2021 Elevating Quality Beyond Compliance Study ~ Survey Results Whitepaper

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GENS & ASSOCIATES

Introduction

Our 2021 Elevating Quality Beyond Compliance Study aimed to explore the various dimensions of quality throughout organizations. From strategic initiatives to organizational and investment strategies, the study was designed to provide data on the progression of companies towards becoming a more proactive, predictive, and preventive (the 3P's) quality organization. The goal was to establish a baseline of where industry is currently at while also developing a deeper appreciation and understanding of the different approaches to Quality and the impact it has on elevating overall organizational performance.

This white paper provides insights from the study, explores our viewpoint on what quality looks like for organizations, the impact of the Covid-19 pandemic on quality-related functions such as Risk Management and Supplier Quality Management, and includes reflections from our quality experts and research collaborators on how they interpreted the results based on their quality-related work and experiences. The key study learnings include:

1) The lack of standards for foundational Quality processes (CAPA, Deviations, etc.) results in significant resources still being applied to tactical work
2) Closing the loop in Knowledge Management is the key for improving cross-functionality
3) Business Benefit potential is higher with a coordinated enterprise approach
4) Technology modernization is shifting towards an enterprise orientation with advanced technology investment accelerating in the GMP area
5) Supplier and Risk Management are both priorities driven by the pandemic experience and a greater focus on the patient and customer experience

Whitepaper structure:

- Study Overview and Demographics
- Current Quality Baseline, Organizational Strategies, and Cross-Domain Comparisons
- Opportunities for improvement across Quality Domains and Embracing the 3P's
- Pandemic Impact on Supplier Quality and Quality Risk Management
- Technology Strategy and Priority Investments
- Study Conclusion

We hope you find this information insightful and valuable. Please contact us with any questions.

Study Overview

The needs and expectations for Quality exists in every functional area of a company, as well as throughout the entire product lifecycle. Our study goal was to design a survey that allowed us to generate a broad understanding of quality across organizations and learn how companies are investing in their quality capabilities. We are interested in exploring the impact of company size, product portfolio, organizational strategies and hierarchies, and investments in technology and quality programs on the overall quality performance.

We referenced other Quality studies and reports, such as the *FDA Quality Metrics Research* from University of St. Gallen and KPMG's *Quality 2030: quality inside* (references in appendix) that examined the hidden costs of poor quality, research on the use of quality metrics, and health authority driven initiatives to establish Quality standards. Although the research and data were insightful, they often focused on a single aspect of quality within an organization, usually manufacturing-related quality. From our design sessions, we learned there are big aspirations to improve the degree of cross-functionality between the different quality domains within organizations to showcase quality as whole-company responsibility and not just for certain quality roles or teams. Along this line of thinking, we aimed to explore the full range of different quality dimensions and couple that with trending strategic initiatives to help companies identify the steps and strategies to support their quality beyond compliance journeys. The learning dimensions prioritized during the study design was to explore organizational strategies for maximizing knowledge management and performance, identify practices leading towards integrating a culture of quality across functions, the role of advanced technology in a shifting landscape, and the optimization of quality management system (QMS) elements. The survey was also designed to measure and understand different strategic initiatives to determine which ones were practical vs. those that were more aspirational.

Early in the design process, we developed a diagnostic tool and called it the Opportunity Tool Kit (Figure 1). The initial thinking was for companies to receive the results and be able to see where they might fall on a Quality spectrum based on their quality practices and organizational characteristics.

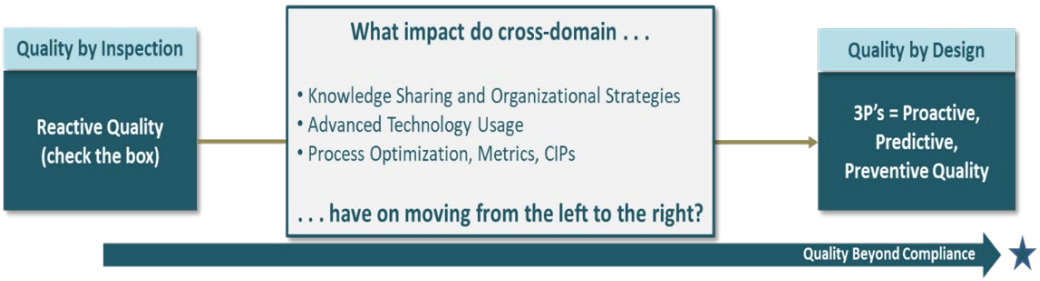


Figure 1: Opportunity Tool Kit

On one end of the spectrum was 'Quality by Inspection'. This area is characterized as a 'Check the box' reactive quality culture, often driven by regulations and compliance. On the far end of the other side is

the well-known concept of 'Quality by Design' and we defined it as the place where the 3P's reside: an organization that embraces the Proactive, Predictive, and Preventive quality culture and heading in that direction are the Quality beyond compliance aspirations. This tool kit was developed to help illustrate the different establishments of Quality at an organization and if there are opportunities for that organization to adopt or try a new strategy or practice to help them move from the left to the right. Our hope was for the data to show the impact of cross-domain knowledge sharing, integration of technology, cross-functional process improvement, etc. had on progressing companies towards the Quality by Design culture. The sample size for this study was not large enough to provide a distinctive conclusion on those impacts but we do have a better understanding on the importance of approaching quality from multiple angles in order to make a collective difference on effectiveness and efficiency improvements. In conversations with our SMEs, we all agreed the majority of industry fall within the left side of the spectrum. For instance, the SMEs shared how many companies continue making program investments focused on reducing study failures, reducing rejected IP, and improving outcomes of an audit, which are all reactive approaches to Quality.

QMS elements, which included a variety of processes, practices, and quality activities, were scored for their efficiencies, and compared from one domain to the next (full list of QMS elements in Appendix). Various business benefit achievements from recent program investments were examined, as well as upcoming changes for any shifts in the approach to managing quality across different functional areas. The survey asked our participants to share their current use of technologies in the Quality space and determine the areas they are most actively investigating in for the near future, which we believe provides valuable information for vendors and providers to ensure alignment with industry. We provide a section summarizing technology for quality and the priority investments later in this paper.

The key learning from the compilation of data is the importance of considering multiple aspects of quality in order to improve overall performance. It is critical to break down the domain walls and ensure that cross-functional quality within an organization becomes a possibility. Although quality approaches may need to differ for various quality functions, we believe the pivotal step for companies to consider is boosting the collective ownership of quality with an end-to-end perspective; the quality of raw materials in R&D will impact what is produced in manufacturing which will impact a patient or customer experience with that final product, impacting company reputation. All quality domains are connected and to continue a 'to each their own' approach would be a disadvantage for any company.

Ultimately, participating companies can use the study findings to support their quality improvement journey by confirming or discovering new strategies to improve quality performance by domain, by understanding their ranking to peers, the status and investment timeline to optimize QMS elements to boost operational effectiveness and efficiency, and by gaining detailed knowledge of the software provider landscape.

Survey Demographics and Design Strategy

Our survey design process started with interviewing both industry and provider SME networks to explore different Quality-directed learning opportunities, followed by several working design sessions to establish and test those priorities in focus groups (see Figure 2). We appreciate the 20+ organizations who all contributed to the review and improvement of the study design. Special thanks to our partnership with several Quality experts from peer consulting firms including James Man and Richard Fautley from Syneos Health, Nicole Falk from KPMG, and Alex Tryba and Gero Neidlinger from Main5.

The virtual design sessions and focus groups took place from April through May of 2021 and the survey responses were collected from May 24 – September 24, 2021.

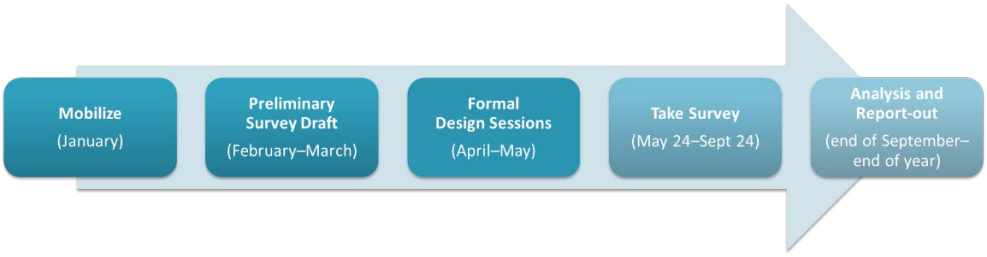


Figure 2: 2021 Quality Benchmark Survey Approach and Timeline

We developed a Quality Domain Framework for the study. The 4 Quality Domains are: Corporate Quality, Commercial Quality, R&D Quality, and Regulatory Compliance (see Figure 3). Corporate Quality represented the overarching quality functions at a company. R&D Quality consists of pre-clinical and clinical research and development; Commercial Quality is made up of the manufacturing, production, and supply chain quality functions as well as public interactions. Regulatory Compliance domain represents the quality functions within regulatory that support all aspects of the product lifecycle. Recognizing that quality functions may be expressed differently for individual companies, the framework was presented to be inclusive and not limited to what was explicitly defined in the graphic.

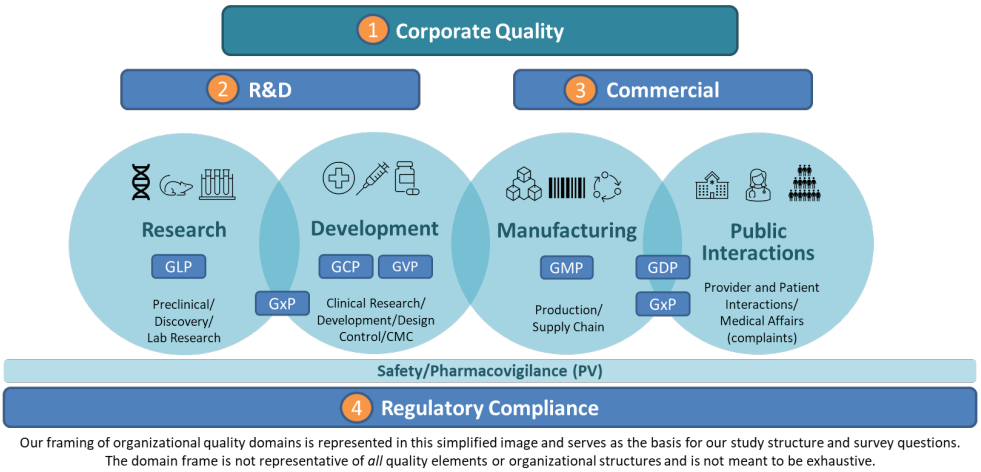


Figure 3: Quality Domains

For this study, 22 participating companies represented a range of companies by size and geographic location (see Figure 4). We treated the data as more directional and look forward to future opportunities to expand the sample size for increased confidence with empirical data.

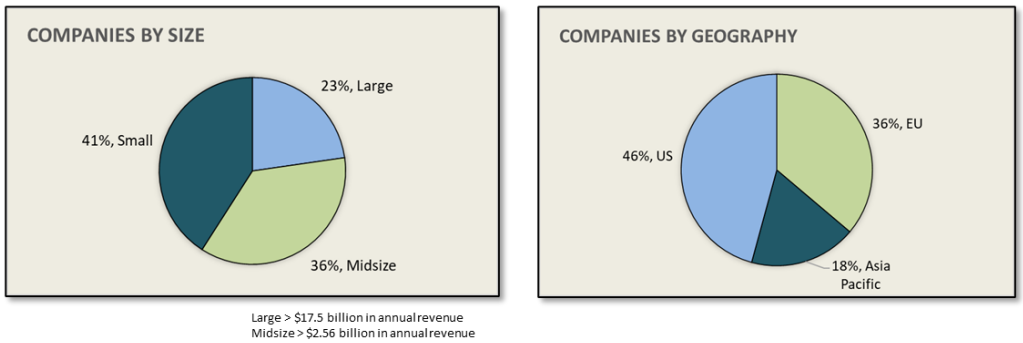


Figure 4: 2021 Quality Benchmark Demographics

The survey was designed for various quality functions to complete their corresponding sections (those that worked within R&D Quality answered the questions within the R&D Quality Domain section and so on). Individual cross-domain reports allowed companies to better understand their internal quality landscape. Figure 5 reveals the product portfolio for the participating companies, most with biologics and/or pharmaceuticals products.

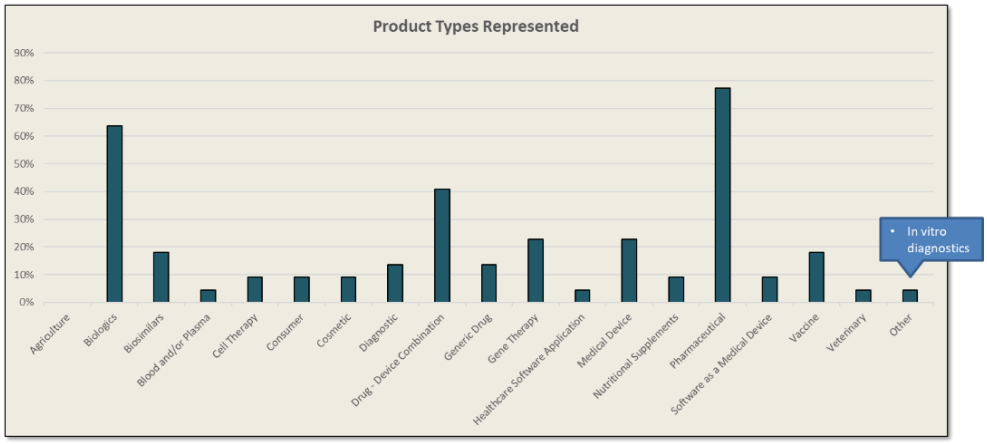


Figure 5: 2021 Quality Benchmark Product Portfolio

Current Quality Baseline

A core component of all our benchmarks is a peer-to-peer comparison, broken down by company tier size (Figure 6). The score for each company was calculated based on their responses for QMS Efficiencies, Metrics Characteristics, Risk Characteristics, Benefits Achieved, and Time to Report across their different Quality Domains. Unlike our larger empirical studies, the distribution of these 22 companies did not reveal any obvious tier size advantage or better quality performance. Looking at the

data and reviewing the findings with our Quality SMEs, we believe that Quality strategies, process improvement work, system upgrades, and integration are still in the early stages. Companies are very interested in exploring modernization options, as well as shifting the thinking about Quality from a compliance driven task to business improvement paradigm which is viewed as an enterprise asset.

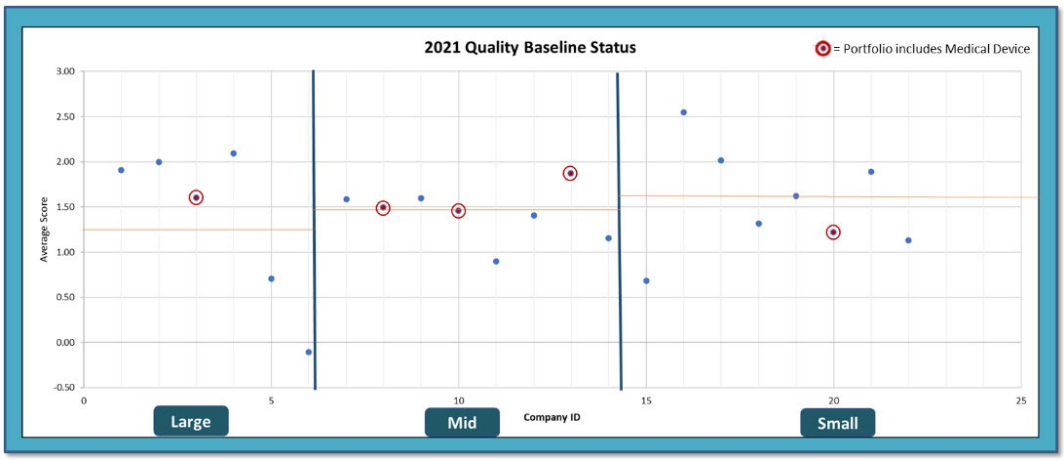


Figure 6: Peer-to-Peer Quality Performance Status

In KPMG's article, *Quality 2030: quality inside*, they describe what a transformed quality function in the future could accomplish, including preventing "compliance issues, potential fines, and reputation damage before they occur, reducing "the burden and reliance on internal audit by proactively identifying quality risks", and leveraging "technology that can automate and monitor quality real-time, resulting in a continuous improvement loop". These are all key components of the Quality by Design concept that has been around for many decades yet, the conversation about this culture of quality remains stagnant. In our study, a SME collaborator described it as the 3P's: Predictive, Preventive and Proactive Quality, which we incorporated into a diagnostic tool for companies to use based off the results from this study (detailed in the executive summary). *Quality 2030: quality inside* states that current quality functions, "grapples with a number of limitations and requires structural change to become future-ready. Therefore, industry frontrunners will leverage learnings from previous attempts to transform, insights from other industries, and innovative partnerships to enable strategic quality goals and objectives." The data from this study addresses some of these limitations, mainly cultural ones that require a shift in thinking about quality, and measure how companies are organized structurally. Conversations with participating companies and collaborating SMEs tells us that the incentives for quality transformation have not been optimal enough to produce sustaining change.

Organizational Strategies

The first Quality domain we explored was Corporate Quality; this section of the survey was designed to explore existing quality reporting hierarchies, organizational size impact on quality functions, and general cross-collaboration knowledge sharing strategies. The data showed that although 84% of participants have a chief quality officer or head of quality, there were no clear reporting relationship

standard practices or pattern by size of company. It is still very common for Quality functions to exist as separate entities within a company. In general, the data suggested a lack of awareness on any particular quality strategies organizations are moving ahead with. We believe this indicates a status quo approach to quality, which is characterized by that traditional mindset of compliance driven quality. Not only are organizational behaviors more commonly reactive, each quality domain also views quality processes as their own. Most companies that we spoke with value the notion that Quality should be everyone's shared responsibility, but we were not able to capture that ideal with our data. Our interpretation of the data is that quality is very critical for all organizations but managing quality is very much a siloed approach where each quality domain manages their own functions. Although there continues to be thoughtful conversations about end-to-end process thinking for quality, it is not a common industry practice today. Our data did not show clear plans for change, in terms of organizational reporting strategy, yet we do see the trend towards centralization in the next 2 years, supporting our belief that companies understand and appreciate the benefits of more quality collaboration and are aspiring towards the cross-domain 'culture of quality'.

At the end of each section of the survey, we asked our participants to share with us additional quality-focused strategies and practices that have been successful at their companies. Several responses highlighted the successful use of review boards, in particular Change Control review boards. Other responses focused on Management reviews, quality system maturity reports, and establishing formal governances. We recognize all these as valuable and smart applications to provide oversight on quality and foster cross-domain collaborations.

Part of most organization's quality management oversight includes the use of Quality Councils and Knowledge Sharing Forums. During out initial survey design, many of the Quality experts emphasized the importance of these councils and forums since they can indicate how effective a company transfers quality information and experiences across different quality functions. From the data, we learned 60% of companies do not have cross-functional Quality Councils; those that use quality councils remain within a specific quality area and the purpose of their councils were for broad purposes. The data on knowledge sharing practices were similar to the findings for the quality councils, where the focus was on identifying the challenges and inefficiencies and less on sharing that information across functions with the intent to improve the challenges with actions. As companies expand their quality strategies to become more cross-functional, they can also improve the use of their quality councils by narrowing the scope to focus on actions necessary for specific quality-related improvement outcomes.

Cross Domain Comparison Summary

One of the main benefits of dividing the survey into specific Quality Domain sections is being able to compare Quality performance and characteristics across functions within individual organizations. This brings great value to participating companies by providing a bird's eye view of Quality across their enterprise and giving measurement to Quality efficiencies and practices from one functional area to another. Having the direct comparison of Quality programs, strategies, and the business benefit status can highlight where the organization is succeeding in terms of Quality management while also revealing

existing gaps, disconnects and areas of opportunity to improve Quality activities. We understand that R&D Quality functions may require a different approach to managing their QMS elements compared to the Commercial Quality functions, however, we believe great learning opportunities and benefits exist if those connections between the different quality domains were more open and fluid. Having a pulse on how one group deals with challenges may allow another group to discover a solution that could be beneficial for their domain as well and help to practice the end-to-end thinking on quality.

In general, the cross-domain analysis is more applicable for the individual participating companies since that data provided more comprehensive information for the corresponding company. Due to a lower sample size, the summary trends of the domain comparisons are directional data only. Although the impact of particular strategies and approaches remain elusive for the overall cross domain comparison, we are able to see some trends that make sense. Figure 7 summarizes the overall Domain comparisons for QMS efficiencies, status of domain metrics program, and the business benefits status.

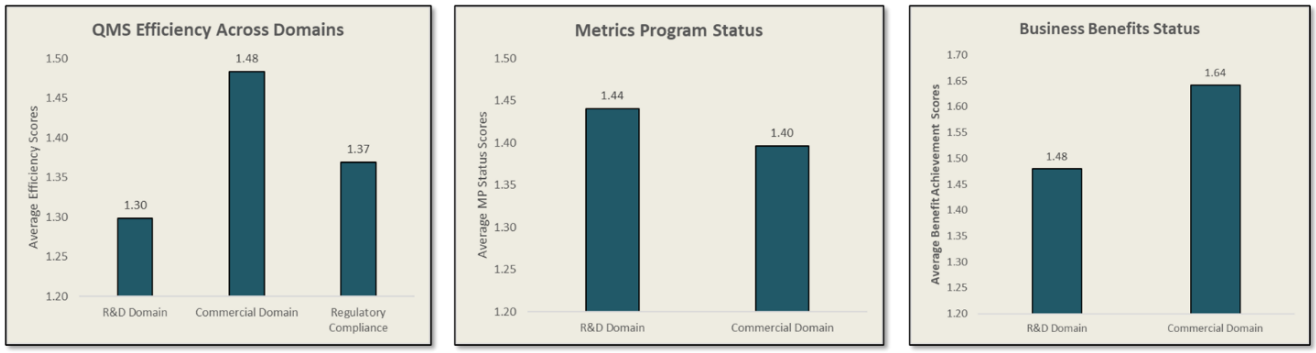


Figure 7: Cross-Domain Comparisons

QMS efficiencies in the Commercial domain measured greater than the other quality domain areas. From referencing other research and work, we do see that most quality related research are in the commercial domain. The processes and practices tend to be more formal and regimented in the commercial areas due to the QC and QA heavy production mode, especially when compared to the R&D domains where the culture tends to be less rigid and encourages what the name describes: to research and discover. In general, the more efficient QMS elements for all domains were often the elements that were easier to be characterized as more measurable and definable, such as equipment maintenance and calibration, audits and inspection management, and Annual Product Quality Review. QMS elements such as Quality Risk Management, Supplier quality control and Knowledge and information sharing were notably less efficient across domains. These QMS elements tend to be more cross-functional and naturally more complex to manage.

The overall cross-domain comparison also showed the Commercial Domain had a much higher planned investment in advanced technologies and their business benefit status was also higher. We had anticipated this result as commercial organizations tend to be more mature with Process Management and Line Key Performance indicators. Additionally, the rapid shift to virtual inspections helped drive priority investments towards innovative virtual inspection technology.

The study asked companies to describe business benefits derived from recent quality program investments within specific domains. For those working in the Commercial Domain, there were many more instances of responses stating they've 'reached an optimal level' for business benefit achievement compared to the R&D domain where benefits were more commonly 'partially achieved'. Again, we believe there are cultural elements at play for these responses, where R&D areas focus on "discovering" and by the time a product arrives in the commercial domain, the focus shifts to "optimizing". The top 5 strategic initiatives are the same for both the R&D and Commercial domains, which were 1) Implementing or improving QMS software, 2) Improving quality and effectiveness of CAPAs, 3) Improving supplier management, 4) Establishing or enhancing metrics program to track quality performance, and 5) Integrating workflow and data across systems within domain. Interestingly, both domains had comparable establishment of metrics programs and similar levels of planned change for their strategic initiatives, so it is hard to draw a conclusion as to what specific factors contributed to greater QMS efficiency, whether it is the use of technology, greater headcount, process maturity, domain culture, or something else.

Tables 1 and 2 compare business benefit status for R&D Quality to Commercial Quality with some similarities and differences. In Table 1, reduction of product recall and patient safety issues were the obvious top priorities over time while more benefit outcomes on virtual inspections and business process management are welcomed and can improve overall performance. In our 2020 World Class Regulatory Information Management study of 70 companies, end-to-end process work, specifically in change control and label management areas, were top initiatives as both the commercial and R&D quality domains contribute to those efforts.

Highest Benefit Realization (Optimal + Partially Achieved)	R&D	Commercial
Reduction of Product Recall	n/a	81%
Reduced Patient Safety Issues	65%	75%
Improved Outcomes of an Audit or HA Inspections	58%	73%
Better Integration of Business Processes	74%	67%
Fewer Study Failures / Quicker Course Correction	67%	n/a

Table 1: R&D vs. Commercial Domain for "highest benefit" realization

Table 2 demonstrates the targeted benefit priorities in the next 2 years with improved access to real-time information and improved customer relations as a result of improved complaint processing are both equal priorities regardless of domain. We see cross-functional end-to-end process work and data connectivity as key investment areas through other research that resulted in real-time information as a critical business benefit for internal efficiency and external customer relationships.

Targeted Priorities in the Next 2 Years	R&D	Commercial
Improved access to Real-Time Information	32%	33%
Improved Outcomes of an Audit or HA Inspections	26%	17%
Improved Customer Relations as a result of improved Compliant Processing	25%	22%
Better Integration of Business Processes	16%	22%

Table 2: R&D vs. Commercial Domain for "targeted benefit" priorities in the next 2 years

Opportunities for Improvement Across Quality Domains

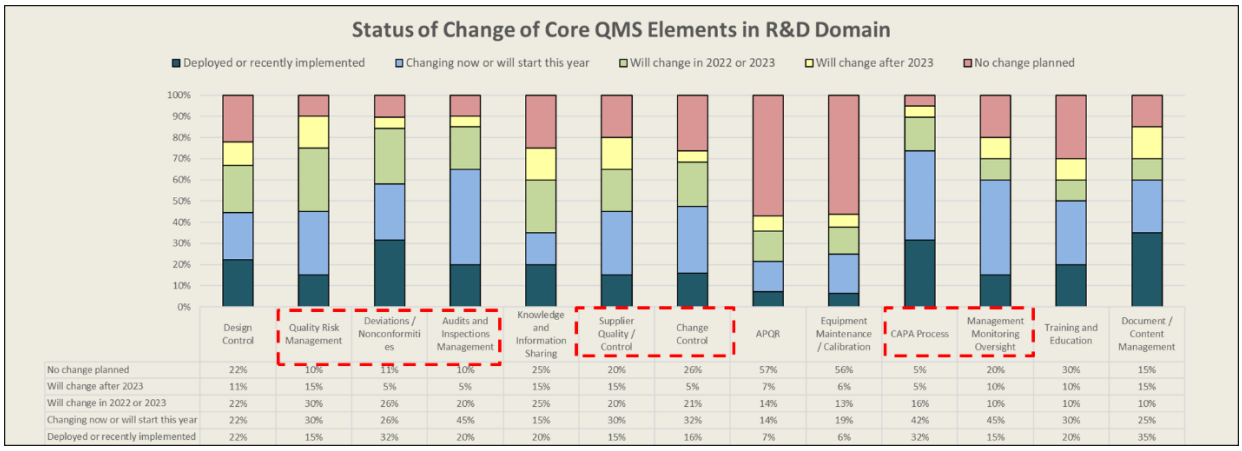
A key learning theme was focused on the combination of factors that impacted a company's quality experience. Throughout the study, we cut and recut the data in different ways to test our theories on whether certain strategies or organizational practices resulted in higher efficiencies or improved quality performance. For example, we hypothesized that companies using cross-functional quality councils would have overall higher QMS efficiency scores; however, there were no strong correlations. What we realized was how there are many factors that impacts a company's quality experience including organizational structure, process maturity, system integration, use of KPIs and technology, and degree of cross-functionality. A singular focus on a critical component, such as the establishment of an effective Knowledge Sharing forum, is not effective for overall quality improvement. The degree of quality improvement becomes much more significant when all the factors are considered: establishing the knowledge sharing forum where the combination of domain specific KPIs and metrics are shared and used to drive actions across functions for an end-to-end quality process that is managed with the use of technology and system integration for consistency. We believe the improvement of cross-functionality *and* process maturity for managing these elements will lead to better efficiencies.

Embracing the 3P's

Thinking about the elements in a multi-dimensional and integrated way helps companies embrace the culture of becoming a learning organization, which we see as a critical step towards the Quality by Design concept. Another major factor is changing the way companies usually think about quality. The KPMG research found ~40% of quality resources were spent on reactive activities such as nonconformity resolutions, corrective actions, and complaints handling, amongst their client work. In fact, most organizations we spoke with agreed that the use of lagging indicators and tracking of events that have already happened are their core common metrics and KPIs. If companies are to embrace the 3P's, a first step could be integrating predictive tools and identifying metrics and KPIs that are not currently being tracked. By using leading indicators (e.g., early warning indicators) instead of lagging ones (e.g., number of complaints), the focus on quality can shift to prevention instead of remediation. Adapting to this new proactive perspective may not come naturally at first, but there will be many rewards and benefits to

encourage the new practice. The FDA commissioned a multi-year study from the University of St. Gallen to examine quality metrics and quality management to develop an enhanced Pharmaceutical Production System Model. Although the study focused mostly on manufacturing and production (data collected from 381 manufacturing sites and 66 QC lab locations), there were valuable insights that could be applied to other quality functions as well, such as assessing behaviors and capabilities and cultural and technical competencies. The St. Gallen FDA Quality Research states that "Quality excellence describes an advanced approach to quality which goes beyond merely being compliant with regulations. Quality excellence is patient-driven, culturally embedded and built into the processes and behavior of an organization."

Lack of industry standards leads to continuous effort on fundamental processes such as CAPA and Deviations Management. In our study, we asked each domain about their plans for change to the core QMS elements. We were surprised to find that in both the R&D (Figure 8) and Commercial domains, the data indicates more than 50% of participants are either changing now or plan to change in the next 2 years for the following processes: CAPA process, audits and inspection, change control, and deviations management because we understand these to be foundational processes; what kinds of changes are companies doing for these processes? And how long will they continue to invest resources for what should be a standardized process by now?



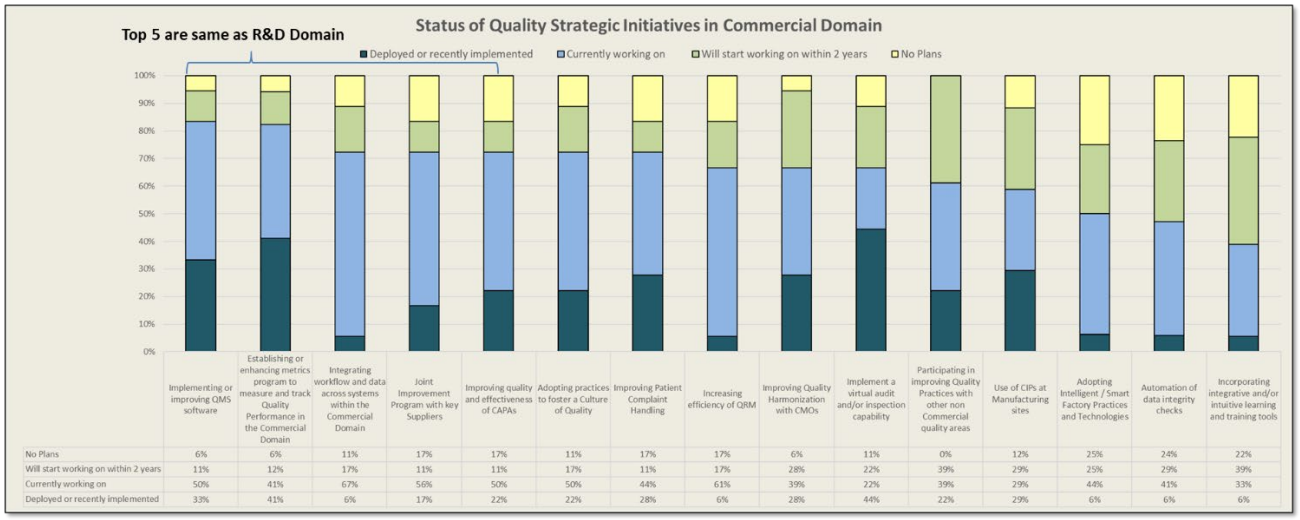
	Design Control	Quality Risk Management	Deviations / Nonconformities	Audits and Inspections Management	Knowledge and Information Sharing	Supplier Quality / Control	Change Control	APQR	Equipment Maintenance / Calibration	CAPA Process	Management Monitoring Oversight	Training and Education	Document / Content Management
No change planned	22%	10%	11%	10%	25%	20%	26%	57%	56%	5%	20%	30%	15%
Will change after 2023	11%	15%	5%	5%	15%	15%	5%	7%	6%	5%	10%	10%	15%
Will change in 2022 or 2023	22%	30%	26%	20%	25%	20%	21%	14%	13%	16%	10%	10%	10%
Changing now or will start this year	22%	30%	26%	45%	15%	30%	32%	14%	19%	42%	45%	30%	25%
Deployed or recently implemented	22%	15%	32%	20%	20%	15%	16%	7%	6%	32%	15%	20%	35%

Figure 8: Changes to QMS Elements in R&D Domain

It has been almost 20 years since the FDA launched their Pharmaceutical Quality for the 21st Century Program where the goal was to establish industry standards, in particular the CGMP area. Their initiatives included encouraging the early adoption of new technologies, facilitating industry application of modern quality management techniques, including implementation of quality systems approaches, and encouraging implementation of risk-based approaches on critical areas. The efforts have made progress, such as collaborating with the ICH to develop a "pharmaceutical quality system based on an integrated approach to risk management and pharmaceutical science". They helped develop guidelines for ICH Q4B (Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria), ICH Q8 (Pharmaceutical Development), ICH Q9 (Quality Risk Management) and ICH Q10 (Pharmaceutical Quality Systems), which is a framework to promote continuous improvement of quality throughout the product

life cycle. Yet, our study results and conversations with our quality SMEs reveal that not only are companies dissatisfied with the quality performance at their companies (too siloed), they are still working on optimizing processes that should be fundamental, resulting in significant resources being applied to tactical work. According to KPGM, the actual total cost of quality is significantly higher than historically reported, "with hidden costs - driven by complicated policies, unclear CAPA processes, unnecessary escalations, and excessive internal auditing - often raise the total to as much as 5-6% of total revenue instead of the reported 1-2%."

There are plenty of opportunities for improvement across all quality domains. Figure 9 presents the work happening with strategic initiatives in the Commercial Domain and the top 5 are the same for the R&D Domain. As companies continue to develop quality strategies and explore news ways to improve quality, our study can help reiterate that while many strategies are well known, the establishment and integration is not yet mature.



	Implementing or improving QMS software	Establishing or enhancing metrics program to measure and track Quality Performance in the Commercial Domain	Integrating workflow and data across systems within the Commercial Domain	Joint Improvement Program with key Suppliers	Improving quality and effectiveness of CAPAs	Adopting practices to foster a Culture of Quality	Improving Patient Complaint Handling	Increasing efficiency of QRM	Improving Quality Harmonization with CMOs	Implement a virtual audit and/or inspection capability	Participating in improving Quality Practices with other non Commercial quality areas	Use of CIPs at Manufacturing sites	Adopting Intelligent / Smart Factory Practices and Technologies	Automation of data integrity checks	Incorporating integrative and/or intuitive learning and training tools
No Plans	6%	6%	11%	17%	17%	11%	17%	17%	6%	11%	0%	12%	25%	24%	22%
Will start working on within 2 years	11%	12%	17%	11%	11%	17%	11%	17%	28%	22%	39%	29%	25%	29%	39%
Currently working on	50%	41%	67%	56%	50%	50%	44%	61%	39%	22%	39%	29%	44%	41%	33%
Deployed or recently implemented	33%	41%	6%	17%	22%	22%	28%	6%	28%	44%	22%	29%	6%	6%	6%

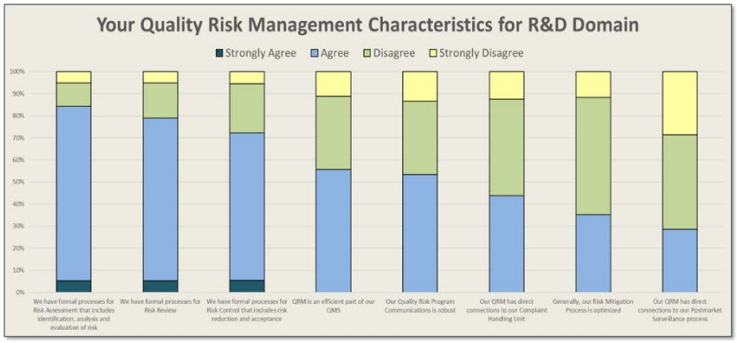
Figure 9: Strategic Initiatives in the Commercial Domain

Closing the loop on many of these strategies are the key to making gains on the quality improvement journey. Injecting some innovative thinking for quality is also highly recommended. Technology advancements and solutions will continue to evolve and help alleviate some of the tribal-knowledge or person-dependency activities (a major source of inefficiency), really helping to streamline quality processes and bringing those advancements to light. We have also seen many companies prioritize the need to harmonize and standardize systems and data elements, not just in quality, but in regulatory and safety as well. Harmonizing and standardizing systems and data elements across domains will really support teams to move away from tactical and repetitive work, allowing them to focus more time on higher value activities such as focusing on patient / customer satisfaction and company reputation. Our SME's shared a noticeable shift in their current client work where there is much more focus on patient and customer experience, helping to push regulations-driven quality towards quality beyond compliance.

Pandemic Impact on Supplier Quality and Quality Risk Management

Supplier quality management (SQM) and quality risk management (QRM) were identified as priority areas to focus on throughout our study. We view these two QMS elements as challenging processes to manage for most companies because they are complex, cross-functional, and often involve a lot of stakeholders. Massive supply chain disruptions in all sectors and large-scale unpredictability with risks and risk management resulting from the COVID-19 pandemic only add more layers of complexity to the mix.

For strategic initiatives, 60% of the R&D domain and 56% of the Commercial Domain are currently working on improving their SQM; 45% of participants in the R&D domain described their SQM as "Not efficient", and >50% of survey respondents have current plans to change their SQM across domains, which we believe are driven by the pandemic experience. Due to the on-going pandemic, companies must continue reassessing their supply chains because consistency and reliability for high supplier quality is essential for all organizations. Traditional drivers of supply chain management, such as cost-control and efficiency, are no longer the only priorities; companies now must re-strategize to ensure supply continuity and resilience to disruption risks. We all witnessed this firsthand at the beginning of the pandemic where masks and pharmaceuticals were resonant examples. Supply shortages caused by the pandemic current events have laid bare the realities and strategic risks associated with the globalization of supply chains, specifically the reliance of manufacturing supplies from countries like China. Companies might be interested in lining up backup suppliers or finding new sources of raw materials, but these come with risks as well, including quality and efficiency risks. When the pandemic is over, it will be interesting to see how SQM shifts for organizations. There may be an opportunity here for application of advanced technology to help integrate this process across all quality domains to streamline the process and provide real time information and access to all users and impacted parties. 30% of survey participants are considering a knowledge management (KM) sharing forum for SQM because they do not currently have one, while 40% do have a KM forum but it is not cross-functional.



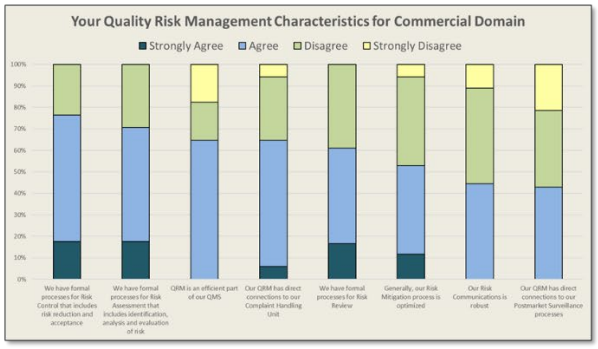


Figure 10: Quality Risk Management

Quality Risk management is the other priority area for improvement that we noticed throughout the survey. For strategic initiatives, 65% of the R&D domain and 61% of the Commercial Domain are currently working on improving their QRM; 42% of participants in the R&D domain described their QRM

as “Not efficient” or “Very Inefficient”. Given the current global environment and the scale of unpredictability, calculating risks have never been harder or riskier. Since there are so many different types of quality risks (e.g., program risks, product risks, supplier risks, etc.), we decided on a general approach to understanding Quality Risk Management characteristics of organizations. All organizations need to assess risk effectively and efficiently. To do so requires the use of a risk management process, so we structured our question around ICH Q9, which provides a framework for Quality Risk Management to help teams identify and mitigate risks. In the commercial domain, there was noticeably more “Strongly Agree’ responses across the characteristics than the R&D Domain. In general, we saw that QRM is fragmented within organizations. Our SME’s commented how most vendors should have solid capabilities to support and manage a variety of Risk Management processes including risk assessment, risk review, risk mitigation, etc.

Technology Strategy and Priority Investments

Across Life Science divisions, the 3 common themes in technology conversations include:

1) What is my Digitization Strategy?
2) How can I simplify and better connect our systems to further enhance productivity, efficiency, and achieve real-time information access?
3) What should be managed via the Cloud/Software as a Service model and what do we keep internally?

For Quality, our view is the modernization cycle that has enhanced other divisions such as Clinical, Regulatory, and Manufacturing over the past 10 – 15 years is now on the doorstep for Quality. Modernization cycles in our opinion take 5 – 7 years to complete and enhancing Quality contribution to the greater organization is clearly at the forefront. Figure 11 represents the investment effort in several technology areas. Improving the transactional system (e.g., QMS Platform) is typically the first step in the modernization cycle and is a prerequisite to more advanced technology utilization. There is a clear priority for QMS modernization, reporting / data analytics enhancements, integrations across systems, and Master Data Management for almost all participants.

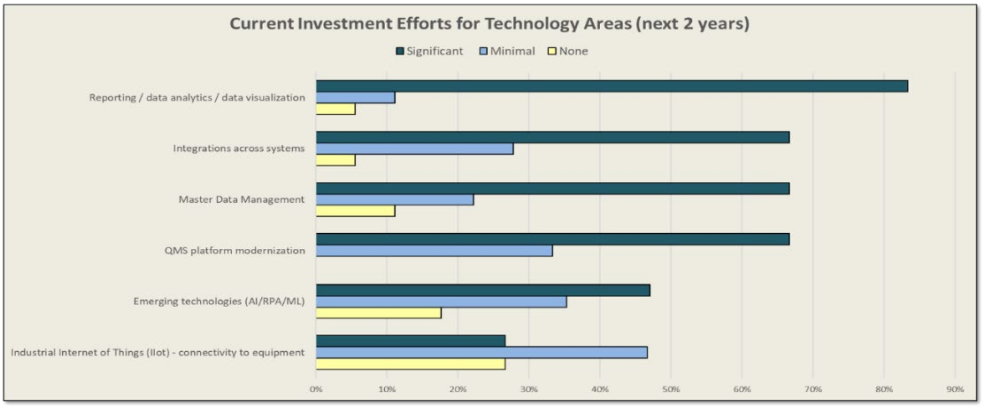


Figure 11: Investment Effort

The other dimension on modernization is the decision to consolidate providers (extended platform) or to stay in a "best of breed" technology strategy.

It is very clear in Figure 12 that both Content Management and eQMS capabilities are rapidly shifting to an enterprise approach while most have standardized their Learning Management System. We also see several emerging providers and historic market leaders offering more modules in their overall Quality solutions (referring to Content Management, LMS, and eQMS). Longer term, this will impact the overall economic health of small niche solution providers.

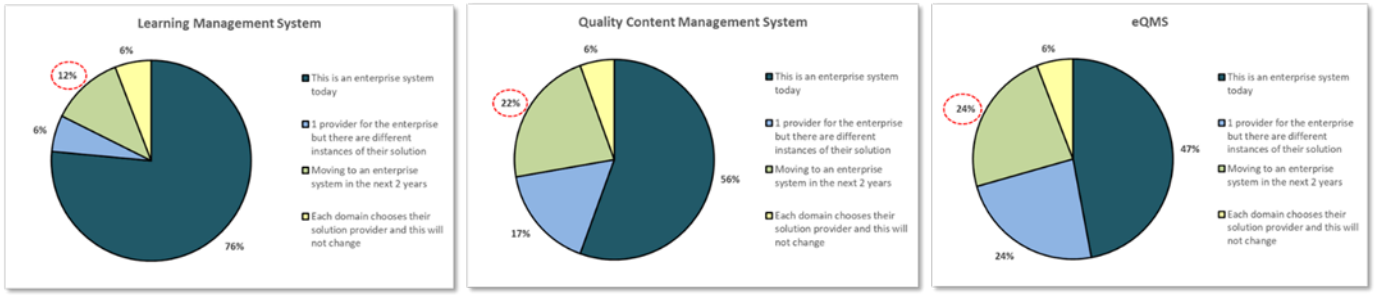


Figure 12: System Strategy by Solution Type

One of the key themes we see with our collaborators is that existing data is underleveraged. As technology adoption grows and new solutions emerge, it will be interesting to see how quality functions use the technology to leverage their data in ways that support progress towards those 3P's.

The Commercial domain has a wider variety of active experimentation with a focus on Virtual Reality (for inspections), Business Process Management, and Document / Process Automation.

Structured Content Authoring (SCA) has the highest degree of interest in the R&D Domain and this aligns with our 2021 SCA Pulse Survey (n = 25) where the Clinical Protocol, Label Documentation, and the Clinical Study Report where top interest areas.

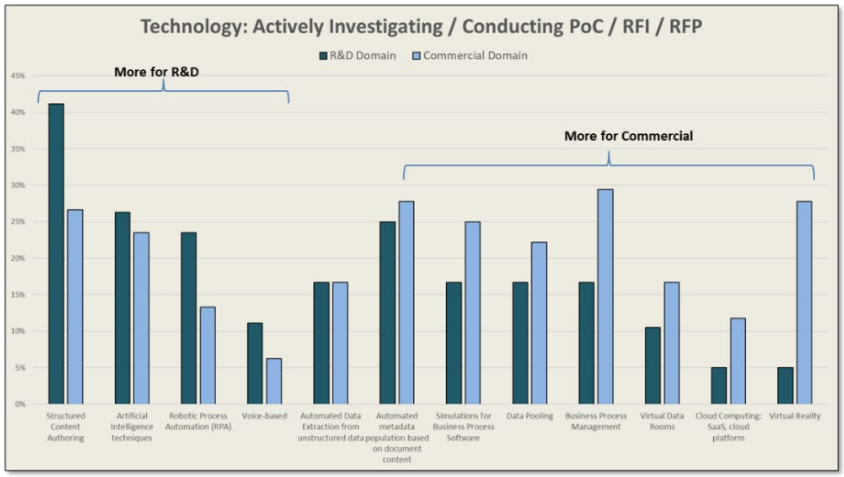


Figure 13: R&D vs. Commercial Domain for Active Investigation for Technology

Finally, we typically review software provider market share, customer satisfaction, and our innovation index data in our study reports, however, with 22 companies participating representing each tier of the market, we believe the sample size might not reflect (with confidence) the actual market standing. Please contact us if you wish to explore what we learned on individual software provider landscapes.

Study Conclusion

Although Quality beyond Compliance remains an aspiration for most companies, the path to get there is becoming more visible. Our study detected some hints of hesitancy from companies to make bold business cases to accelerate the Quality organization improvement space, as most are still in the initial stages of weighing the pros and cons of quality-related strategies and approaches. Quality by Design concepts are well known and the conversations surrounding the culture of quality are starting to gain some steam, perhaps even driven by the pandemic environment and more focus on the customer and patient experience. The next milestones will be establishing industry standards for fundamental processes to ensure and enable a shared vision of quality beyond compliance.

Ultimately, what we discovered from the study is companies are eager to learn how to make quality a more strategic investment. Organizations are starting to invest in solutions to help connect and automate quality capabilities. As more and more companies shift their thinking on Quality by championing quality as an enterprise asset, taking an end-to-end perspective on quality processes, practicing ways to incorporate the 3P's, and easing up on the siloed approach to managing quality, we will see the acceleration of overall quality improvement. The key to progress is cross-functionality, holistic shared quality vision and value, implementing preventive quality measures, and establishing formal governances. As we stated in the executive summary, boosting the collective ownership of quality within companies is the goal. We hope you find this study summary helpful. Please contact us with any questions.

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Steve has deep experience in strategy formulation and implementation, organization development and performance, industry benchmarking, information management strategy, and facilitating strategic change. He consults with all sized companies and those that are growing and scaling. He has a Master of Science in Organization Development from American University with distinction for his field work and a BS in Business Computer Science. Steve is a frequent speaker and was named to both the 2017 PharmaVoice 100 entrepreneur category and the 2020 Innovations in Pharmaceutical Development for his contributions to industry. sgens@gens-associates.com

Appendix

QMS Elements

1. Annual Product Quality Review
2. Audits and Inspection Management
3. CAPA Process
4. Change Control
5. Deviations / Nonconformities
6. Design Control (for Medical Device)
7. Knowledge and Information Sharing
8. Management Monitoring and Oversight
9. Document / Content Management
10. Quality Risk Management (general risk)
11. Supplier Quality / Control
12. Training and Education (i.e., LMS)
13. Equipment Maintenance and Calibration (Laboratory) (*R&D Domain Only*)
14. Post Market Surveillance (*Commercial Domain only*)
15. Product Disposition / Batch Release (*Commercial Domain only*)

Recent Gens and Associates Inc. Benchmark History

1) 2013 Managing Regulatory Information as a Corporate Asset (n = 37)
2) 2013 Regulatory Operations Pulse
3) 2013 CTA Pulse
4) 2013 EDMS and Digital Archive: One in the same?
5) 2014 Regulatory IT Resource Pulse
6) 2014 Next Generation RIM and Regulatory Intelligence: Strategy, Investments, and Status (n = 41)
7) 2015 Product Registration Investment Pulse
8) 2015 Next Generation Content Management (n = 21)
9) 2015 Addressable Market update (solution and services)
10) 2015 Legacy Product Outsourcing Pulse Survey
11) 2016 Pursuing World Class RIM: Strategy, Measures, and Priorities (n = 54)
12) 2016 Enterprise Content Management Governance Structure Pulse Survey
13) 2017 Safety Systems Trends: Innovation, Operating Model and Growing TCO Pulse (n = 17)
14) 2017 Regulatory Services and Software Addressable Market Analysis Update (top 500)
15) 2018 Pursuing World Class RIM: Connections to QMS, Supply Release and Product Change (n = 72)
16) 2018 Submission Content Management Capability Change Investment Pulse (n = 10) – Top 30
17) 2020 World Class RIM: IS Industry at a Performance Tipping Point *(n = 70)*
18) 2020 COVID-19 Regulatory Impact Pulse Survey (*n = 183 – Individual Response Survey)*
19) 2021 Structure Content Authoring Pulse Survey (n = 25)
20) 2021 Elevating Quality Beyond Compliance (n = 22)
21) 2021 IDMP Architecture Pulse Survey (n = 13)
22) 2022 World Class RIM: Accelerating Business Value (open – expecting 80 + organizations)

Company Website

www.gens-associates.com

References and Sources

1) Quality 2030: quality inside, KPMG, 2019. (https://assets.kpmg/content/dam/kpmg/xx/pdf/2019/09/quality-2030-quality-inside.pdf).

2) FDA Quality Metrics Research 3rd Year Report, University of St. Gallen, December 2019. (https://item.unisg.ch/en/divisions/production-management/st-gallen-fda-quality-metrics-research).

3) Pharmaceutical Quality for the 21st Century A Risk-Based Approach Progress Report, Department of Health and Human Services U.S. Food and Drug Administration, May 2007. (https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/pharmaceutical-quality-21st-century-risk-based-approach-progress-report).