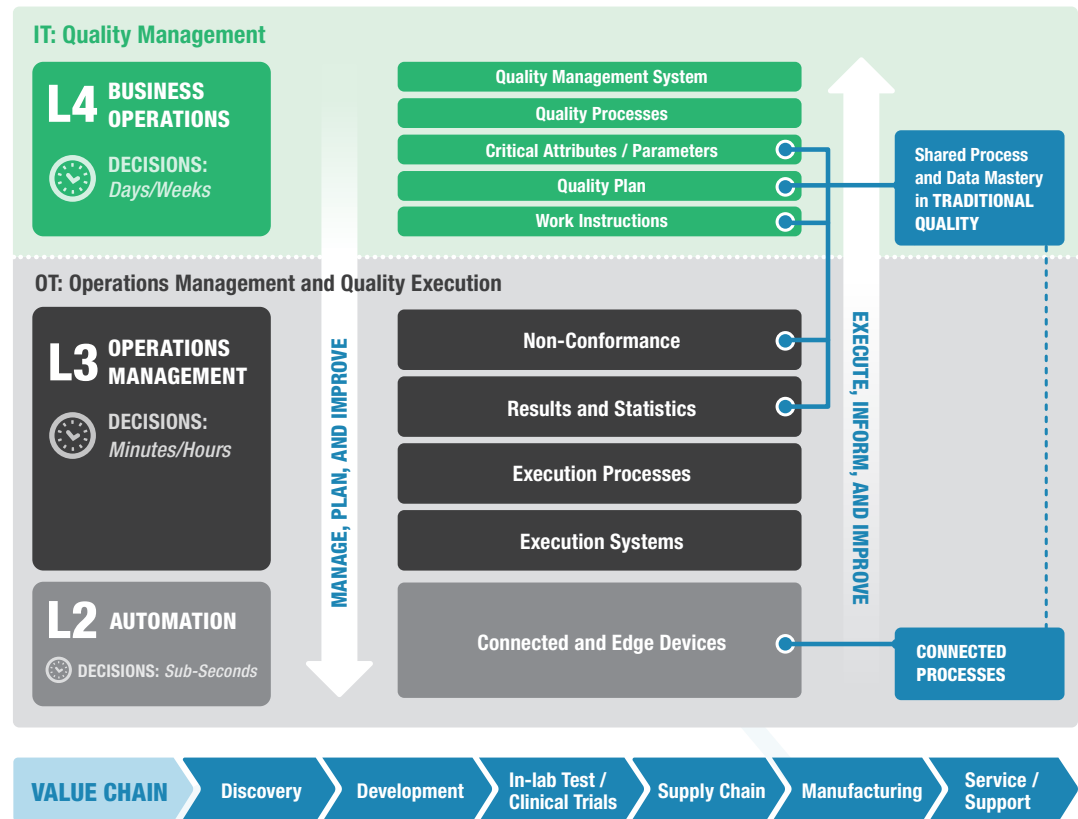
Connectivity

Broadly stated, “connectivity” is the connection between business information technology (IT) and operational technology (OT), where business technology includes the enterprise quality management system (EQMS), enterprise resource planning (ERP), and product lifecycle management (PLM), and OT is the technology used in laboratory, manufacturing, and service. Industry 4.0 transforms connectivity through a proliferation of inexpensive connected sensors that provide near real-time feedback from connected people, products and edge devices, and processes.

- **Connected people** can leverage personal smart devices or intelligent wearable devices that sense workers. Connected worker initiatives typically have goals of increased efficiency and safety.
- **Connected products** can provide feedback on their performance across their lifecycle. They can communicate use conditions, performance, and failure to perform.
- **Connected edge devices** efficiently connect sensed equipment. This approach helps to avoid overburdening central OT systems by streaming large volume of sensor data. In this way, edge devices often perform analytics at the device, make predictive/prescriptive decisions (shut this machine down, and come for repair), and decide which data to send to central OT systems.

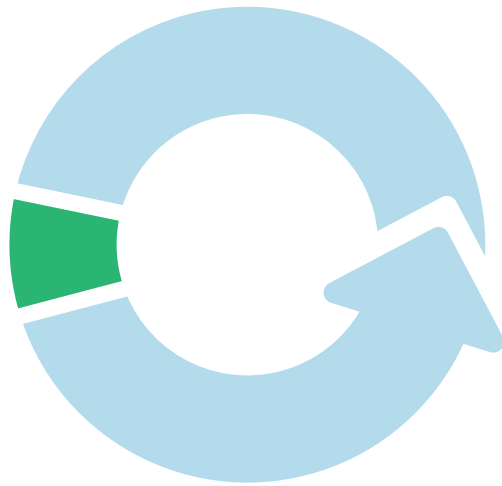
- **Connected processes** provide feedback from connected people, products, and equipment into processes. Important applications of these concepts include Connected Products, Connected Laboratories, Connected Supply Chain, Connected Operations, and the Connected Worker.

IT/OT CONVERGENCE EXPLAINED WITH ISA-95

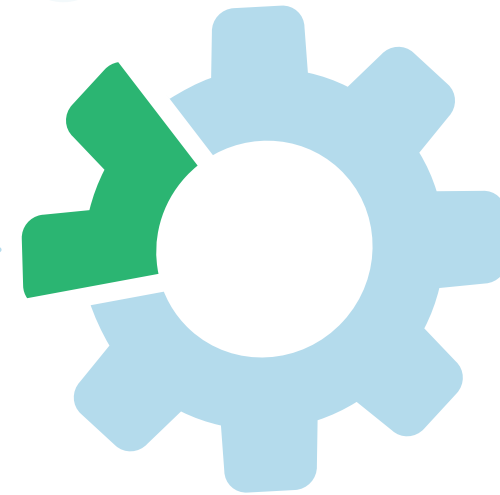


Connectivity (Cont.)

How does a leader leverage this information to maximum effect? Quality Management often sits in the IT domain, while Quality Execution is in the OT domain. The market has struggled to build an effective bridge between management and execution due to a divide between IT and OT. This gap results in challenges during design transfer and continuous improvement. Leaders should ensure that data, processes, and people work together to enable effective, data-driven, and bidirectional communication across the IT/OT divide.



Only 7% of the market (N=562) have automated design transfer, while the majority use spreadsheets and documents.



Those that have invested in EQMS technology have under-prioritized integration to operations; only 16% are connected to manufacturing operations (N=173).

Collaboration

Collaboration is critical for quality management, as quality is by nature cross-functional and global. Companies execute traditional quality business processes with the help of digital messaging (email), automated workflows, and portals. Much of the market has yet to take advantage of automated workflows and portals, and in fact, only 21% have adopted a core EQMS.

Collaboration has changed dramatically in recent years, within and across companies and with customers. Social media has enabled the public to directly weigh in on quality, which has increased the visibility of quality issues. Manufacturers have started to leverage social listening to protect brands and learn new insights, which in turn fuels innovation.

Social media has applications to improve competency and quality culture as well. Some technology providers have leveraged collective intelligence and lessons corporate-wide, and possibly industry-wide. Social enables manufacturers to create virtual Centers of Excellence with much broader participation.

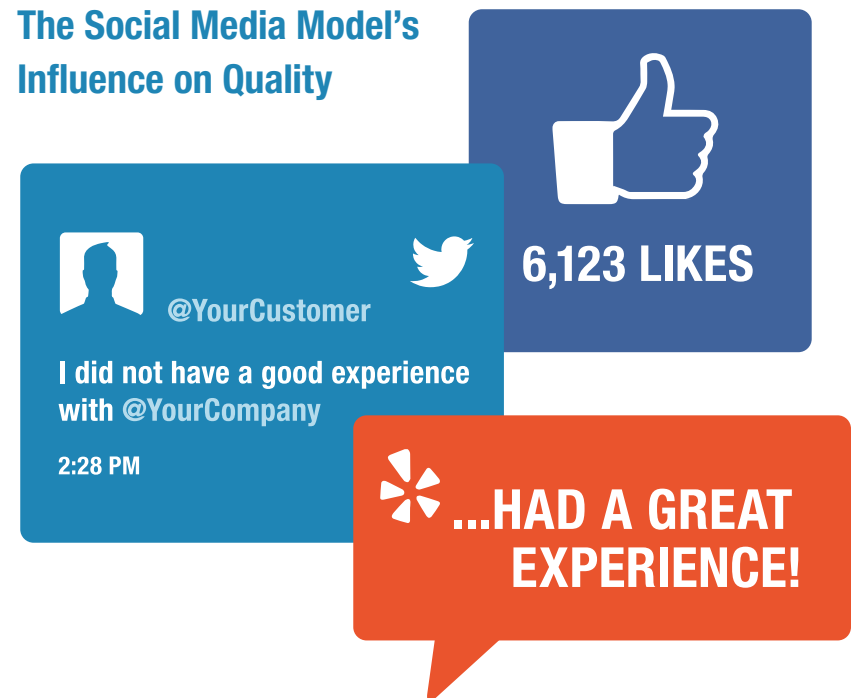
Blockchain is another transformative technology with future potential for quality, particularly in SQM and traceability. It is essentially a secure, public, distributed ledger. Each block is a record that contains a time stamp and linked to relevant blocks and data. Blockchain originated as financial technology but industrial companies are now trying it out. For example, the U.S. FDA hopes to drive innovation by securely connecting all digital records including social media to better understand the patient experience with health care and life science products. Third party groups are also using blockchain to ensure sustainable fishing by tracking fish source, processing, and sales history.

How does blockchain impact quality? Deep, versatile supply chains provide many quality challenges. One challenge is pass-through

characteristics or those attributes that should be tested at lower levels of the supply chain and cannot be economically revalidated. Block has the potential to connect those tests to provide visibility to quality tests through the chain. Traceability is another challenge, especially in a recall scenario. Blockchain has the potential to address questions like, “Where did this part come from; who touched it along the supply and demand chain, and where is it now?”

Collaboration is powerful fuel for innovation and quality improvement, and has been profoundly transformed by connectivity, data, and analytics. Leaders should consider how they collaborate and build a secure and reproducible data sharing strategy that meets objectives such as better competency, more streamlined oversight, improved security, and audit-ability.

The Social Media Model's Influence on Quality



App Development

App development is something everyone can relate to – there are apps for everything. Apps are the mechanisms through which companies fulfill processes, collect and expose data, visualize analytics, and establish collaboration.

Traditional quality apps are most commonly web-based, and nearly all of them have been optimized for mobile, although it usually requires a large mobile device such as a tablet. As software has become more powerful, the trend has been to develop role-based apps for a better, simpler experience through multiple interfaces divided by role.

Technology providers are increasingly providing native mobile apps downloadable on Android, iOS, and possibly other platforms, to provide a higher quality experience that works on smartphones. Mobile app platforms extend this still further by allowing companies to create and publish apps themselves. Mobility provides greater accessibility, participation, adoption, and efficiency. While we often connect the idea of mobile apps with smartphones and other mobile devices, companies can write apps for a wide array of hardware.



MOBILITY AND INTERACTIVE APPS FUEL QUALITY MANAGEMENT

WEARABLES are devices that sense and connect human performance. Widely used by consumers (e.g. Fitbit™), wearables also are applied in industrial settings to improve safety and efficiency.

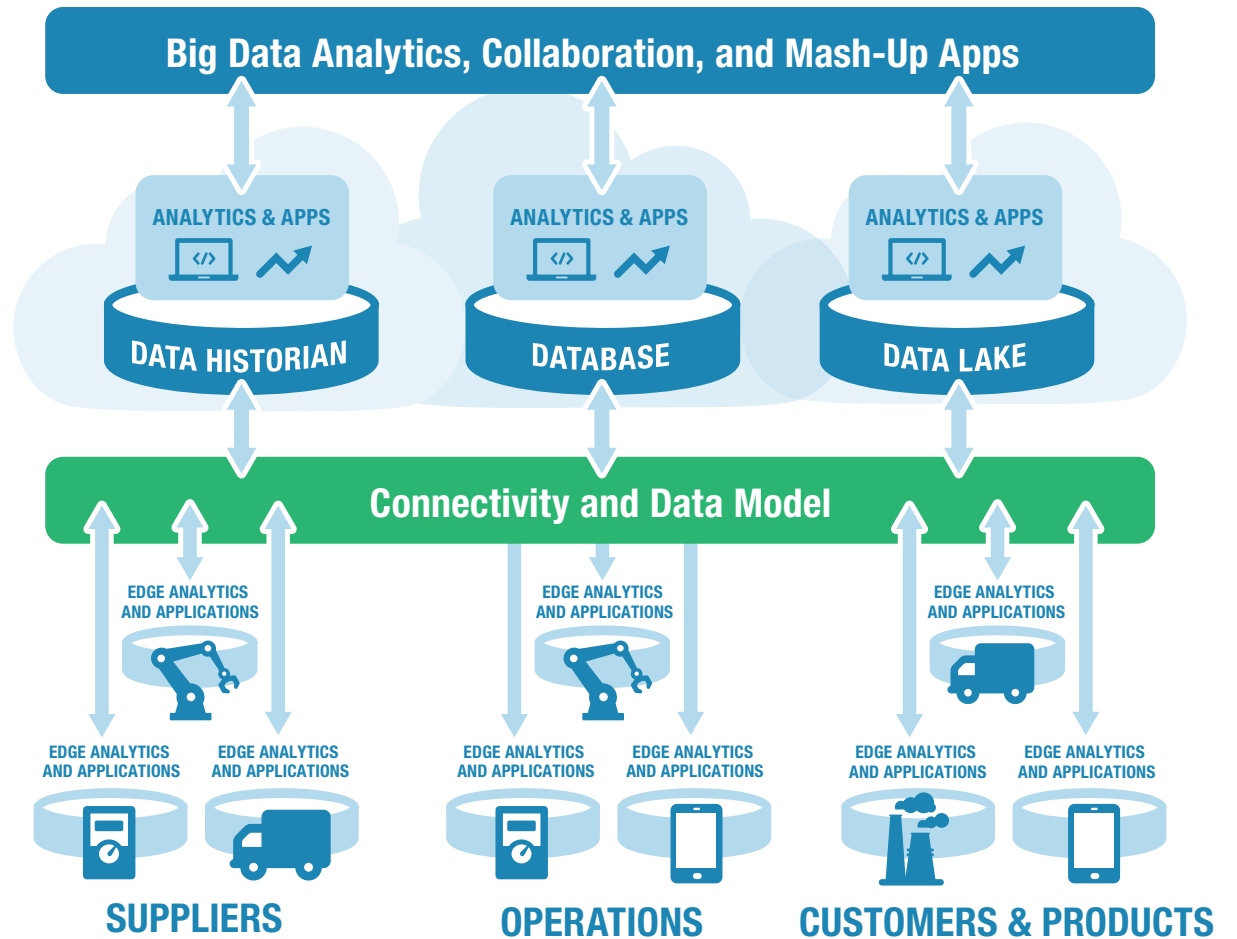
AUGMENTED REALITY (AR) is an overlay of virtual content on physical assets or surroundings. This has many applications in operations, allowing workers to “see” machines earmarked as predicted to fail soon and how to fix them, or the same with product.

VIRTUAL REALITY (VR) simulates the real world and offers value for operations and management. It can be used to improve competency and reduce risk by simulating operations prior to executing in the physical world. Recently, companies have launched mashup apps that combine content (video, weather, text, schedules, etc.) from multiple sources into a single view and interface. This trend is important for quality, which touches all facets of management and operations, and will include data streams from multiple sources.



App Development (Cont.)

Apps can be much more than a simple web-based User Interface (UI) – they play an important role in the delivery of intelligence, participation, and adoption. As apps advance in terms of presenting relevant content to the user, where the user is, and in context with the world around him or her, they become increasingly powerful enablers of collaboration, competency, and efficiency.



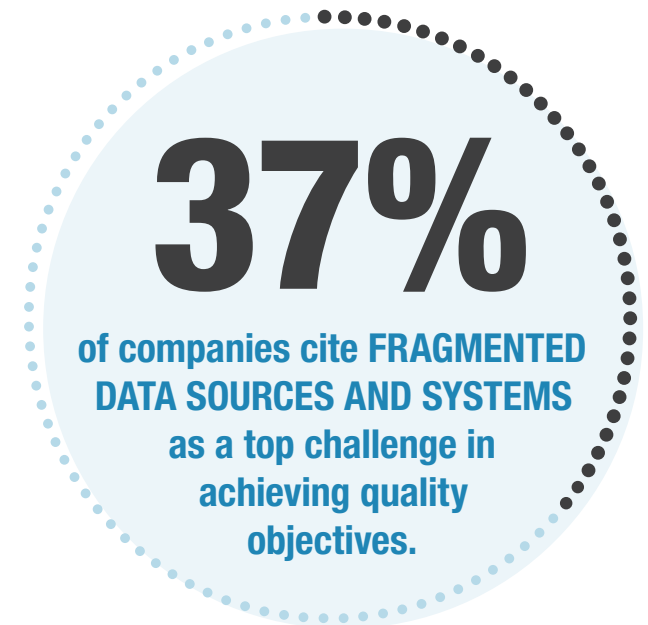
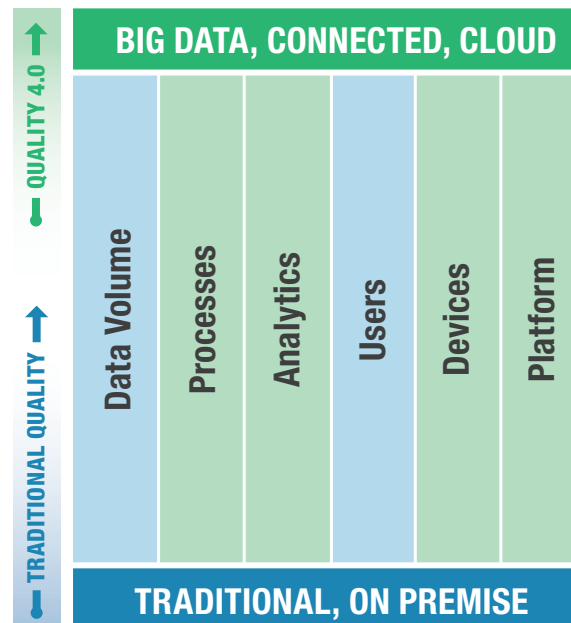
Scalability

Scalability is the ability to support data volume, users, devices, and analytics on a global scale. Without global scale, traditional quality and Quality 4.0 are much less effective, unable to harmonize processes, best practices, competencies, and lessons learned corporate-wide. Thirty-seven percent of companies struggle with fragmented data sources and systems as a top challenge in achieving quality objectives. Cloud computing is an important contributor to scalability. Through Cloud, manufacturers can acquire Software as a Service (SaaS), easily adding capabilities and users, data, analytics, and devices without the need to acquire, install, and manage the software on premise. Cloud also provides Infrastructure as a Service (IaaS) by enabling globally accessible and high availability (high uptime) solutions. Some providers deliver a Platform as a Solution (PaaS), providing the core software plus an extended ecosystem of partners that all connect to enrich the core software.

Data scalability is also important, particularly with connected devices. Data lake technologies have been developed to support the voluminous data sets inherent with connected devices and Big

Data. These non-traditional databases enable storage and correlation across many disparate types of data.

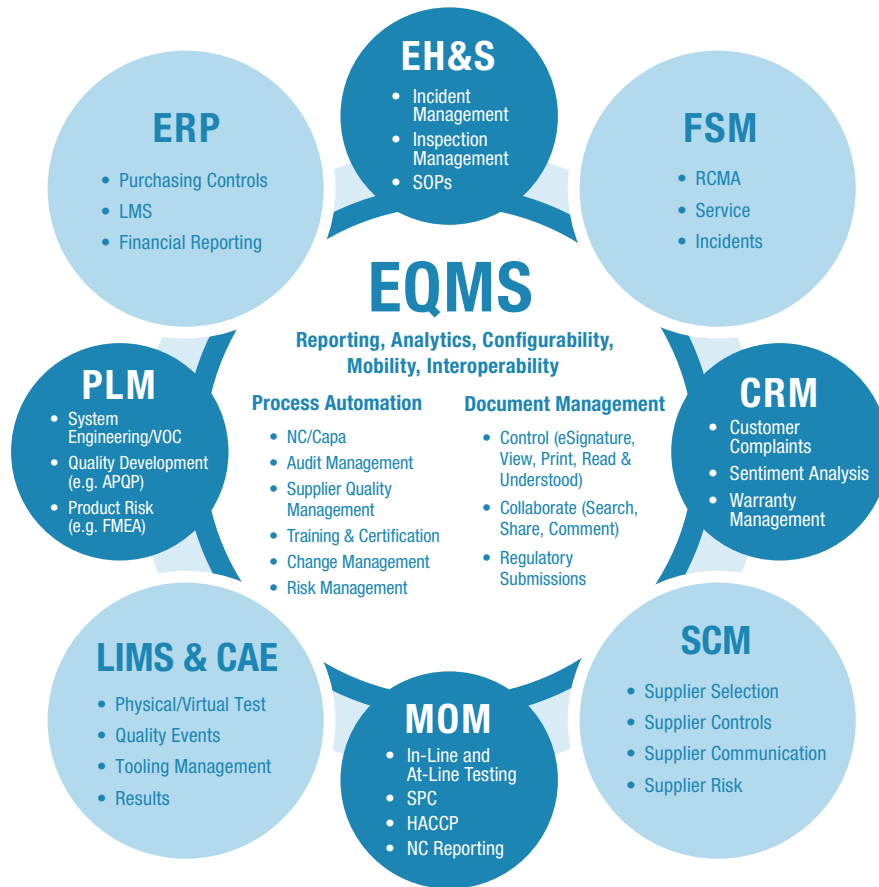
Scalability is critical when industrializing solutions. Assess the current scalability of in-house systems, and be sure to consider both global reach and data complexity when deploying either traditional quality or Quality 4.0.



Management Systems

The EQMS is the hub of quality management activities, providing a scalable solution to automate workflows, connect quality processes, improve data veracity, provide centralized analytics, ensure compliance, and foster collaboration within a common app. It is a hub because quality touches every part of the value chain and how it's managed.

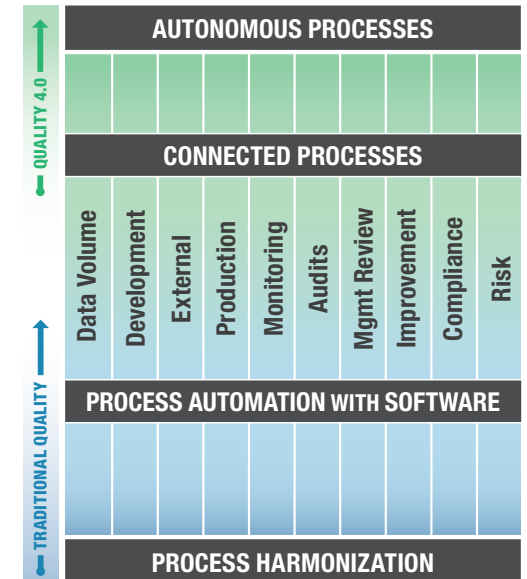
The market has made some progress on EQMS adoption, but many are still critically lagging. Even those that adopt EQMS have not adopted it in an integrated fashion. In fact, only 21% of the market has adopted EQMS, and of those, 41% have adopted a standalone unintegrated approach.



7% OF MANUFACTURERS plan to connect EQMS to Industry 4.0 technologies.

Companies delay adopting quality technology partially because of fragmented core processes – it is challenging to adopt technology to automate fragmented processes. For instance, while CAPA/non-conformance is globally harmonized at 25% of manufacturers globally, 36% of manufacturers have not harmonized any processes, and the median harmonization rate of a single process is merely 8%. Consistency is critical in order to improve global results and competencies.

Manufacturers should harmonize processes, automate these processes with software, connect automated processes to other systems and operations, and leverage collective analytics and learnings to continuously improve system autonomy. This approach shifts the focus of high-value staff away from the mechanics of execution and toward innovation and improvement.



Compliance

Compliance activities include conforming to regulatory, industry, customer, and internal requirements. Life science manufacturers have a particularly heavy compliance burden. However, compliance is important to quality teams across industry since quality often takes a lead role in ensuring that processes, products, and services conform with requirements. Manufacturers already leverage technology to reduce the cost and effort to comply. Technology to aid in compliance has evolved by platform and process area. Early compliance technology required substantial custom code to address requirements. While compliant, custom code was difficult to upgrade and revalidate. This has often resulted in "version lock", a scenario where companies postpone upgrades by many years to avoid the cost and effort of migrating and revalidating code and data.

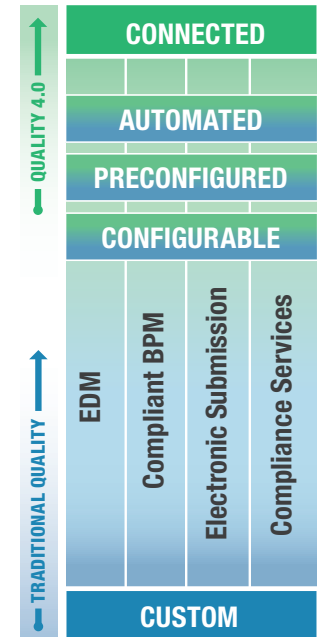
Technology providers have worked to improve flexibility and reduce the cost and effort associated with initial deployments and future upgrades. The first step in the market was to greatly expand configurability, and therefore nearly eliminate the need to customize. More recently, technology providers invested in building robust

pre-configurations to common processes (CAPA, eight disciplines (8D), non-conformance, etc.). These now require much less configuration to deploy, improving time to value. Pre-configuration scope continues to expand. Technology providers have tools to automate life science validation and reduce the effort required to execute performance qualification (PQ).

Quality 4.0 introduces even more opportunities to automate compliance. Social collaboration provides a mechanism to share successful and failed approaches to compliance across groups, sites, and regions. Analytics can be used to alert organizations to potential compliance breaches or act to prevent the breaches. Integrated IT/OT data models and/or collaboration technologies like blockchain can provide a data-driven approach that automates audit-ability.

Today's technology plays an important role in compliance management, reducing compliance burden and risk, which will continue to expand with the proliferation of Quality 4.0. Manufacturers should re-assess their current compliance strategy and identify improvement opportunities.

Top Strategic Objective for Quality Management



Culture

Many leaders have an initiative to develop a culture of quality, since quality often owns process execution with insufficient participation and ownership from other functions. A company that has "a culture of quality" exhibits four key elements: process participation, responsibility, credibility, and empowerment. Traditionally, companies set goals for cross-functional process participation, cross-functional responsibility for quality, credibility for quality and its work across functions, and cross-functional empowerment. Empowerment is competency to perform quality plus ownership of quality success. This is quite difficult to accomplish in traditional settings, in part due to regulatory burden, poor metrics and metric visibility, fragmented data systems and sources, and fragmented processes. Quality can seem like a labyrinth to outsiders; more like a policing engine than a vehicle for improvement and performance. Only 13% of cross-functional teams clearly understand how quality contributes to strate-

gic success. Quality 4.0 makes a culture of quality more attainable through better connectivity, visibility, insights, and collaboration. Connected data, processes, analytics, apps, etc., improve the culture of quality through shared/connected information, insights, and collaboration. Quality 4.0 makes quality processes and outcomes more visible, connected, and relevant.



36% OF COMPANIES
cite a lack of culture of quality
as a top challenge to achieve
quality objectives.



ONLY 13%
of cross-functional teams
clearly understand how quality
contributes to strategic success.



Leadership

The quality function has an image and credibility gap with the rest of the organization. In part, this is because quality is seen as a department, as the quality police, and as a group with unclear alignment to corporate success. Conversely, leaders in many other functions are planning to use Industry 4.0 technologies to drive quality improvement. Quality *improvement* is clearly interesting to many, and *quality* is often a corporate value, but the work that the quality function does isn't clearly connected to quality improvement or the corporate value by other functions and top management.

This gap starts with objectives. The quality team must realign its objectives and initiatives so that they clearly link to strategic objectives.

Objectives guide which initiatives receive attention and resources, and initiatives drive actions. An organization with compliance-related objectives and initiatives will prioritize compliance-related practices, whereas an organization with performance initiatives will prioritize performance-related practices. By resetting objectives, the quality team repositions its value proposition to other functions and top management. In fact, 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. Quality leaders should lead quality across the organization, with increasingly broad ownership by cross-functional

ONLY 13% of companies say **QUALITY IS A PRIORITY FOR TOP MANAGEMENT.**

ONLY 37% say that **QUALITY IS CRITICAL FOR CUSTOMER SATISFACTION.**

ONLY 26% say that **THE QUALITY FUNCTION HAS A CLEAR AND COMPELLING ROLE** in delivering corporate strategy.



Leadership (Cont.)

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 4.0 technology. In many ways, this is a positive shift and one that quality leadership should support, reinforce, and lead, to improve outcomes.



Manufacturers with Compliance Objectives

Best practice	Increased likelihood of adoption
Automated Risk Management with software	33%
Supplier quality data collected automatically through web-based portal	21%
Automated Chance Management with software	21%
Automated Compliance Management with software	20%
Automated Employee Training with software	18%

Manufacturers with Performance Objectives

Best practice	Increased likelihood of adoption
Automated Quality Product Realization processes with software	164%
Automated Statistical Process Control (SPC) with software	126%
Automated Supplier Quality Management with software	77%
Real-time visibility of quality metrics in manufacturing	42%
Real-time visibility of quality metrics in supplier performance	40%

Competency

Competence is an individual’s ability to complete a task effectively and efficiently. Organizations have battled to improve the baseline competency of personnel, and to scale specialized knowledge. The least mature organizations rely on individuals to share knowledge among themselves.

Many have deployed structured approaches, which include Learning Management Systems to train competencies, assess competency through certification and Training Management, scale experience through centralized groups such as centers of practice/centers of excellence, and develop expertise. Quality leaders looking to improve upon the structured approach of traditional quality can use several Quality 4.0 approaches:

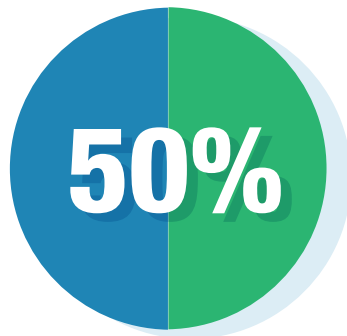
EXPERIENCE: Leverage social media to share experiences and lessons learned across internal groups, or even across industry.

EXPERTISE: Develop new expertise through learnings from ML/AI. Leverage mashup apps and AR/VR to improve the expertise of workers.

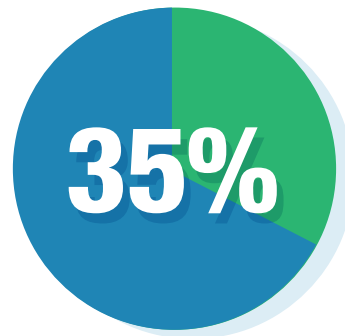
APPRAISAL: Deploy connected worker strategies to sense worker actions, ensuring compliance, competency, efficiency, and safety.

MANAGEMENT: Encapsulate these learnings in Learning Management Systems, and provide VR experiences to improve training delivery.

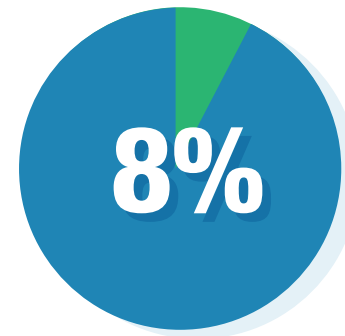
Workers and their skills are critical to the success of business. In fact, three of Deming’s 14 points directly relate to training (#6, #13, #14). While competency may not be top of mind in Quality 4.0 initiatives, it could be the most powerful improvement resulting from Quality 4.0.



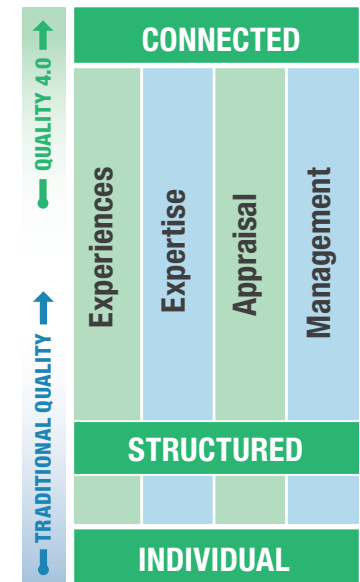
of companies say that **EMPLOYEE TRAINING** is one of the most critical process areas in their enterprise.



of companies have **AUTOMATED TRAINING MANAGEMENT** with software.



of companies have **HARMONIZED TRAINING MANAGEMENT** across the company.



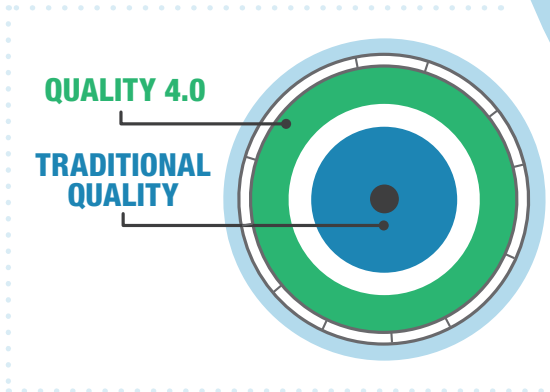
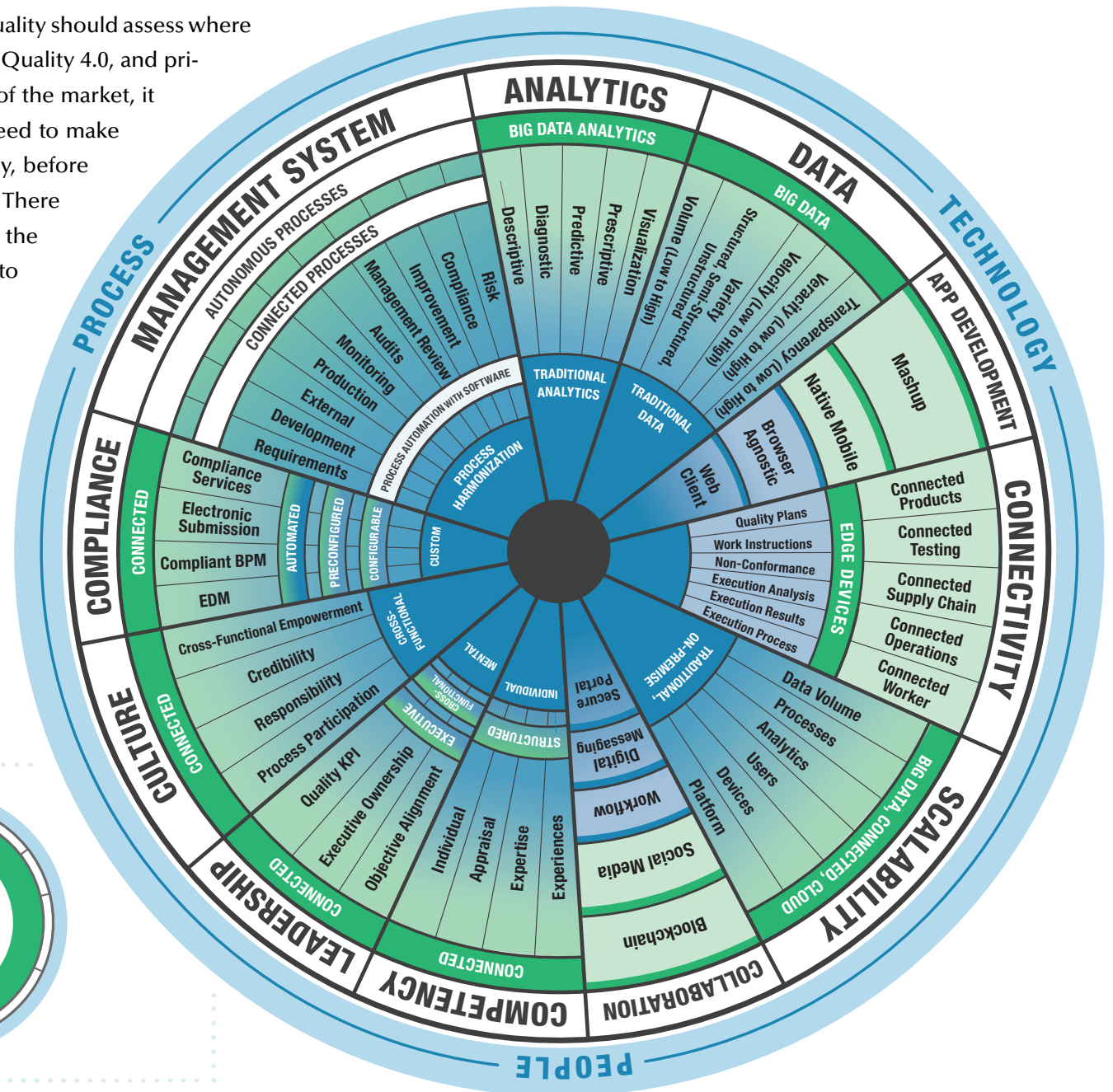


SECTION 4

Summary and Recommendations

Quality 4.0: A Big Picture View

Manufacturers looking to improve quality should assess where they stand on each of the 11 axes of Quality 4.0, and prioritize investments. Given the state of the market, it is likely that many companies will need to make investments first in traditional quality, before they can fully leverage Quality 4.0. There are clearly interrelationships among the axes, and adding new capabilities to certain axes enables new applications on other axes.



Recommendations

Quality 4.0 is the digitalization of quality leveraging the technologies of Quality 4.0. People and processes are important to all areas of business but are particularly key to quality. Therefore, while Quality 4.0 makes critical new technologies affordable and accessible to the broad market, its story is really about the application of these technologies to solve long-standing quality challenges and to re-optimize to provide novel solutions. Quality 4.0 is real, gaining momentum, and a technological gift to quality. Quality leaders should prioritize Quality 4.0 plans; those that stay on the sideline are at risk of being marginalized.

- 1. Given the current state of the market**, manufacturers should assess quality maturity, and if necessary improve traditional quality capabilities to fully leverage Quality 4.0. Those that do will differentiate themselves in performance, whereas those that do not run the risk of being inundated with data or drawing erroneous conclusions based on poor data veracity.
- 2. Recognize the reality and powerful potential of Quality 4.0** on enterprise performance. Companies have already deployed Quality 4.0 analytics, apps, data, and connectivity strategies, and are realizing benefits and achieving differentiation.
- 3. Many manufacturers already have a Digital Transformation strategy** and are already acting on it. Quality leaders should immediately determine if this strategy exists in their organization and interpret the company's approach using the information in this ebook. The next step is to align quality objectives around those strategies, and develop, communicate, and gain support for supporting initiatives. Structure quality initiatives to improve traditional quality and to deploy Quality 4.0.

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