
2021 Quality Management Trends Report

For Consumer Goods,
Chemical, Food & Beverage
and Cosmetics Companies

veeva

ENGINE
INSIGHTS



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Introduction

Quality management responsibilities and expectations are continually increasing. Quality professionals must keep up with changes to ensure they are delivering as much value to their organization as possible. Knowing how to prioritize initiatives and investments isn't easy, since determining return on investment (ROI) isn't straightforward.

To help quality professionals understand how their processes and approaches compare to those of other companies and the future outlook, ENGINE interviewed quality and environmental health and safety (EHS) professionals to develop the present "2021 Quality Management Trends Report," commissioned by Veeva.

We conducted an online, quantitative survey of 260 professionals in January 2021. We recruited participants in the US and Canada from consumer products and chemical (CP&C) companies that make products via process manufacturing. To qualify, respondents must play a role in ensuring quality and/or EHS. Additionally,

we conducted 12 qualitative phone interviews in North America and Europe with similarly qualified participants.

THE RESEARCH WAS DESIGNED TO PROVIDE AN UNDERSTANDING OF:

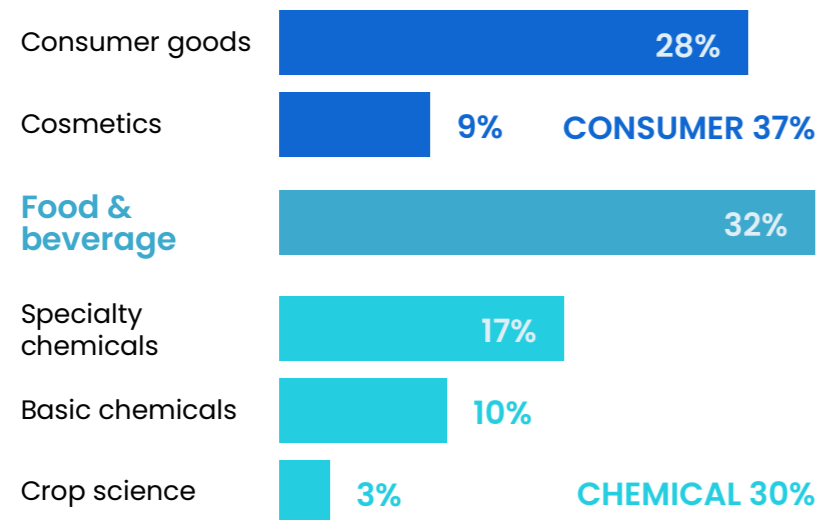
- ▶ The current state of quality management, including practices and maturity.
- ▶ The challenges to advancing maturity that quality professionals face.
- ▶ How quality professionals are addressing those challenges and where companies are investing.

In this research we learned that becoming fully mature in managing quality by making full use of a global Quality Management Software (QMS) drives efficiency and effectiveness, which ultimately means investments in QMS deliver ROI.

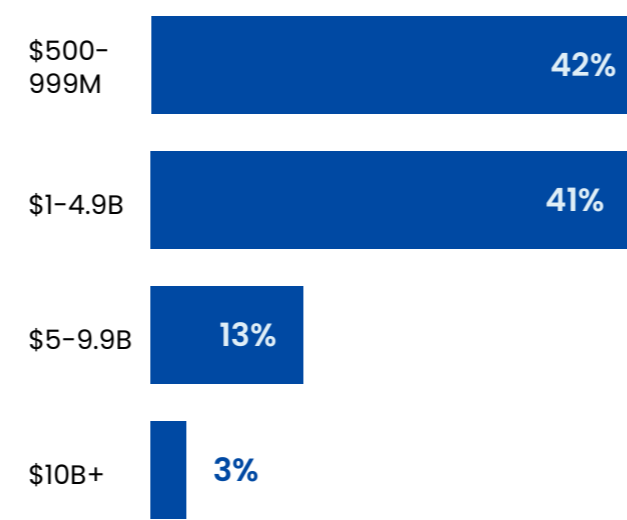


Survey Respondent Profile

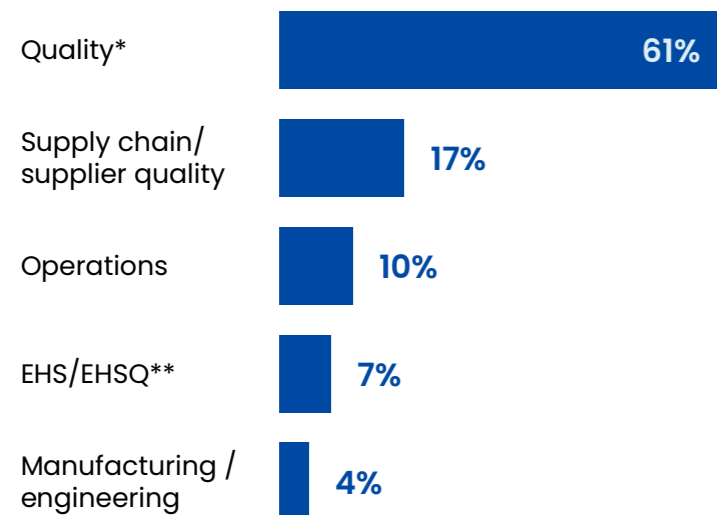
Industry



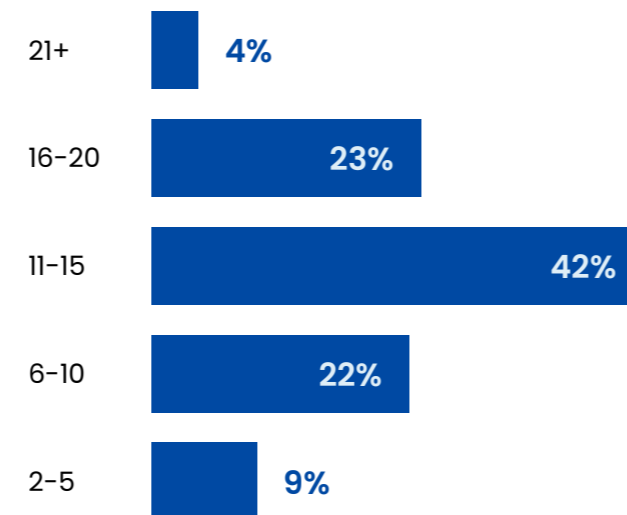
Company revenue



Job Function



Years of Experience



*Quality management / control / systems / assurance
 ** EHSQ is EHS & Quality

Executive Summary

- ▶ **Quality & EHS are converging.** Quality professionals are often responsible for EHS, as well as quality. Consumer products and chemical (CP&C) companies typically have separate tools for quality and EHS, but professionals want a single solution that handles both.
- ▶ **Quality management is maturing as companies seek greater efficiency and effectiveness.** CP&C companies are well along the path to maturity in managing quality. Quality management maturity means using a QMS globally across the organization, shared data that provides a single source of truth, automated processes, common workflows, transparency internally and across the supply chain, accountability, and a systematic way to identify and exploit opportunities. Although quality management is relatively mature, there is room for companies to mature further.
- ▶ **Companies are taking a hybrid approach, primarily using a cloud QMS to manage quality** but still relying on business tools such as spreadsheets and shared drives. Companies use quality/EHS software for numerous processes, most notably supplier management and spec management.
- ▶ **Technology improves quality outcomes** and is having a major impact on quality management practices. The most significant impact is improved quality driven by process automation which reduces human error. QMS delivers process efficiency gains through automation and continuous improvement, as well as visibility across the organization of all processes, documents, etc.
- ▶ **Quality professionals have many, interconnected challenges related to processes, data and people.** The most common challenges are having a global document repository and an easy-to-use QMS that delivers process efficiency and effectiveness. A centralized document repository can organize vast amounts of documents and provide transparency. Ideally, an easy-to-use eQMS system enables a culture of quality, overcoming resistance to change. Supplier management, followed by product recalls and their associated costs, are top challenges related to regulations, standards and industry expectations. Decentralized and legacy processes lead to challenges managing suppliers, as does decentralized data.
- ▶ **The pandemic has increased the urgency to manage risk and move forward with digital transformation.** Additionally, the pandemic has made adding headcount less important. There may be opportunities for companies to move funds budgeted for headcount toward digital transformation and QMS. Remote auditing has become increasingly important due to the pandemic.
- ▶ **Companies are investing in digital transformation and cloud-based QMS.** These investments will alleviate a range of challenges, especially those related to supplier management. Companies require a QMS solution with a supplier portal that handles documents, audits, and supplier scoring. Other top investment priorities for 2021 are data analytics visualization tools and automation.
- ▶ **ROI is understood, but hard to quantify.** Measuring QMS return on investment is challenging because many metrics are difficult to quantify, especially when talking about cost avoidance vs cost savings. Due to this challenge, many do not have any formal or informal processes in place to measure their QMS ROI. Despite these challenges, quality professionals believe investment in a QMS is the right decision.

KEY TAKEAWAY:

Becoming fully mature in managing quality by making full use of a global QMS drives cost savings and improved customer outcomes, which ultimately means investments in QMS **deliver ROI.**

Current Practices



Quality plays a key role in an organization's overall strategic and business objectives.

Almost all in-depth interview participants confirmed that quality plays a key role in an organization's overall strategic and business objectives and quality's role continues to expand, driven by consumer safety considerations. A few felt their current role should be bigger, although their organizations are moving in the right direction, giving quality "a seat at the table." Quality is becoming more fully integrated with other departments and garnering the same level of importance.

"Quality is pervasive within the company... Quality in the sense of 'how does the consumer see it?' is what really matters... We like to have high value products for consumers, and quality is a key part of making that happen... **We're right there next to the manufacturing and engineering and research and development with an equal partnership at the table.**"

– Consumer Goods, Quality Assurance

"We feel like we produce the best chemical line in the entire industry... **Quality has a seat at the table**, and what I mean by that is: it's just as important as funding, it's just as important as inventory... **It's paramount.**"

– Chemicals, Quality Control

"Quality is a **license to operate**. Without us, it doesn't exist."

– Consumer Goods, Quality Assurance

Quality plays a key role in an organization's overall strategic and business objectives.

We are continuing to work to increase the relative importance of quality and quality management across the corporation. We've made important strides in the last five to ten years, especially in quality management, as contrasted with product quality. This means utilizing and better approaching quality management to ensure not only product quality but process efficiencies to be faster, support innovation, etc. At Thanksgiving, you have the kids' table and you have the parents' table. We used to be in the kids' table, and now we have the seat at the parents' table. The question is 'do we also have the voice?' It's a work in progress.

– *Consumer Goods, Quality Management*

Key reasons mentioned for quality's strategic importance include:

- ▶ Consumer safety
- ▶ Product compliance
- ▶ Customer experience
- ▶ Quality is needed to release a new product or enter new market
- ▶ Quality is a "license to operate"
- ▶ Consumer insight / voice of the customer drives innovation
- ▶ Enabler of best-in-class products

Quality and EHS are converging.

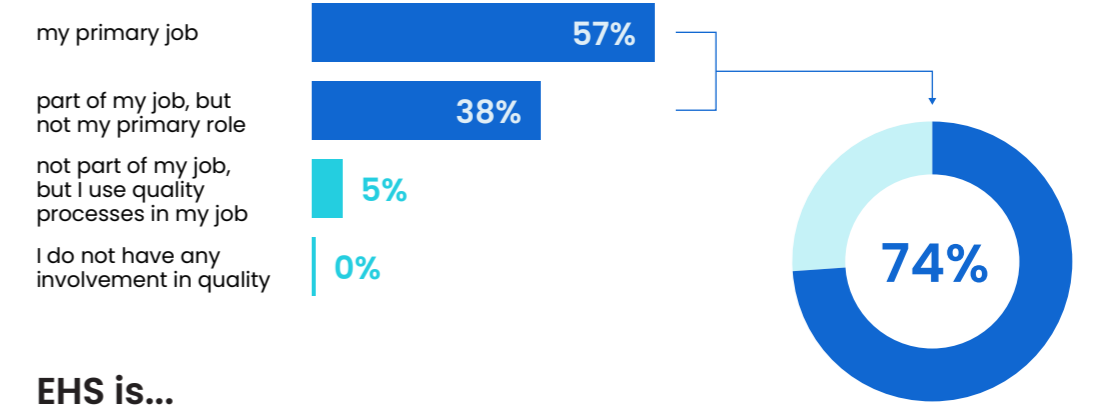
Most survey respondents have a role in both quality and EHS. Having a dual quality and EHS role is most common among food & beverage companies (81%), followed by consumer goods companies (76%), followed by chemical companies (63%). Typically, quality and EHS solutions are separate tools that work together, but professionals would prefer they were both in a single solution.

What is your role in ensuring quality at your company? What is your role in ensuring environmental health and safety (EHS) at your company?
 Base: Total (n=260)

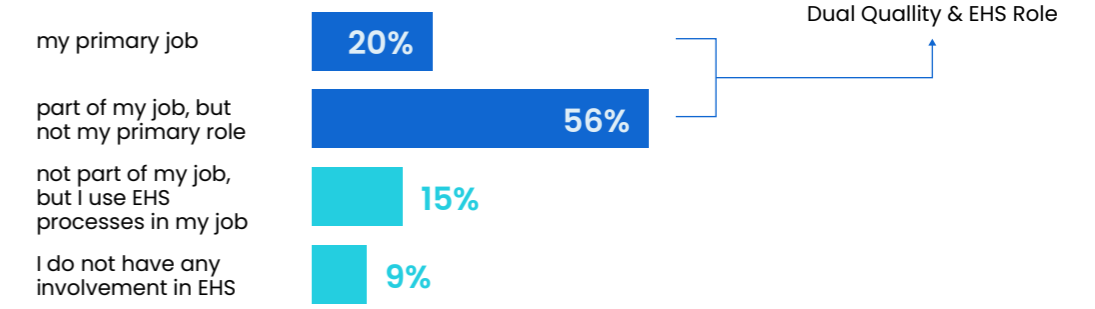
How are the EHS and quality solutions/tools you use integrated? Q40. What are your preferences for integrated EHS and quality solutions?
 Base: Use EHS Solutions/Tools (n=179)

Quality & EHS Roles

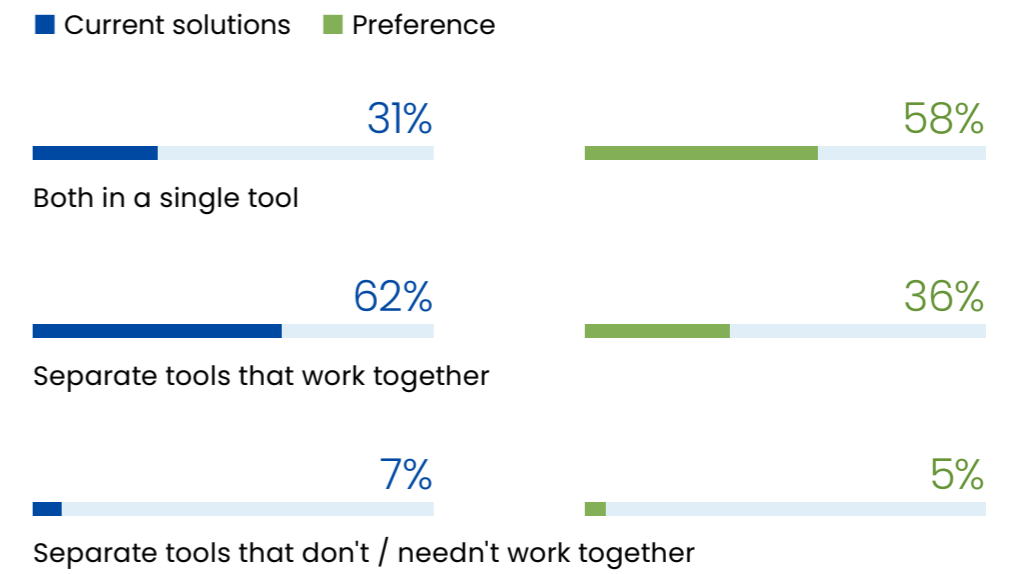
Quality is...



EHS is...



EHS & Quality Solution Integration



KEY TAKEAWAY:

Quality and EHS are **converging**.
Most quality professionals also have an EHS role and therefore want a single software solution that handles both quality and EHS.

Quality management maturity means much more than using a QMS.

Quality management maturity means using tools globally across the organization, but it also means shared data that provides a single source of truth, automated processes, common workflows, transparency, accountability, and a systematic way to identify and exploit opportunities. Thus, whether and how a company uses a QMS is not the sole determinant of how a quality professional rates their maturity.

“For us, organizational quality management maturity means **‘Automation of Quality Processes.’** Getting to the next level of maturity would be defined as **‘Automatic Quality.’**”

– Consumer Goods, Quality Assurance

We have a mixture of old local systems. Depending on the site, part of it or all of it may be under the global system. My first role is to harmonize for all sites and all processes.

– Specialty Chemicals, Quality Management



Many companies are well along the path to quality management maturity.

Maturation will continue. There is room for many companies to mature further and most quality professionals expect they will do so. For example, companies are making solutions and processes consistent throughout the organization, enhancing transparency across the supply chain, and automating processes to reduce human error.

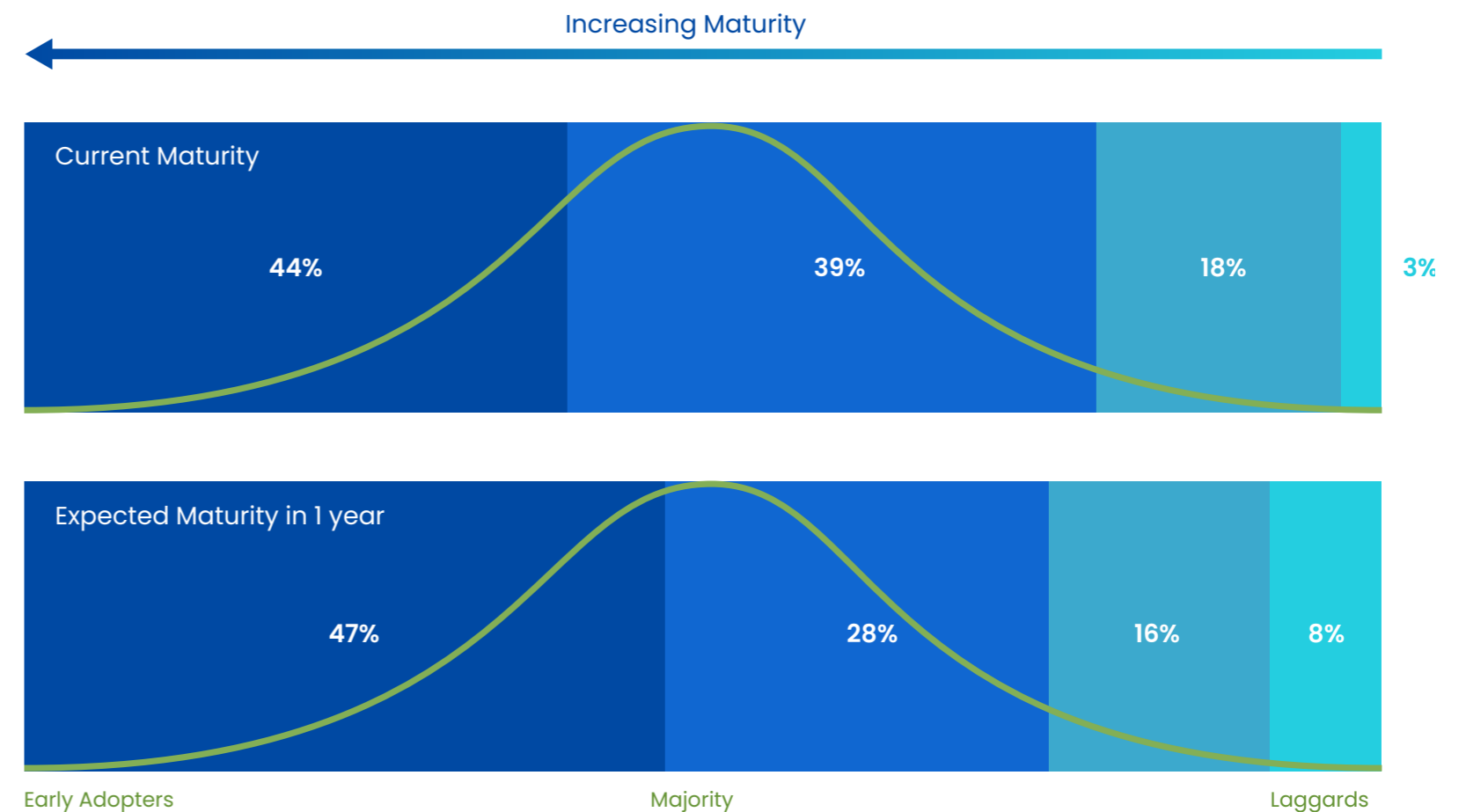
Quality Management Maturity

Fully Mature. Common global cloud eQMS across all sites. Decentralized processes. Work completed across HQ, regional sites, affiliate sites. Processes defined & driven through system workflows, automated where possible. Established KPIs. Reliable data quality and metrics.

Reaching Maturity. Common eQMS across most/all products. HQ/regional control of quality processes. Work or data requests delegated to affiliates. Basic workflows drive processes, document control, training.

Starting to Mature. Processes via email and spreadsheets. Information in local shared drives. Duplicate quality data exists. Siloed systems.

Immature. Manual processes via email and spreadsheets. Records and documents not well controlled.



Which best describes the maturity of quality management in your organization? What do you expect the maturity of quality management in your organization will be a year from now? Base: Total (n=260)

Customers are pushing for more transparency and accountability.

Becoming more mature makes quality management more efficient – i.e., the organization can do more with less – and more effective – i.e., quality is higher. These factors directly lead to return on investment in quality maturity. Furthermore, quality maturity provides transparency and accountability up and down the supply chain. Customer requirements of transparency and accountability are increasingly non-negotiable.

We are in the process of arguing for and procuring a QMS. There is a push to do this now due to customer obligations, which have become more and more intricate over the years. Customers are pushing their liabilities down through the supply chain. They want greater and greater transparency and accountability and say our current systems are inadequate. We're still doing risk assessments in spreadsheets. Our customers are saying that's no longer a viable option. Customers recognize that if you don't tie the risk assessments to your management system and your task flow work processes, then you're missing opportunities to improve processes and reduce risk. This is a huge challenge for us, and with our antiquated systems, it's just becoming impossible to keep up.

– Specialty Chemicals, QHSE

Adoption of QMS is high, but most also use other tools.

3rd party cloud software is the most commonly used tool to manage quality. In addition to 3rd party cloud software, companies continue to use processes that rely on spreadsheets, shared drives, documents and email. Many use a combination of tools as they move toward a unified approach across the organization. QMS is in the mix of modes of communication companies use.

*What software tools do you use to manage quality processes, documents, and training?
Select all that apply. Base: Total (n=260)*

*How does your company collaborate and communicate across teams, sites, and suppliers?
Select all that apply. Base: Total (n=260)*

Software Tools

77%

3rd party cloud-based software tools

53%

Custom-built in-house software tool

71%

Combination of spreadsheets, shared drive, word documents and email

19%

3rd party on-premise software tools

Communications Method

82%

Email

70%

Digital collaboration tools

19%

Fax

78%

Phone, tele-/video-conference

50%

Hard copy documents

73%

Cloud QMS

46%

On premise QMS



Companies use cloud QMS for supplier management and spec management, plus many other processes.

Companies use software tools for a range of quality management and EHS processes. The most common uses are supplier management and specification management, followed by customer complaints management and risk management & RCA. Uses are by no means mutually exclusive, as companies use software for multiple processes.

What quality management / EHS processes are you using software tools for today? Select all that apply. Base: Use 3rd Party Cloud Based Software Tools (n=199)

Process Software Tools are Used For

49%

Supplier Management

37%

Change Management

31%

Process Hazard Analysis

46%

Specs Management

37%

Failure Mode & Effects Analysis (FMEA)

29%

Non-Conformance Management

44%

Customer Complaints Management

37%

OHS Agency Reporting (OSHA, WSIB)

28%

Advanced Product Quality Planning (APQP)

41%

Risk Management & RCA

35%

Incident Management

27%

Job Safety / Hazard Analysis

38%

Corrective & Preventative Actions

34%

Audits & Inspections

24%

Process Hazard Analysis

38%

Production Part Approval Process (PPAP)

31%

Advanced Product Quality Planning (APQP)

37%

Document Control & Training Tracking

31%

Job Safety / Hazard Analysis

Efficiency gains and insights are key QMS benefits.

Almost all in-depth interview participants report QMS benefits from:

- ▶ Process efficiency gains through automation and continuous improvement.
- ▶ Global visibility across the organization including all processes, documents, SOP's, CAPA's, etc.

“We are trying to reinvent or improve our quality processes in order to drive efficiency. Supplier validation is one [benefit], but there are plenty others. If we manage deviation faster, if we manage change control more efficiently... all of this is driving speed, and speed is money.”

– Consumer Goods, Quality Assurance

“We're hoping to... better [understand] what drives the risk of producing something that causes a marketplace incident. Because amongst all the things that quality is driving, a marketplace incident - which in the worst case can result into a recall - are probably one of the most disruptive and most costly events that can occur.”

– Consumer Goods, Quality Management

Some interview participants also mentioned the following benefits:

- ▶ Geographic expansion
- ▶ Better reporting capabilities
- ▶ Common KPIs across the organization
- ▶ Predicting quality issues before they happen
- ▶ Risk management
- ▶ Waste reduction
- ▶ Better data analytics
- ▶ Innovation / speed to market
- ▶ Workforce training
- ▶ External workflows / communications with suppliers

Challenges & Concerns



Quality professionals have many, interconnected challenges related to processes, data and people.

Companies' top quality management challenge is to maintain a centralized global repository of all documents across the organization. Another key challenge is fully integrating an eQMS into organizational workflows to enable process efficiency and effectiveness. Similar in importance are remote communication, resources to address nonconformances and respond to audits, quality culture, and using data to make decisions proactively.

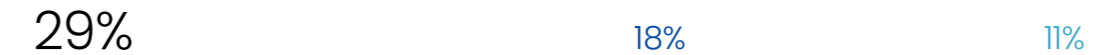
“[A top challenge is for staff,] especially newer staff, to know where to look [for information]... Everybody wants to be able to access everything very quickly.”

– Consumer Goods, Quality Management

Please rank up to three of your organization's top quality management challenges. (1 = most challenging) Base: Total (n=260)

Top Quality Management Challenges

RANK: ■ 1st ■ 2nd



Maintaining a centralized global repository of all documents across the org.



Easy to use eQMS to enable efficiency and effectiveness of process



Technology to effectively communicate remotely



Having sufficient resources to promptly address nonconformances and respond to audits



Promoting a culture of quality across the organization



Using data to be proactive and make data-driven decisions



Lack of executive support for eQMS



Ensuring effective supply chain communication and compliance

Document repositories and easy to use QMS systems solve important challenges.

A centralized documents repository solves the challenge of organizing vast amounts of documents. It also enables transparency.

We have a large portfolio of significantly more than a thousand products. For every product, we have many, many different documents. To produce every single product, we need raw materials. For all the raw materials, again, we need a bunch of documents. This goes a step further if also we consider site certifications and which customer gets the product from which site. To have all this in one nice system would be really a benefit.

– Specialty Chemicals, Quality Management

Ideally, easy-to-use QMS systems enable a culture of quality. Culture is a central element of quality management because the quality function is only successful when the rest of the organization is on board.

People think about documentations, records and SOPs but that's maybe 20-30% of managing quality. The rest is the quality culture, the quality mindset that you deploy in the organization so people actually follow the SOPs, understand them and internalize them. The strength of good systems is that they achieve the objective with the right user experience. This drives adoption and builds a stronger quality culture. We have a new system that takes three clicks and you're done. Using this system, people say, 'I actually want to work with the system' and 'I actually want to do the job right because the system allows me to.'

– Consumer Goods, Quality Management

Companies need more effective training for both onsite and remote employees.

Integrating external e-learning platforms and identifying an initial set of training for newcomers are also challenges, as is the time needed to review and approve related documents and training materials.

"[EHSQ] training... is not managed by HR; it's very siloed... To follow up on the effectiveness is very difficult, because it's very manual... As of today, we are not able to have a process, a system that makes sure that we train all workers."

– Consumer Goods, Quality Management

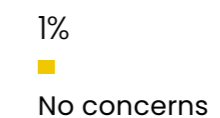
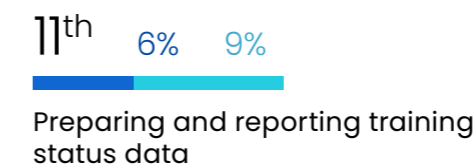
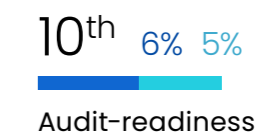
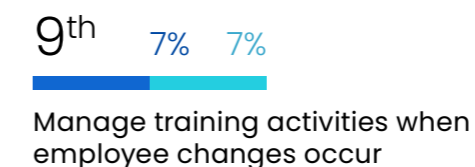
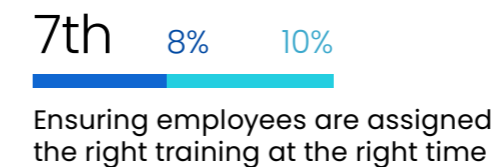
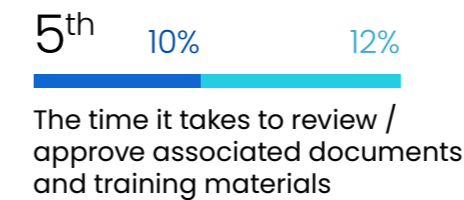
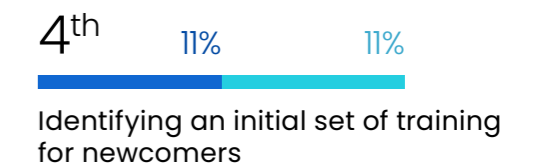
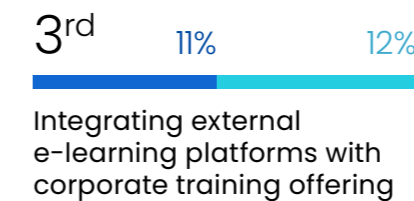
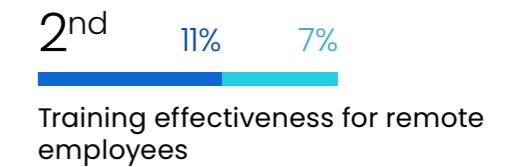
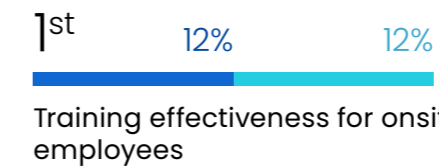
"Measuring training effectiveness isn't something we master completely on the global quality processes... Because I see some failures in this area, my conclusion is that the training we have is not sufficient."

– Consumer Goods, Quality Assurance

Please rank up to three challenges your organization has managing employee training. (1 = most challenging) Base: Total (n=260)

Top Training Challenges

RANK: ■ 1st ■ 2nd



Companies struggle to manage suppliers, so there is significant opportunity for improvement.

Lack of adequate systems and specs compliance are companies' biggest supplier management challenges. However, there seems to be a lack of consensus about which supplier management challenges are most pressing. Most of the supplier management challenges we asked about were selected as first or second most challenging by roughly the same number of respondents.

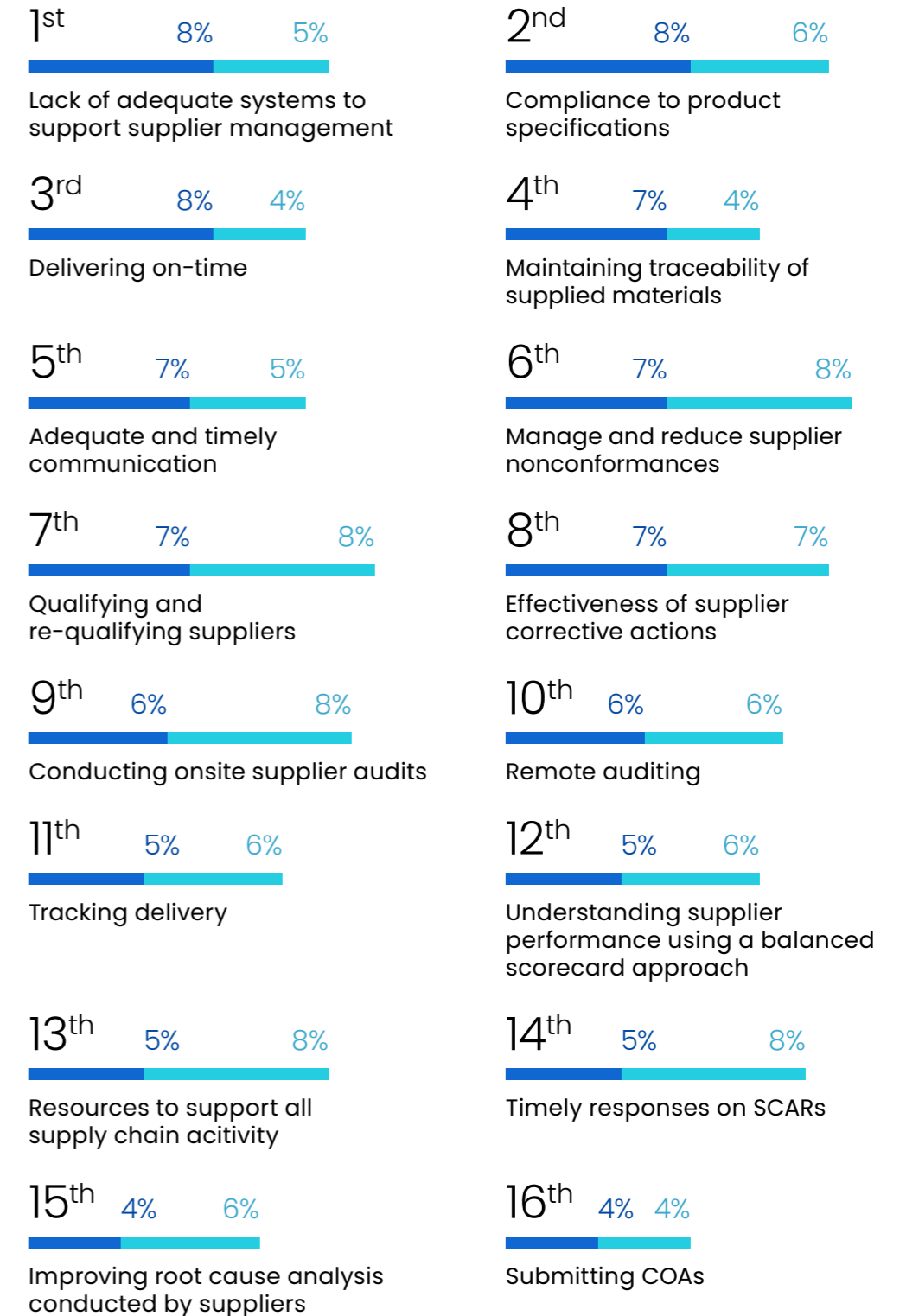
Timeliness and maintaining traceability of the supplied materials are among the top supplier management challenges, but communication, nonconformances, qualifying, corrective actions, and audits all face challenges, as well. Only submitting COAs and improving root cause analysis are clearly less critical than other challenges considered.

Maintaining traceability is challenging for more consumer goods and chemical companies than food & beverage companies. Adequate and timely communication and effectiveness of supplier corrective actions are challenging for more food & beverage than consumer goods and chemical companies. Tracking delivery is challenging for more consumer goods companies and food & beverage companies. Timely responses on SCARs is challenging for more chemical companies and consumer goods companies.

Please rank up to three challenges your organization has managing suppliers. (1 = most challenging) Base: Total (n=260)

Top Supplier Management Challenges

RANK: ■ 1st ■ 2nd



Challenges managing suppliers revolve around collecting, organizing and maintaining supplier data.

Even though the survey results were inconclusive in identifying top challenges, the in-depth interviews revealed that the connecting thread is supplier data management. Decentralized and legacy processes lead to challenges managing suppliers, as does decentralized data. Processes that rely on email and suppliers that are not responsive are also problematic.

"We are an aggregation of companies [with many] legacy suppliers... Some of them are old and some of them not... The practices on supplier management have changed a lot, and so we have a whole history to catch to make sure that for all suppliers we have a nice and neat and up to date qualification."

– Specialty Chemicals, Quality Management

"We [lack] centralized non-conformance management. For example, we have three factories in France; each factory manages non-conformances with the supplier. But in fact, we have the same supplier in three factories, so we don't have this vision on a corporate level."

– Specialty Chemicals, Quality Management

To qualify a new supplier, our regulatory group must collect information from the supplier. Namely, things like safety data sheets, technical data sheets, examples of the CMA, and examples of other types of documentation. Right now, that is completely an email process. We ping the supplier and say, 'please send me this information regarding product XYZ.' We might get it, we might not. Nothing ties that activity back to a supplier scorecard and how that supplier is servicing us.

– Specialty Chemicals, QHSE

The pandemic has increased the urgency to manage risk and move forward with digital transformation.

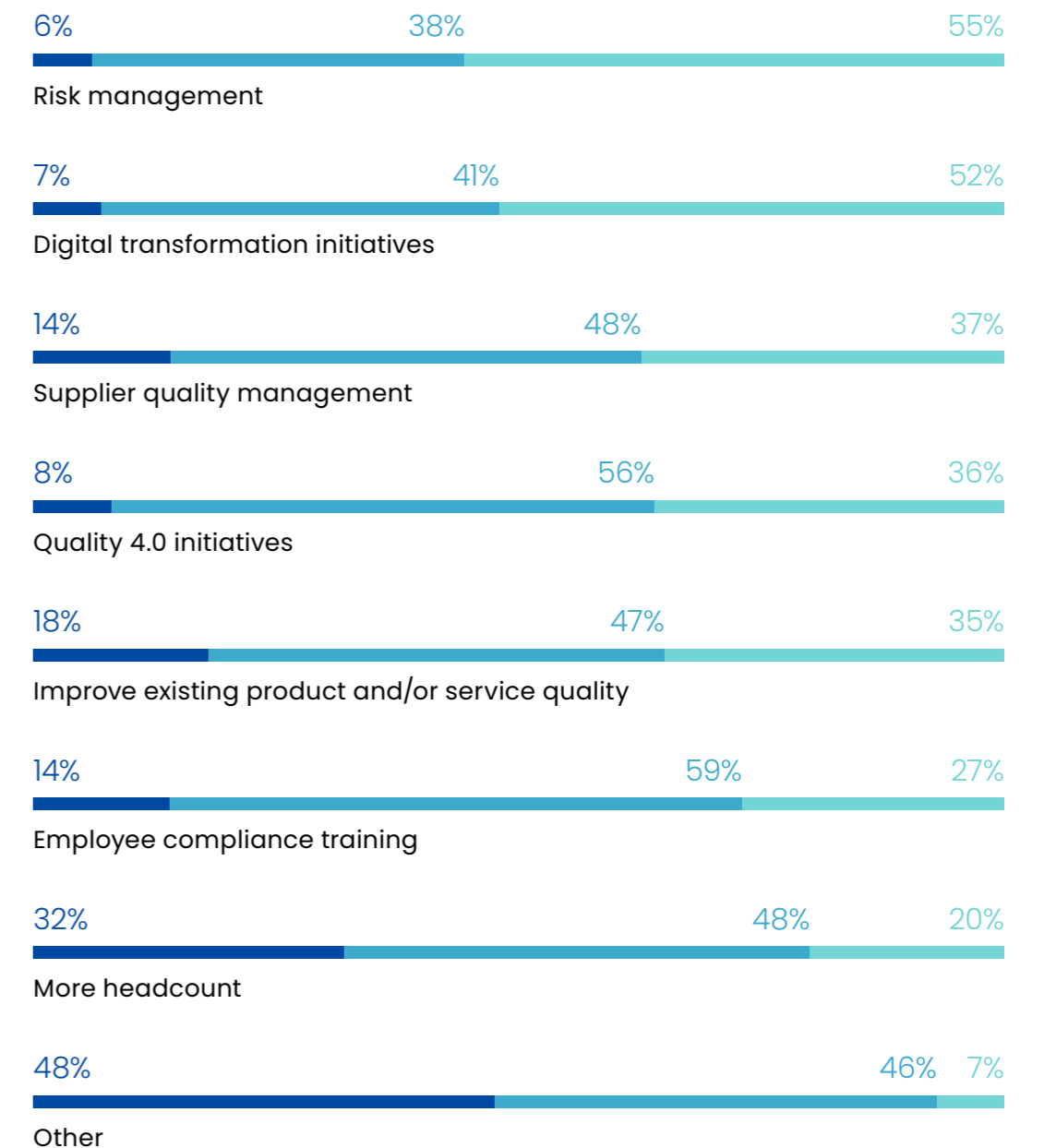
Additionally, the pandemic has made adding headcount less important. There may be opportunities for companies to move funds budgeted for headcount toward digital transformation and QMS. According to the in-depth interview participants, remote auditing is also particularly important during the pandemic.

For almost all the pandemic impacts included in the survey, the percentage of respondents who said the pandemic made the impact a higher priority was larger than the percentage of respondents who said the pandemic made the impact a lower priority.

How has the pandemic impacted the importance of the following? Base: Total (n=260)

Pandemic Impact on Importance

■ Made it a lower priority ■ Did not change its priority ■ Made it a higher priority



"I would've never been able to have my quality team fully remote had I not had Veeva... Everybody picked up a computer, went home... Had we not had that, we would've not been able to maintain stock and inventory 100% efficiency the way we have."

– *Consumer Goods, Quality & Compliance*

KEY TAKEAWAY:

The **pandemic** has increased the **urgency** to manage risk and move forward with digital transformation.

Planned investments in digital transformation and QMS will address multiple pressing challenges.

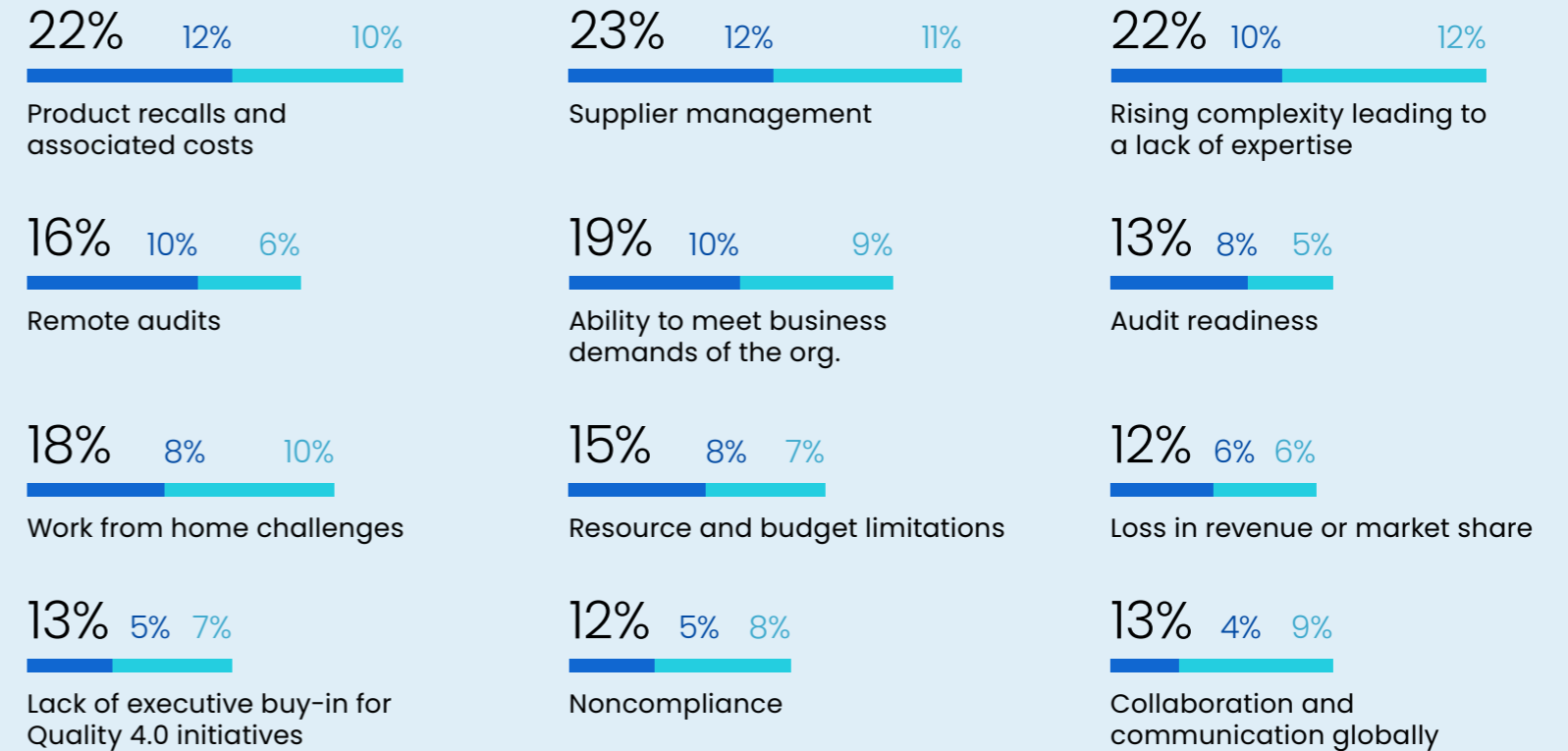
The top future challenges related to regulations, standards and industry expectations relate to product recalls, supplier management and complexity, followed by remote audits and meeting business demands. Investments in digital transformation and QMS will help alleviate multiple anticipated challenges. Supplier quality management is another common investment priority for 2021, which is to be expected given the range of supplier management challenges companies are dealing with.

Thinking about new regulations, standards, and industry expectations in 2021 and beyond, please rank up to three quality challenges are you most concerned about. (1 = most concerned) Base: Total (n=260)

What financial investments in quality management are you planning to make in the next 12 months to help overcome these challenges? Select all that apply. Base: Concerned About Some Quality Challenges (n=257)

Challenges Related to Regulations, Standards and Industry Expectations

RANK: ■ 1st ■ 2nd



Investments Planned for Next 12 Months to Overcome These Challenges



SPOTLIGHT ON Consumer Goods

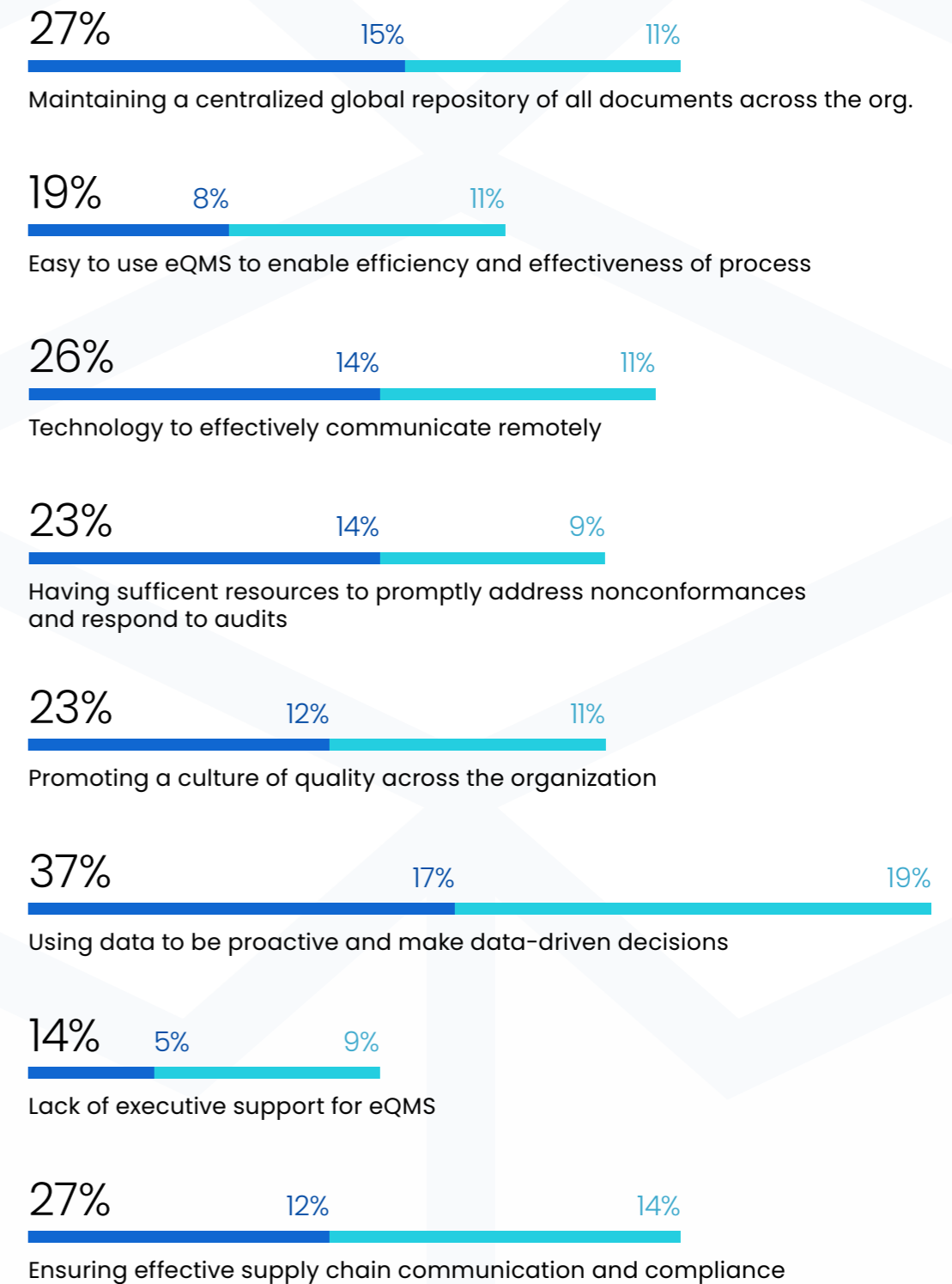
Consumer goods companies differ from other industries in their practices, maturity and challenges. Using data to be proactive and make data-driven decisions is the top challenge for consumer goods companies.

- ▶ 76% have a dual quality and EHS role.
- ▶ 86% are at one of the top 2 maturity levels
- ▶ 72% use 3rd party cloud-based software tools
- ▶ Top training challenges: Training effectiveness for onsite employees and ensuring training compliance
- ▶ Top supplier challenge: Compliance with product specifications

Please rank up to three of your organization's top quality management challenges. (1 = most challenging) Base: Consumer Goods (n=98)

Top Quality Management Challenges

RANK: ■ 1st ■ 2nd



SPOTLIGHT ON Food and Beverage

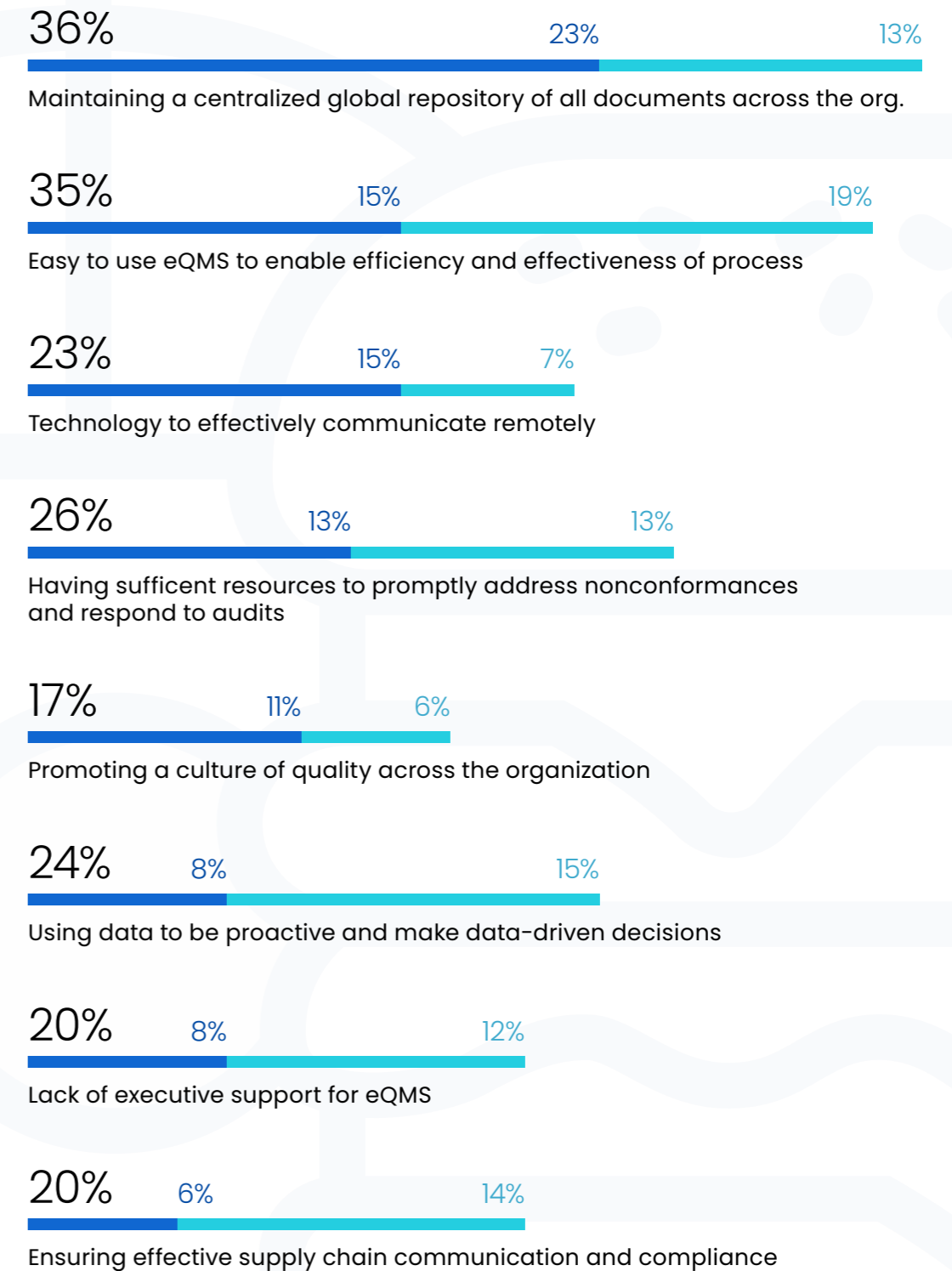
Food & beverage companies differ from other industries in their practices, maturity and challenges. Maintaining a global repository of documents is the top challenge for food & beverage companies.

- ▶ 81% have a dual quality and EHS role.
- ▶ 71% are at one of the top 2 maturity levels
- ▶ 88% use 3rd party cloud-based software tools
- ▶ Top training challenges: The time it takes to review/approve associated documents and training materials
- ▶ Top supplier challenge: Adequate and timely communication

Please rank up to three of your organization's top quality management challenges. (1 = most challenging) Base: Food & Beverage (n=84)

Top Quality Management Challenges

RANK: ■ 1st ■ 2nd



SPOTLIGHT ON Specialty Chemicals and Crop Science

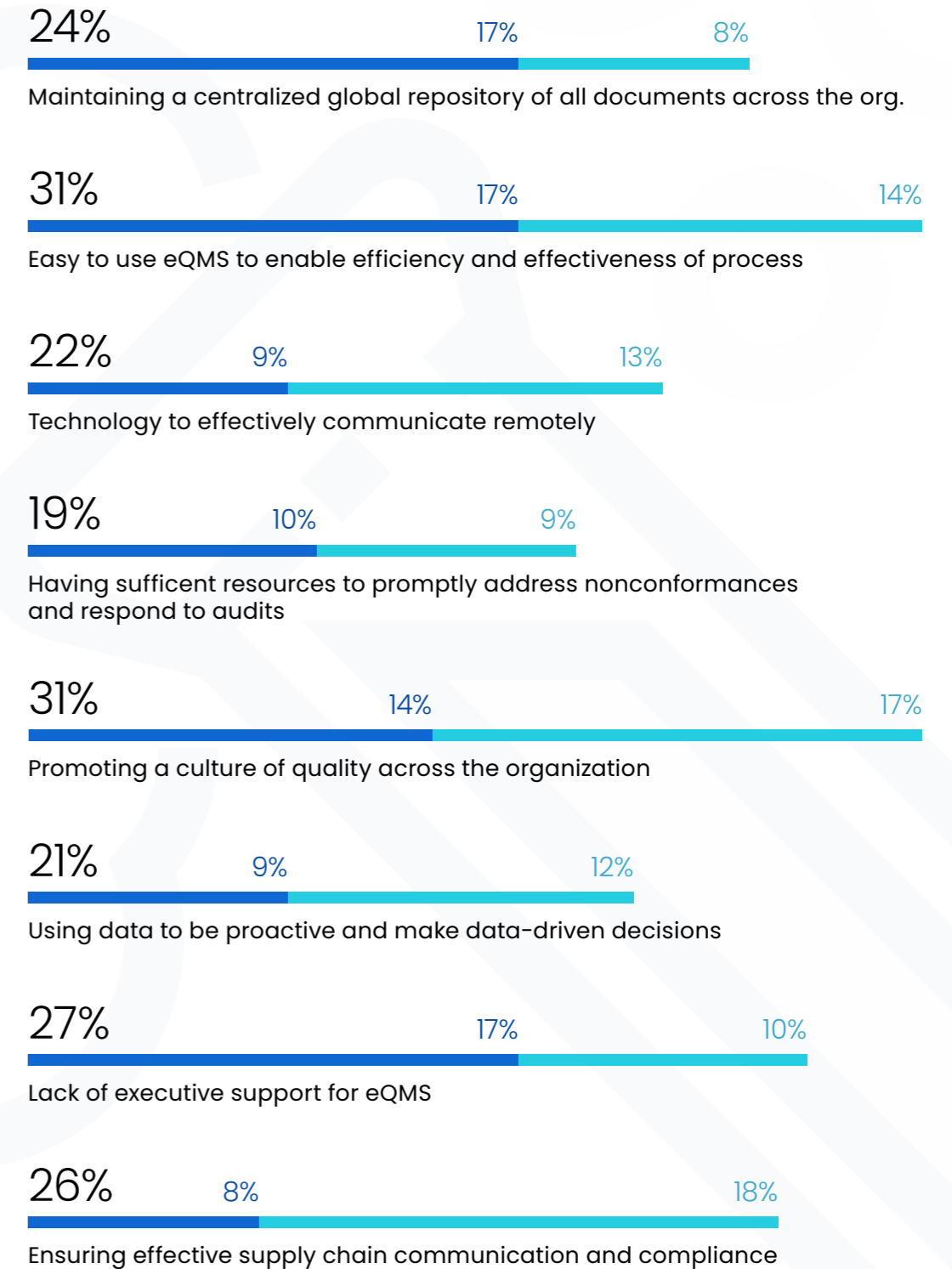
Specialty chemical and crop science companies differ from consumer product companies in their practices, maturity and challenges. An easy-to-use eQMS to enable efficiency and effectiveness of process is the top challenge for specialty chemical and crop science companies.

- ▶ 63% have a dual quality and EHS role.
- ▶ 77% are at one of the top 2 maturity levels
- ▶ 69% use 3rd party cloud-based software tools
- ▶ Top training challenges: Integrating external e-learning platforms with corporate training offering
- ▶ Top supplier challenge: Lack of adequate systems to support supplier management

Please rank up to three of your organization's top quality management challenges. (1 = most challenging) Base: Chemicals (n=78)

Top Quality Management Challenges

RANK: ■ 1st ■ 2nd



Solution Insights



Technology investments improve quality outcomes

The most significant impact is improved quality driven by process automation which reduces human error.



Technology helps us get closer to the idea of '100% inspection automatic product release.' You could call it 'automatic quality everywhere.' This entails testing all the products without human intervention. Starting with controlled inputs means you can trust your processes to deliver controlled outputs. We're removing the human touches. Every touch is a loss, which we are trying to get away from. We're using data to get to the next frontier.

– Consumer Goods, Quality Assurance

Everybody comes from a different background, from different industries, and they have no understanding of GMPs. Instilling best practices is a big culture shift. A QMS platform allows that. It's not one person saying, 'we're doing it this way.' It becomes a culture in the company.

– Consumer Goods, Quality Management

Technology investments have a major impact on quality management practices.

All in-depth interview participants agree that technology is having a major impact on quality management practices.

There are quality requirements to ensure transparency. Products are labeled properly, we have the appropriate claims, and so forth. It's also important for anybody internally that's interested in understanding how are we releasing a product or the testing requirement for something. Veeva QualityOne provides data transparency and allows easy access by all teams. They can find it right in Veeva.

– Consumer Goods, Quality & Compliance

"Technology plays a role in making things better... The better you can get at the system to support your business, that's the best thing ever. [It] just makes your work life easier."

– Consumer Goods, Quality Assurance

Other technology impacts on quality management practices include:

- ▶ Making better decisions related to product quality and consumer expectations
- ▶ Help predict failures and avoid rework
- ▶ Economically and efficiently capture and collect more quality data for analysis
- ▶ Makes everyone's work life better / easier
- ▶ Managing risk
- ▶ Automating non-value added tasks
- ▶ Get closer to realizing Quality 4.0
- ▶ Process validation
- ▶ Transparency of products and processes (internally and externally)
- ▶ Unifying organizational quality culture

KEY TAKEAWAY:

Technology investments **improve quality outcomes** and have a major impact on quality management practices.

A supplier portal is the most important requirement of a QMS.

This is yet another indication of just how difficult supplier management is. Concerns around supplier management rise to or near the top of questions about challenges, investments, and solution requirements.

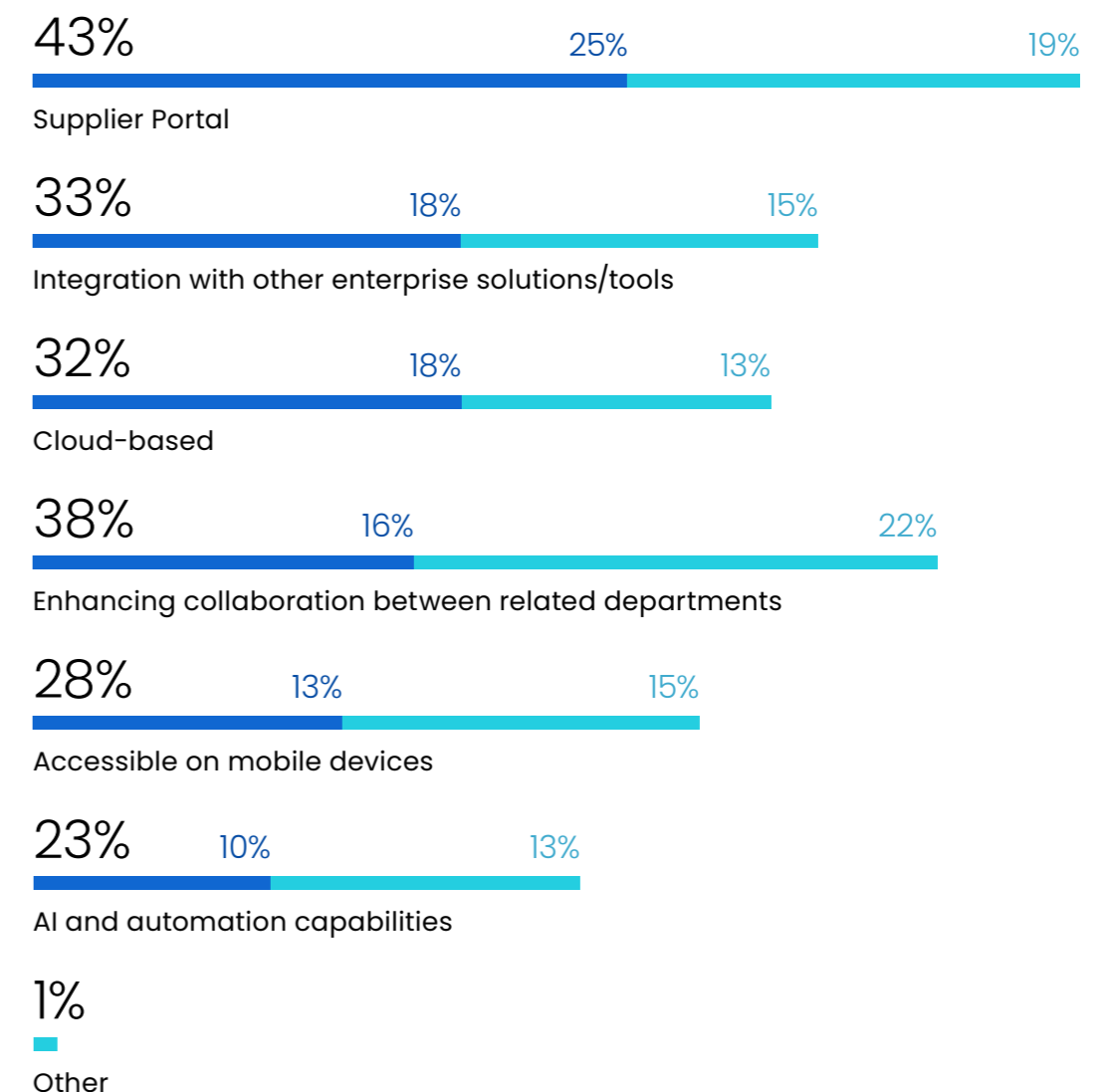
Additionally, a QMS needs to integrate with other solutions, be cloud-based, and enhance collaboration between related departments. We found that QMS is used more often on a desktop or laptop and only sometimes on a mobile device, so it is not surprising the mobile accessibility is not the most important QMS requirement for many.

Although artificial intelligence (AI) and automation capabilities is not the first or second requirement for as many companies as other solution requirements, this does not mean it is unimportant. Rather, companies acknowledge the benefits AI and automation provide to better quality and to greater efficiency.

If there was a solution to centralize your quality system globally, which of the following requirements would be critical to meet current and future objectives? Rank up to three, in order of importance, with 1 being most important. Base: Total (n=260)

Top Solution Requirements

RANK: ■ 1st ■ 2nd



A supplier portal must include several critical capabilities.

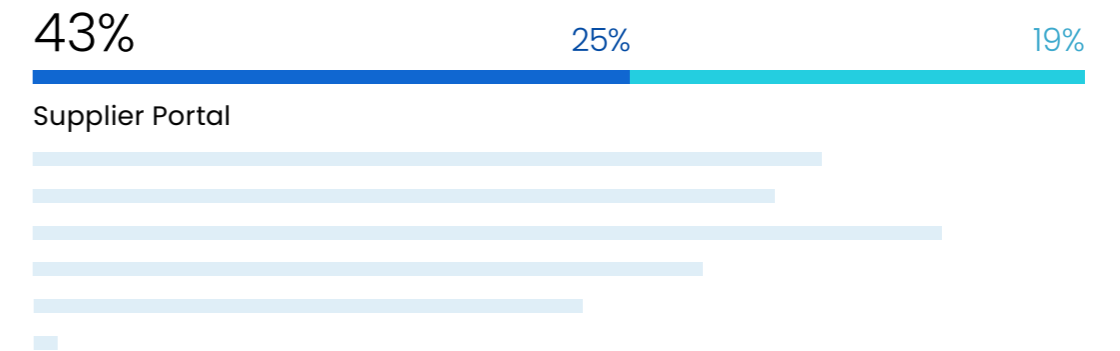
- ▶ Ability to upload and view documents from the entire supply chain, audit suppliers remotely, support a circular economy model and score suppliers are equally critical supplier management capabilities.
- ▶ Ability to view inspection test results from the entire supply chain is not much less important, while CoA management is of lesser importance.

If there was a solution to centralize your quality system globally, which of the following requirements would be critical to meet current and future objectives? Rank up to three, in order of importance, with 1 being most important. Base: Total (n=260)

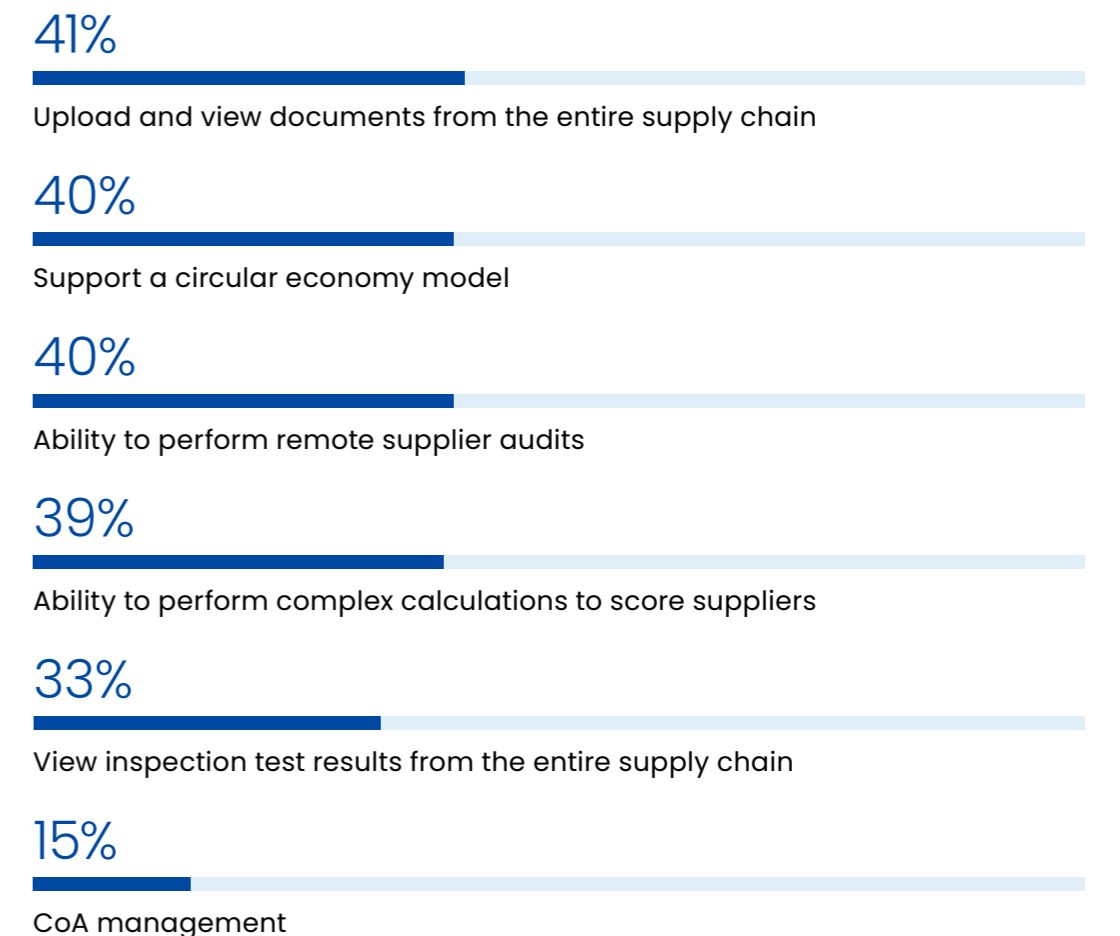
Which of the following supplier management capabilities would be critical to meet current and future objectives? Select all that apply. Base: Supplier Portal Selected as a Solution Requirement (n=142)

Top Solution Requirements

RANK: ■ 1st ■ 2nd



Critical Supplier Portal Capabilities



KEY TAKEAWAY:

Companies struggle to manage suppliers and supplier data.
A **supplier portal** is the most important requirement of a QMS.

AI and automation capabilities must provide data analytics.

Those who require AI and automation in a QMS expect that first and foremost it will provide data analytics.

If there was a solution to centralize your quality system globally, which of the following requirements would be critical to meet current and future objectives? Rank up to three, in order of importance, with 1 being most important. Base: Total (n=260)

What do you expect AI and automation capabilities to provide? Select all that apply. Base: AI and Automation Capabilities Selected as a Solution Requirement (n=96)

Top Solution Requirements

RANK: ■ 1st ■ 2nd



23% 10% 13%

AI and automation capabilities

AI & Automation Expectations

59%

Data analytics

45%

Predictive analytics

42%

Increased efficiency

39%

Improve defect detention rates

35%

Proactive root cause analysis

34%

Reduce human error

Automation makes processes better, especially document review & approval, tracking, and reporting.

Supplier management follows in improvement potential, along with change control and recall prevention. The bottom tier of processes most improved by automation comprises risk management, managing recalls, training compliance, and audit notification.

"We have moved toward an electronic document management system, but our sites still rely 90% of the time on paper because our production is not much automated... You spend a lot of time checking what somebody else has entered... This time would be saved by a computerized system."

– Specialty Chemicals, Quality Management

"With QMS, you would be able to have communication – there's maybe minor changes – and then move through to the final approval. And not having that paper copy in a filing cabinet."

– Consumer Goods, Quality Management

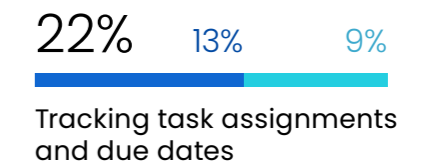
In the context of quality management, which processes do you think can be most improved by automation via software tools? Please rank up to three in the order of improvement possibility, with 1 having the most room for improvement. Base: Total (n=260)

Process Most Improved by Automation

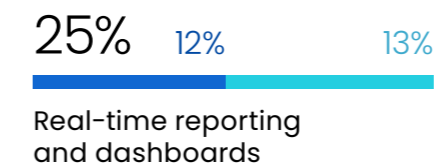
RANK: ■ 1st ■ 2nd



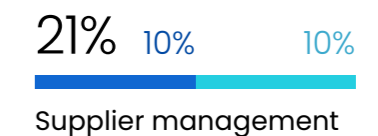
Document review/approval



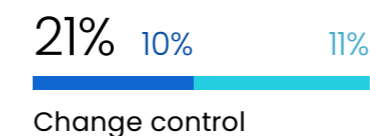
Tracking task assignments and due dates



Real-time reporting and dashboards



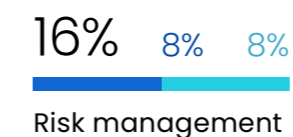
Supplier management



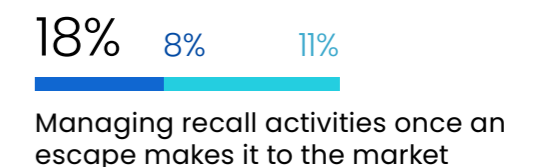
Change control



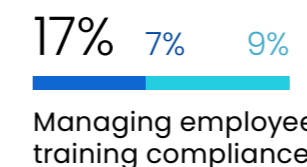
Preventing product recalls by minimizing escapes to the market



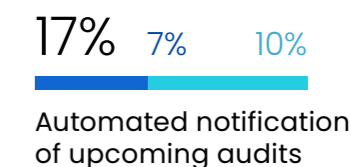
Risk management



Managing recall activities once an escape makes it to the market



Managing employee training compliance



Automated notification of upcoming audits

Resources and resistance to change are the leading barriers to adopting new technology.

Organizationally the leading barriers are cost and IT resources for implementation and migration. Almost all in-depth interview participants cited resistance to change among users as the leading barrier to adopting new technology.

To switch to existing, known ways of managing quality processes that are not internally-approved takes a bit of massaging. It requires saying to the organization, 'we had a way of doing things in the past that was very specific, fit our business needs, and we were the best in the world at doing, but given we want to do in the future, we need to adjust. Others have already gone through the pain of getting better processes and better approaches. Why don't we just copy and paste versus trying to customize, to replicate what we used to do, but which is no longer applicable in our new environment?'

– Consumer Goods, Quality Management

Culture is a challenge. People have a hard time with change. People freak out at even the mention of SharePoint. Training and getting people comfortable with the cloud is a challenge, especially people who don't use a lot of technology and don't understand relationships between objects.

– Consumer Goods, Quality Management

Other barriers to technology adoption include:

- ▶ Concerns about cloud security
- ▶ Adequate user training
- ▶ Customized legacy systems tailored to the business
- ▶ Justifying return on investment
- ▶ User engagement (concern the company is watching the employees)

Organizations are in the early stages of Quality 4.0 adoption.

Almost all in-depth interview participants indicated they are moving in the direction of Quality 4.0 but are still early in the process. Some organizations are trying to understand what Quality 4.0 really means and how to best implement it across their business.

I don't think there's a crystal-clear definition of Quality 4.0. We are relatively well-advanced in the abundance of data we collect online from our production lines. However, I still don't think we fully understand how to best do it and what the real challenges are.

– Consumer Goods, Quality Management

We've gotten a little better at analytics. We have a project we call the IMS 4.0, which is an allusion to Industry 4.0, that relates directly to our integrated management system. We're trying to strategize exactly what we want to do and why we want to do it that way and struggling with internal or external vendors and just how much money we're willing to spend.

– Specialty Chemicals, QHSE

Resources and resistance to change are the leading barriers to adopting new technology.

We're moving towards Quality 4.0, but it's going to be a while before we fully get there. We'll have pockets of our company that are really getting there and others lagging because they're worried about other things, or it's not a priority to invest time and money in.

– *Consumer Goods, Quality Assurance*

We're building a large IT infrastructure. We have a large footprint moving in the direction of full automation. This spans nuts and bolts across the company: finance, marketing, etc. It's a field that's expanding so quickly that while we are applying pieces of Quality 4.0 where they make sense, there's still a large opportunity to expand what we're doing.

– *Consumer Goods, Quality Management*

Other considerations and barriers to adopting Quality 4.0 mentioned included:

- ▶ Lower priority than other initiatives
- ▶ Funding / return of investment
- ▶ Executive buy-in
- ▶ Lack of human resources and necessary skill sets
- ▶ Ability to be agile, especially among large organizations
- ▶ Managing internal and external vendors
- ▶ Legacy systems
- ▶ Culture and change management
- ▶ Organizational alignment of goals, values and needs across all business units

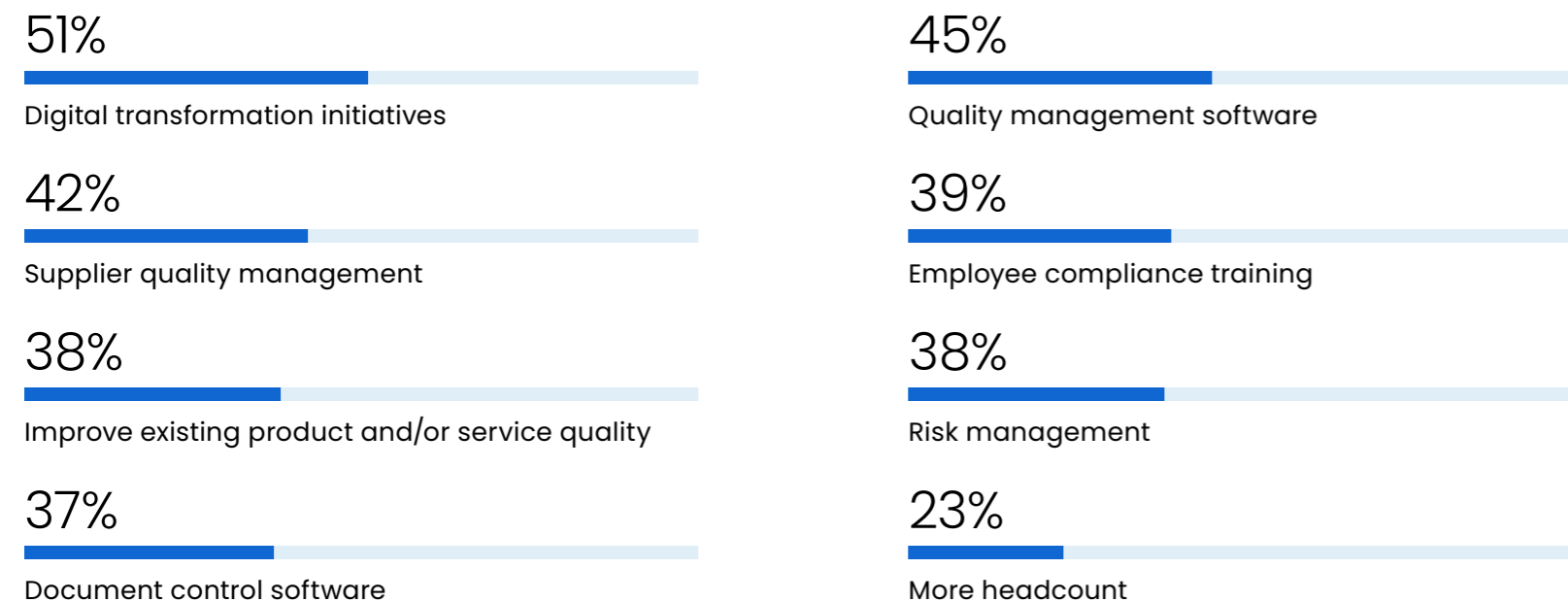
Investment



Last year, companies' most common quality management investments were in digital transformation and QMS.

Investment levels will generally stay the same in 2021 but will increase for some.

Past 12 Months Investments in Quality Management



What financial investments in quality management have you made over the past 12 months? Select all that apply. Base: Total (n=260)

Financial investments made in the past 12 months differ by industry to some degree.

- ▶ More chemical companies (53%) than F&B (36%) and consumer goods (30%) companies invested in risk management.
- ▶ More chemical companies (45%) and F&B companies (43%) invested in improving existing product and/or service quality than consumer goods companies (29%).
- ▶ More F&B companies (29%) than consumer goods companies (16%) invested in more headcount, with chemical companies (27%) in between.

Additionally:

- ▶ More mature companies are more likely to have invested in risk management, whereas less mature companies are more likely to have invested in headcount.

Going forward, companies will invest in data visualization tools, a global QMS, and automation.

The second tier of investments in quality management comprises employee training software, improving software systems integration and extensions to the company's supplier community. Fewer companies will invest in AI and Internet of Things (IoT). Almost every company, regardless of industry, plans to make quality investments this year

In what areas is your organization planning to make financial investments in Quality Management in 2021? Select all that apply. Base: Total (n=260)

2021 Investments in quality Management

43%

Data analytics visualization tools

42%

Upgrading to a global QMS solution

42%

Automating more processes

38%

Employee training software solutions

35%

Improve integration of software systems

32%

Extending to supplier community

20%

AI

15%

IoT

1%

No plans to invest

Our strategic focus is customer experience. You can't have a good customer experience if the processes designed to deliver that in a timely manner are not developed. You can have a great front end, but if it's going into the same email / spreadsheet approach, then processes will still take a long time and still won't be tracked. This means they are not going to deliver a great customer experience.

– Specialty Chemicals, QHSE

Companies that are less mature are more likely to invest in a global QMS solution.

More mature companies already have the basics covered so they are less likely to invest in upgrading to a global QMS or improving integration compared to immature companies that have not yet taken the same steps. More mature companies are more likely to invest in analytics visualization tools. Immature companies are less likely than others to invest in AI and IoT, presumably because they need to address the basics first.

The eQMS is going to solve the most issues. It's globally tying departments together. It's going to fix a lot of horse and buggy activities.

– Consumer Goods, Quality Control

In what areas is your organization planning to make financial investments in Quality Management in 2021? Select all that apply. Base: Immature or Starting to Mature (n=56) Reaching Maturity (n=101), Fully Mature (n=103).

2021 Investments in Quality Management

	Immature or starting to mature	Reaching maturity	Fully mature
Data analytics visualization tools	36%	36%	53%
Upgrading to a global QMS solution	52%	48%	31%
Automating more processes	30%	45%	45%
Employee training software solutions	39%	33%	42%
Improve integration of software systems	41%	45%	23%
Extending to supplier community	34%	36%	27%
AI	9%	25%	20%
IoT	7%	20%	15%
No plans to invest	2%	1%	0%

QMS delivers ROI via cost savings that can be quantified and cost avoidance that cannot.

In-depth interview participants do not have formal or informal ways to measure ROI. Participants did identify several metrics that can impact return, but noted they are difficult to quantify, especially when talking about cost avoidance vs cost savings. Despite these challenges, all believe investment in a QMS is the right decision.

A software solution provides efficiency gain. If we implement the cloud-based Veeva solution, we can release workers from administrative work that doesn't add value and put them on other more important topics. We can measure this efficiency gain, and we probably will.

– Consumer Goods, Quality Assurance

Not having a recall because you did quality management right is something that nobody will ever see.

– Consumer Goods, Quality Management

Metrics related to ROI mentioned include:

- ▶ QMS organization adoption / compliance
- ▶ Cost of quality
- ▶ Right first time / perfect order percentage
- ▶ Supplier performance
- ▶ Efficiency / productivity gain
- ▶ Reduced headcount
- ▶ Reduced non-conformances
- ▶ Expedited change control
- ▶ Fewer product recalls
- ▶ Materials cost reduction
- ▶ Reduction in waste / breakage

One of the main returns on investment is the cost of quality. Having an automated system means our data is accurate. It's comprehensive. Reports that would normally take a supplier three months to generate manually can now be generated within a few minutes. The human error that you see with manual processes goes way down. It's fully automated so the cost to maintain the same quality of product in the field goes way down.

– *Consumer Goods, Quality & Compliance*



SPOTLIGHT ON Consumer Goods

Integration with other enterprise tools and being cloud-based are the top QMS requirements for consumer goods companies. The most common area of financial investment in the last 12 months among consumer goods companies was digital transformation initiatives.

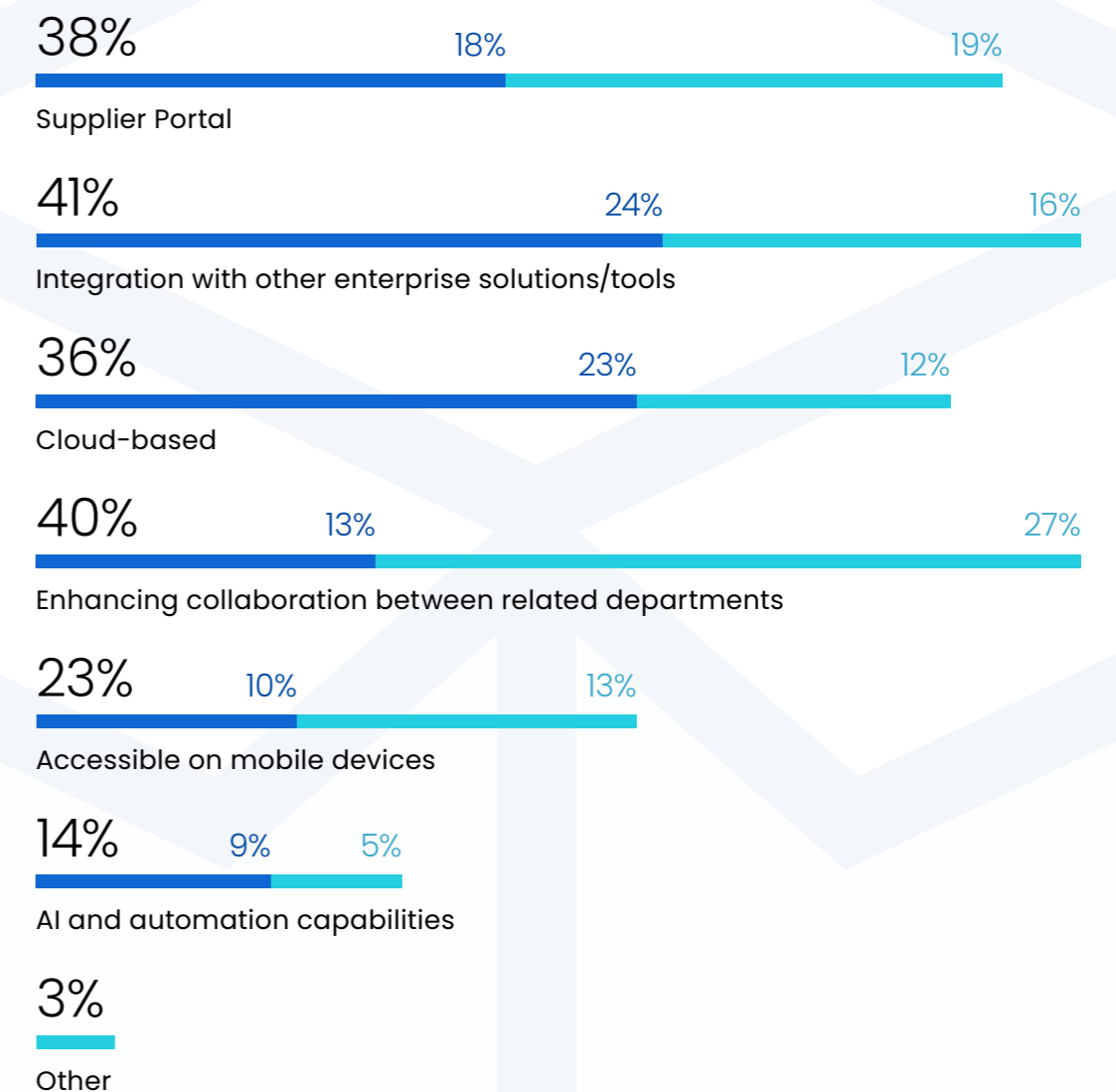
The objective is to come to one global system of truth. We record quality data across various systems, so we don't have a perfect picture. Bringing it to a global platform allows us to do more analytics and generate more insights, more understanding of what drives our quality performance.

– Consumer Goods, Quality Management

If there was a solution to centralize your quality system globally, which of the following requirements would be critical to meet current and future objectives? Rank up to three, in order of importance, with 1 being most important. Base: Consumer Goods (n=98)

Top Solution Requirements

RANK: ■ 1st ■ 2nd



SPOTLIGHT ON Food and Beverage

A supplier portal is the top QMS requirement for food & beverage companies. The most common area of financial investment in the last 12 months among food & beverage companies was quality management software.

"The digitalization of the customer and employee experiences has emerged as a critical mechanism to ensure business continuity."

– Food & Beverage, Quality Control

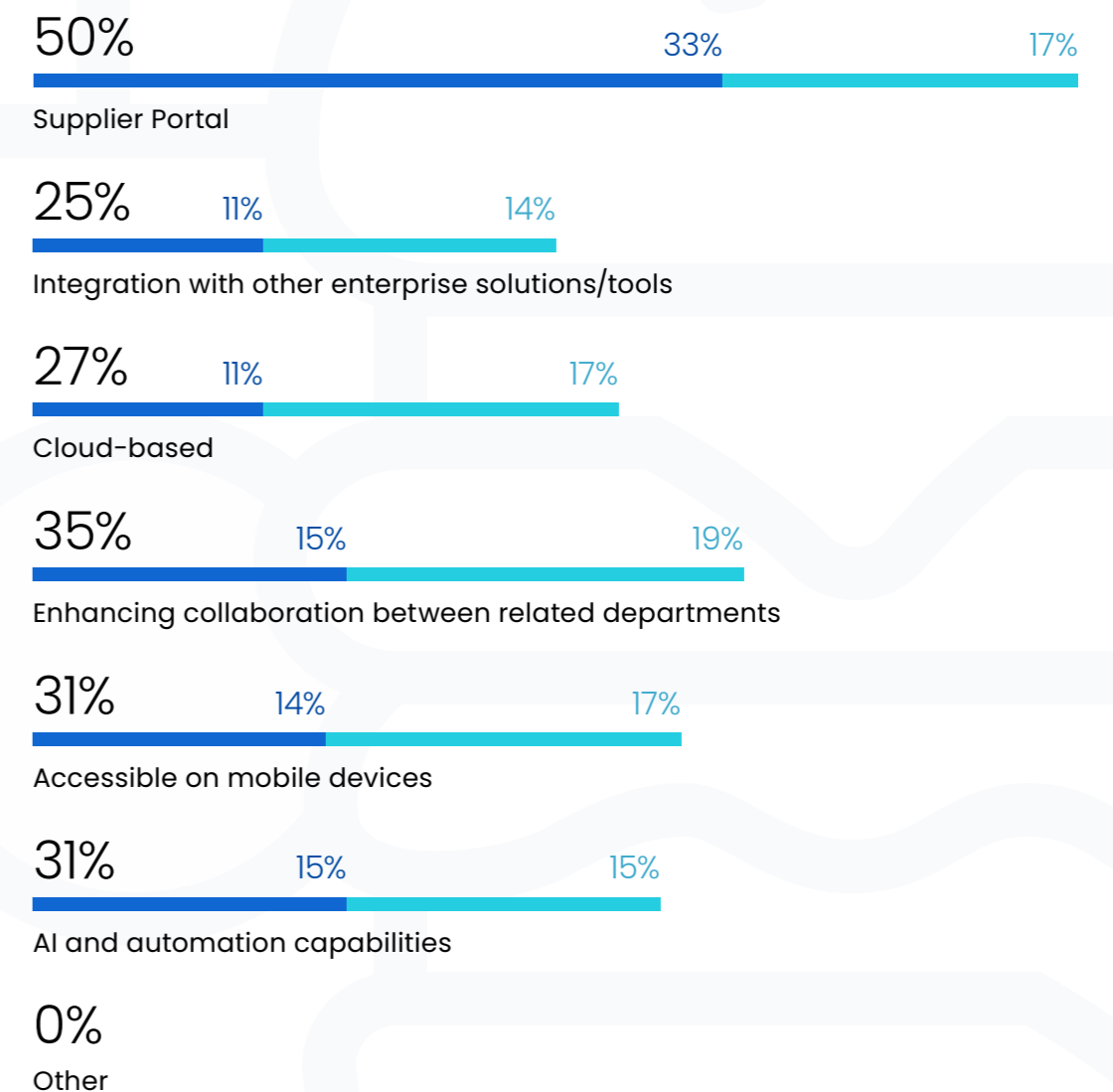
"[Due to the pandemic,] digital transformation went full swing."

– Food & Beverage, Quality Control

If there was a solution to centralize your quality system globally, which of the following requirements would be critical to meet current and future objectives? Rank up to three, in order of importance, with 1 being most important. Base: Food & Beverage (n=84)

Top Solution Requirements

RANK: ■ 1st ■ 2nd



SPOTLIGHT ON Specialty Chemicals and Crop Science

A supplier portal is the top QMS requirement for specialty chemical and crop science companies. The most common area of financial investment in the last 12 months among specialty chemical and crop science companies was risk management.

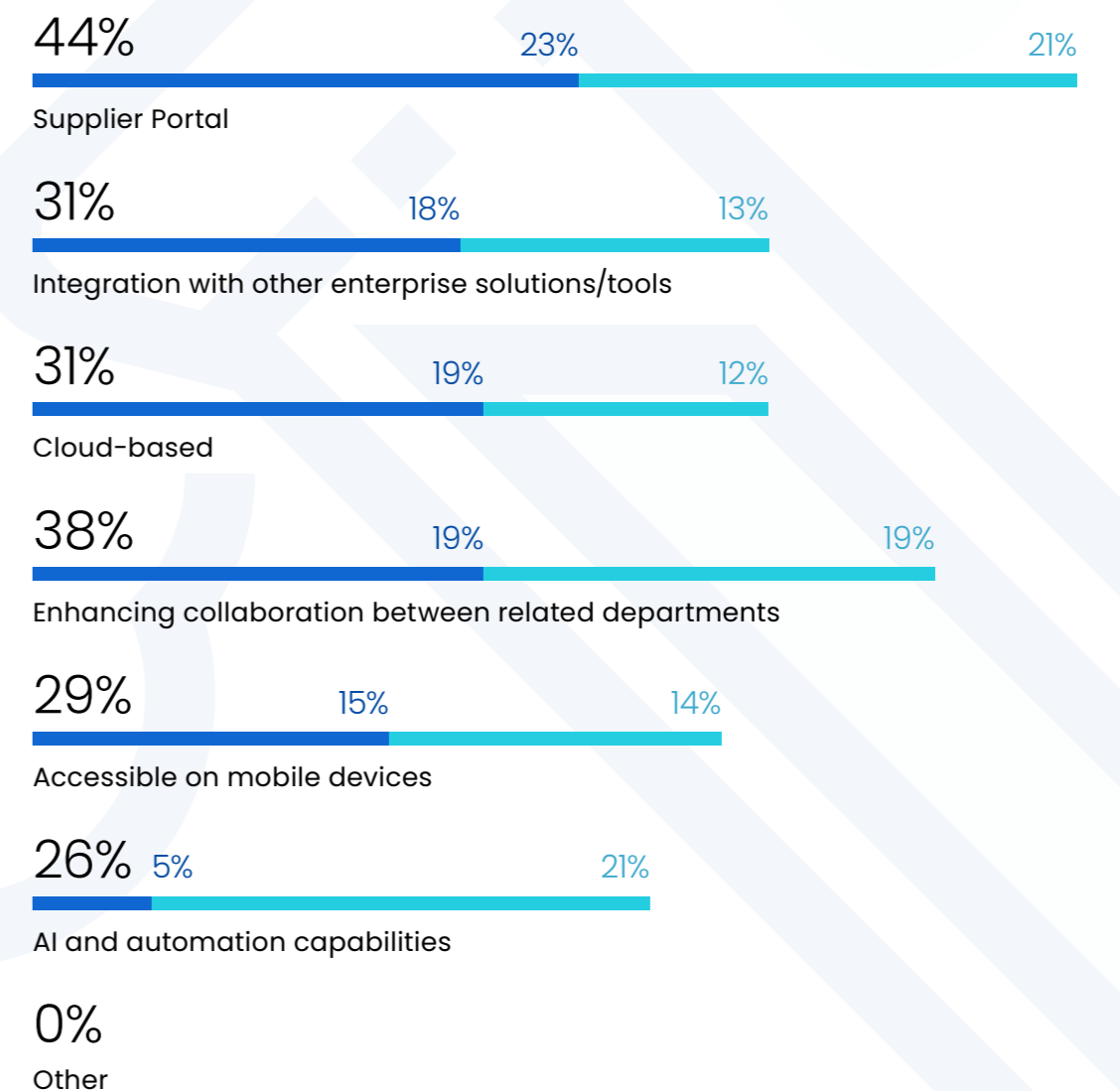
"Everything is in one cloud, so you increase efficiency... We have many employees working with documents, with SOPs, with audit reports, with follow-up of CAPA and so on and so on. If we have that all in one system, potentially including performance management, this makes it much easier. The workflow should be easier, and we really gain efficiency... You can follow up all the things which are software-based in a much easier way."

– Specialty Chemicals, Quality Management

If there was a solution to centralize your quality system globally, which of the following requirements would be critical to meet current and future objectives? Rank up to three, in order of importance, with 1 being most important. Base: Chemicals (n=78)

Top Solution Requirements

RANK: ■ 1st ■ 2nd



Conclusion



“Transformation” sums up the 2021 outlook on quality.

We asked in-depth interview respondents to provide three words that summarize the 2021 outlook on quality. “Transformation” was the primary theme. ENGINE anticipates that this transformation will entail greater quality management maturity across the commercial goods, food and beverage, and specialty chemicals and crop science industries, thanks in part to QMS. We expect this will result in significant enhancements in efficiency and effectiveness that deliver ROI.



KEY TAKEAWAYS:

In summary, the key conclusions from the research are as follows.

- ▶ Becoming fully mature in managing quality by making full use of a global QMS drives cost savings and improved customer outcomes, which ultimately means investments in QMS deliver ROI.
- ▶ Quality and EHS are converging. Most quality professionals also have an EHS role and so want a single software solution that handles both quality and EHS.
- ▶ The pandemic has increased the urgency to manage risk and move forward with digital transformation.
- ▶ Technology investments improve quality outcomes and have a major impact on quality management practices.
- ▶ Companies struggle to manage suppliers and supplier data. A supplier portal is the most important requirement of a QMS.



Consumer Goods

- ▶ 86% are at one of the top 2 maturity levels
- ▶ 72% use 3rd party cloud-based software tools
- ▶ Top challenge: Using data to be proactive and make data-driven decisions
- ▶ Top QMS requirements: Integration with other enterprise tools, cloud-based



Food & Beverage

- ▶ 71% are at one of the top 2 maturity levels
- ▶ 88% use 3rd party cloud-based software tools
- ▶ Top challenge: Maintaining a global repository of documents
- ▶ Top QMS requirements: Supplier portal



Specialty Chemicals and Crop Science

- ▶ 77% are at one of the top 2 maturity levels
- ▶ 69% use 3rd party cloud-based software tools
- ▶ Top challenge: Fully integrating a QMS into organizational workflows
- ▶ Top QMS requirements: Supplier portal

Veeva

Founded in 2007, Veeva (NYSE: VEEV), is a global provider of industry-specific [cloud software solutions](#) that address the unique operating challenges and regulatory requirements of the consumer products and chemical industries. Our solutions help R&D, quality, regulatory and commercial teams unify disconnected processes, documents and data. In doing so, we help our customers eliminate inefficiencies so they can bring high-quality, safe, sustainable products to market without compromising compliance. Veeva is headquartered in the San Francisco Bay Area, with offices throughout North America, Europe, Asia, and Latin America.

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