White Paper

From Paper to Platform: The AI-Driven Evolution of Quality Management Systems

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Introduction

As medical device and in vitro diagnostics companies face increasingly complex regulatory demands, the need for a smarter Quality Management System (QMS) is becoming more urgent than ever. Greater complexity requires a more agile shifting from reactive execution to proactive, data-driven quality management. This white paper explores the transformation of QMSs — from paper-based solutions to connected, AI-enhanced digital ecosystems — and how this evolution strengthens both patient safety and commercial performance through the delivery of high-quality healthcare solutions.

An AI-infused QMS has the potential to elevate regulatory readiness, streamline documentation, and improve risk management. However, organizations must avoid a scattergun approach to AI adoption. Similarly, a wholesale embrace technology is unlikely to succeed when targeted implementation is required. AI will optimize quality assurance and regulatory affairs (QA/RA) operations through its strategic adoption — an evolution not a revolution underscored by controlled implementation, enhanced data literacy, and carefully cultivated change management that keeps a focus on the most important outcome: the provision of safe and effective patient solutions.

Whether you are at the beginning of your digital QMS journey, consolidating fragmented systems, or exploring the potential of AI, this white paper offers actionable insights to align quality with business goals and compliance obligations.

The following pages draw on the expertise of three QMS specialists — one a current practitioner — representing several decades of hands-on experience. During IQVIA's recent LinkedIn Live webinar — From Paper to Platform: The AI-Driven Evolution of Quality Management Systems — all three shared actionable insights, which feature throughout the white paper and are summarized here:

Seven key takeaways

1. **The pace and maturity of adoption varies** but the direction of travel is clear. Agile and effective QMSs will be digital, connected, and — increasingly — infused with AI.

2. **AI could be the answer. But not always**. Not every problem is a nail, so not every solution requires a hammer. Be strategic in your application of AI.

3. **Positive and continuous reinforcement matters.** In the interest of successful change management, explain why new and unfamiliar workflows and technologies will ultimately accelerate timelines and deliver more effective results.

4. **Identify a champion within the business.** Get close to someone in marketing or operations to better understand their needs and to align your delivery with outcomes that benefit the wider organization. They will help QA/RA position the value of investing in digitized QMS solutions.

5. **Turn data into information and information into action.** Leverage AI's ability to interrogate vast volumes of data, and augment its capabilities with human intelligence, insight, and experience to optimize decision making.

6. **Begin with the end in mind.** Develop a clearly defined scope that supports a clearly defined problem statement. This allows you to focus on those things that are beneficial and ensure you have senior stakeholder alignment.

7. **The ultimate endpoint is patient safety.** The output is not technology. Technology is a means to an end, driving the timely provision of safe and effective patient solutions. Don't confuse the two.

Introducing the five-step evolution of QMSs

The first step — a paper-based QMS — remains an option for some, as the survey results below demonstrate. Increasingly, however, companies are moving beyond paper alone. Some are using a combination of paper-based processes together with digital point solutions, with all the challenges that presents — siloed workflows, and no single source of truth among them.

Others, having finally jettisoned paper, are left with an assortment of point solutions, few of which — if any — are connected. In the spirit of connectivity, others are adopting single, enterprise QMS solutions. Meanwhile, those at the limits of maturity are deploying an enterprise QMS with embedded AI.

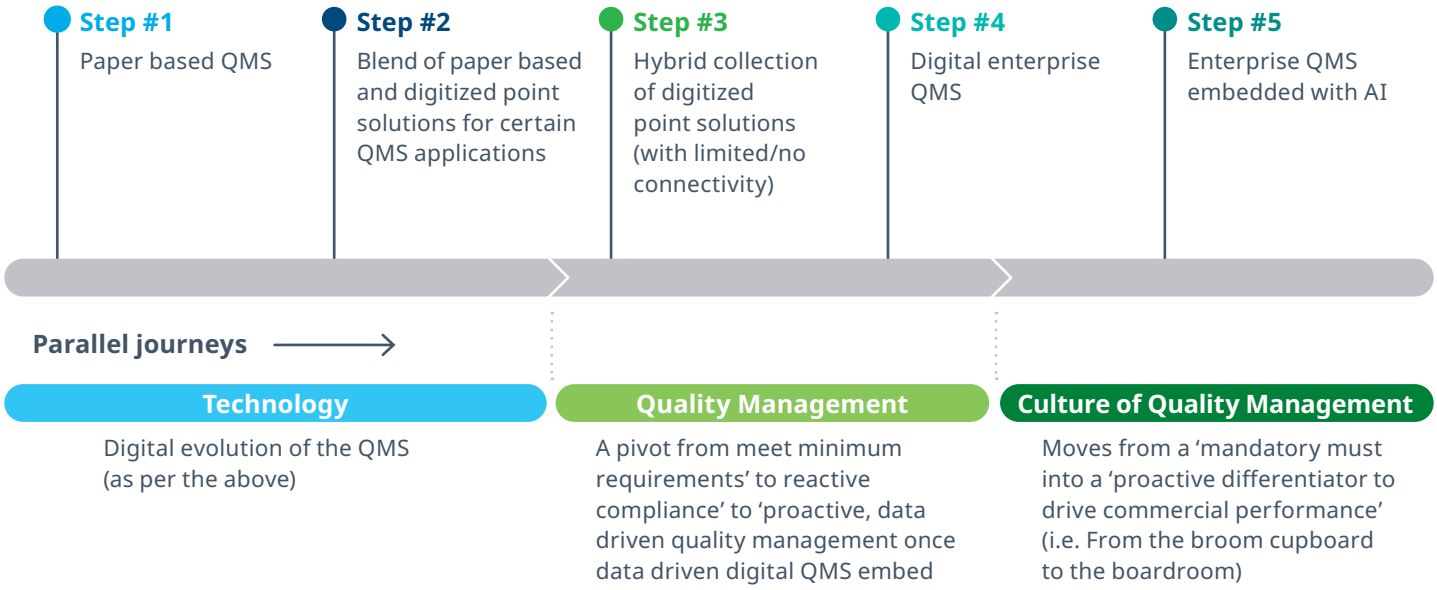
As the graphic demonstrates, technological advancement must be accompanied by parallel cultural and management journeys if organizations are to bring their people along.

Mike King: We would all love to work with a single, AI-enabled solution, but we don't go from walking ten meters to running a marathon overnight. These journeys need clear milestones and checkpoints. Why? Because the output isn't technology, the output is safe and effective global products. Is the technology revolutionary? Yes. Is the journey we're on revolutionary? No. It's all about patient safety.

Hannah Seevaratnam: Paper-based systems are often cumbersome and complex, making the maintenance of logs and the validation of records, for example, very difficult. Equally, using point solutions makes it very challenging to compare data and perform analysis from it. That's why I'm in favor of implementing out-of-the-box solutions.

Sankara Narayanan: Paper-based systems will not suffice. Today's more complex manufacturing demands that quality management also drives operational efficiency. We see that multiple stakeholders now need to participate in quality management. Aging and fragmented systems prevent the creation of effective business practices and increase the risk of failure.

Figure 1: The five-step evolution of QMSs

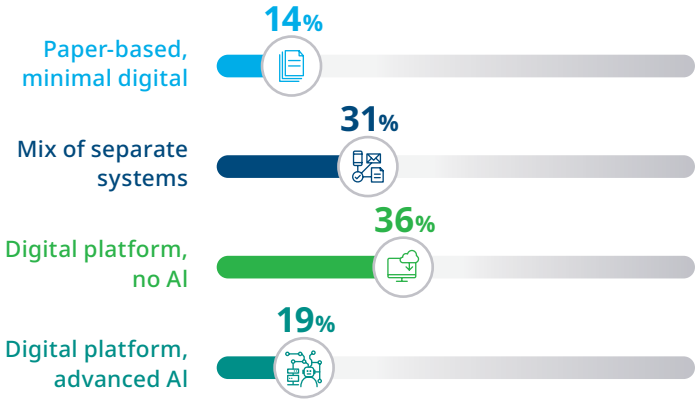


Assessing adoption maturity

In the run-up to IQVIA's most recent LinkedIn Live webinar, we asked QA/RA practitioners where they are on their QMS adoption journey. This poll (see Figure 2) provides an indicative view of the evolution of quality management systems.

According to the results, 14% of organizations continue to rely on a paper-based system, with minimal or no digital footprint. By contrast, one in five are deploying a digital platform featuring advanced AI. In between, just under a third (31%) are using a largely separate mix of paper and digital solutions, while just over a third (36%) have deployed a digital platform with no AI capabilities (this final category encompasses steps three and four in the IQVIA five-step QMS evolution path described previously).

Figure 2: Where is your organization today in its Quality Management System (QMS) evolution?



While these middle two options reflect the state of maturity currently experienced by most organizations, it is the first and fourth options that provide more points of reflection. For some, 14% understates the number of firms — small companies, especially — that remain reliant on paper. For others, the 19% using digital platforms with advanced AI might overstate the adoption of AI — notwithstanding that, in this context, it is AI in all its forms, not only generative AI.

The pace of change will vary from company to company and is informed by a range of issues. Paradoxically, global regulatory complexity — notably, the verification and validation this demands — acts as a brake on new technology adoption for some organizations. Given enterprise solutions — including those infused by AI — have the capacity to ease that complexity, there is a certain irony that compliance fears are slowing uptake.

For others, costs or risk aversion might prove to be barriers, at least in the short term.

King: I grew up in a world that was powered by lever arch files. I then moved into digital point solutions, then a connected digital ecosystem, and now we're looking at AI-enabled platforms. But even today, we come across organizations where the lever arch file is present, sometimes a SharePoint site, too.

We're at a pivot point. How easy is it to make the jump from paper to AI? To borrow a phrase, "it depends and it's complicated." It requires data, document and process harmonization. It also requires cultural harmonization, establishing a point where people understand why certain controls — data literacy programs, onboarding, recertification — are in place to drive design outcomes and production controls for a regulated industry.

Narayanan: Over the next few years, I expect the share of companies using digital platforms with advanced AI to increase significantly.

Seevaratnam: I find it astonishing that 14% of medical device companies are still paper based given the advance in electronic systems. At the same time, I'm thrilled that people are leveraging AI, although 19% seems a bit high given there are so many unknowns.

14% of organizations continue to rely on a paper-based system, with minimal or no digital footprint.

Identifying the role of AI in QA/RA

AI could be the answer when seeking to address process inefficiencies or identify areas of competitive advantage. However, it is not always appropriate, so it pays to think strategically about its application. Consider use cases that simplify processes, augment validation, accelerate decision-making, and predict errors and outcomes.

Seevaratnam: Looking back on previous projects, I would have loved to have seen automation in the generation of validation scripts. It would have saved countless hours spent validating and undertaking various combinations of testing.

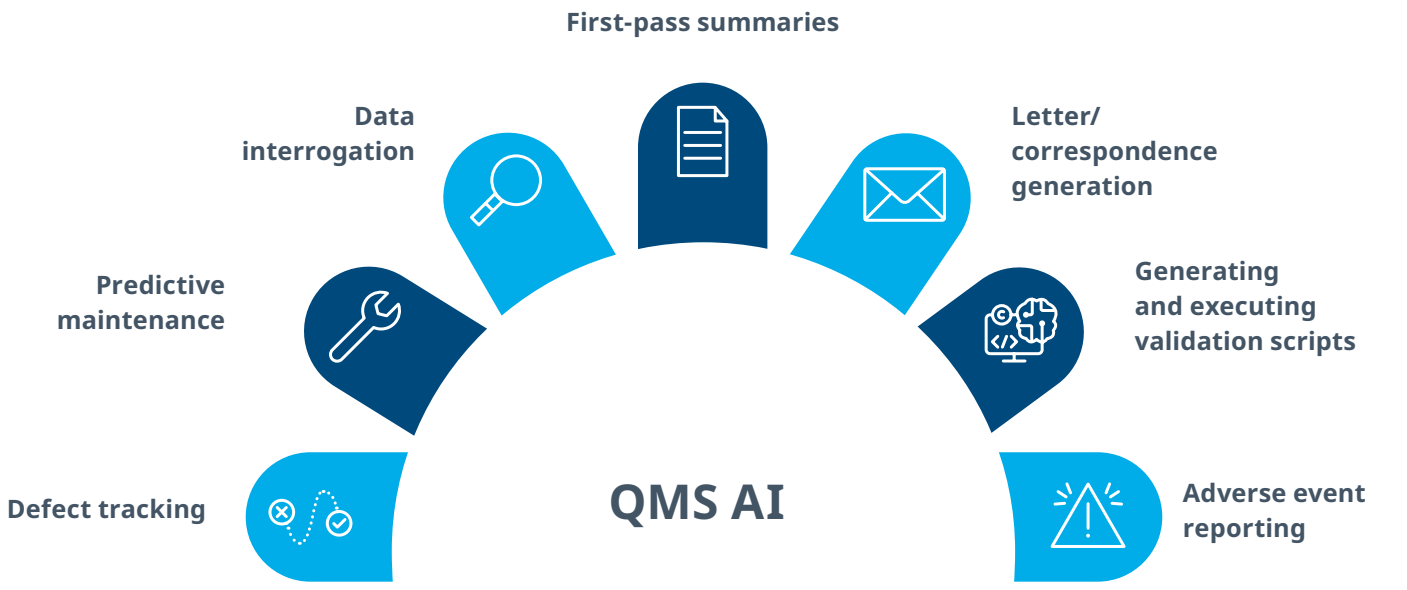
Tools that can automatically review or cross-check validation documentation for completeness and consistency with regulatory standards would be invaluable. Leveraging AI for risk-based data mining and outcome prediction could significantly simplify our processes and enhance decision-making efficiency.

King: There's a phrase we use a lot in the UK: if you've got a hammer, everything looks like a nail. There's always a risk that in the context of current AI advancements, you pick up the magic hammer and start hitting everything. Sometimes you don't need a hammer. Sometimes you need a pair of pliers; sometimes you need a screwdriver. Understanding the issue you are trying to address allows you to make sure you're bringing the right tool to the job.

Narayanan: When exploring AI solutions, make sure that you build them into your workflows while assessing the huge volume of data needed for effectiveness.

King: AI excels at interrogating information. That ability to interrogate existing information, regulations and standards; to give more transparent design inputs; to provide a better understanding of supply and performance; and to offer quality control activity to support adverse event capture and reporting — all these ultimately drive the evolution of better, safer, and faster marketization of good, safe, and effective healthcare solutions. We've got the wealth of data at hand. What we need to do is turn data into information and information into action.

Figure 3: QMS AI use cases



Moving beyond technology: people, culture, and change management

Bringing increased agility and performance to quality assurance is not a technology challenge alone. It is a cultural challenge, too. To optimize QA/RA operations, organizations need to prepare the ground for the coming transformation. It requires project management, change management, and people management.

Successful rollout requires the ability to define scope and purpose with clarity, and the ability to communicate the benefits — and the effort required to reach those benefits — to the whole organization. In other words, those who can best communicate upwards, as well as downwards, are most likely to prosper. It is incumbent on QA/RA professionals to counter misconceptions that their work slows down delivery and threatens commercial outcomes. Sometimes that means identifying champions within key functions of the business. Understand their needs and align the benefits QMS improvement accordingly. Take those champions with you and they can help take the rest of the organization with you, too, by being an independent voice to QA/RA that communicates the value of investment in a company QMS to the broader company.

King: What's required for successful implementation? Good project management and people. Good project managers are worth their weight in gold. That ability to define a clear scope and stick to it. And to manage the risk, milestones, and communication throughout the project is absolutely key. It's about having a clear purpose and being able to explain why the project matters.

The second thing is people. Even though we are talking about technology, it's people who deliver, it's people who use it, and it's people who drive better patient outcomes. Intrinsically, the key to successful technology is the ability to help people use that technology.

Seevaratnam: At Robling, we recently implemented a new CAPA (corrective and preventive action) module. During the training, some people pointed out the workflows are detailed and structured adding more work for the CAPA owners. I had to remind them that even though it may seem like it was taking more time, this new process is more thorough — meeting all our regulatory requirements and leaving no space for interpretation — and that, over time, the learning curve will dissipate and we will all get comfortable with the new system. Positive and continuous reinforcement is very important.

Narayanan: First and foremost, this should not be about implementing AI everywhere, but it should be about offering the right AI solution that has been designed to understand the underlying workflow or data privacy needs. The technology should be relevant to the QA/RA professionals and it should be aligned with globally mandated processes, procedures, documents and data required by regulations and standards.

King: Communicate in terminology that senior stakeholders understand. In our world, we talk a lot about the cost of quality versus the cost of non-quality. But if you can frame the benefits in terms of topline growth, process efficiency, process effectiveness, and compliance — and then you put some tangible outcomes against each of those categories — the business will see improvements as you roll through the project.

Demonstrating value and realizing ROI

As we explored in the previous section, it's not enough to deploy technology. You must be able to make the case for change in order to bring your people with you. And you must communicate economic value. How, then, can organizations best demonstrate the value of QMS adoption? How do they illustrate the likely return on investment (ROI) of growing technical maturity?

At its broadest, value can be proven by showing topline growth and/or by achieving greater operational effectiveness and efficiency.

Beyond these two pillars of financial return, there are other expressions of value that are no less important to a company operating in the healthcare space. For example, adoption of an enterprise digital platform — one that is increasingly likely to be embedded with AI — delivers a greater likelihood of staying on the right side of regulatory compliance, increasing patient safety, and reducing the possibility of reputational damage. Connected QMS ecosystems provide a single source of the truth which, in turn, provides transparent, consistent, and actionable data.

AI promises another source of value: it can offer an antidote to human fatigue.

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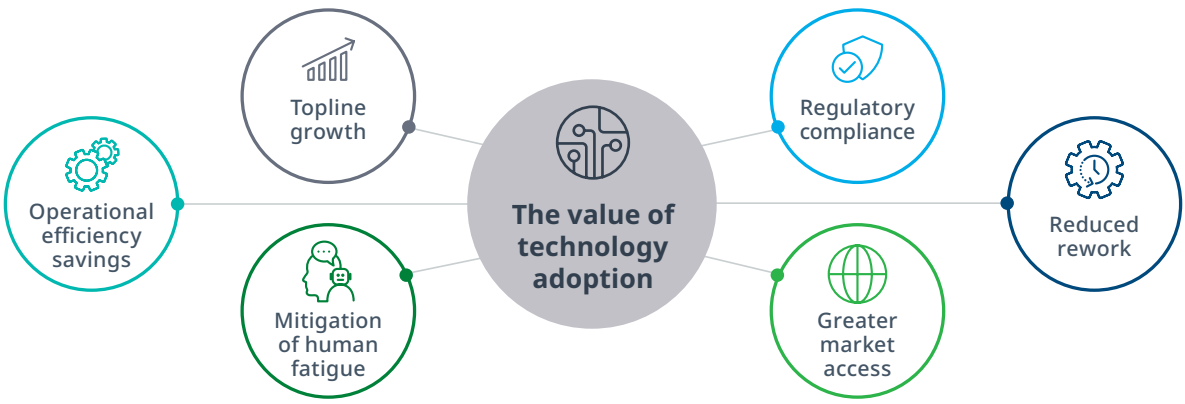
Narayanan: These AI technologies can scan social media platforms, they can monitor customer service inboxes, and they can flag protocol issues or adverse events for human review. The value here is that you mitigate and reduce the risk of human fatigue.

At the same time, humans still retain control, agreeing or disagreeing with what is being flagged before sending that feedback to the AI engine. This is especially useful in areas such as adverse event recording, where you have large cases or high-volume events that require capture.

King: Part of your communication with the C-suite is not just an initial pitch in terms of value, topline growth, and bottom-line profitability. It's also about continually reinforcing how you've improved the risk profile of the organization, driven better audit reports, enabled local market access, or reduced the cost of rework.

Ultimately, every dollar the company invests in QA/RA is a dollar not invested elsewhere. So, you need to ensure that value is clearly seen and that you have stakeholders in the room who will fight for your cause because they understand that the benefits of investing in QA/RA are enterprise-wide.

Figure 4: The value of technology adoption



Conclusion

The choice of the word “evolution” in the title of this white paper is deliberate. The journey to quality management excellence may feature revolutionary technology, but the path to success should be measured and deliberative. As demonstrated over the preceding pages, maturity of adoption varies dramatically while the pace of change that is applicable to one company will not be suitable for another. In a highly regulated, patient-centric environment, evolution is entirely appropriate.

Nevertheless, the direction of travel across the ‘five-step QMS’ evolution is clear. Those still reliant on paper-based systems — wholly or in part — will lack the agility to meet commercial and compliance imperatives. Meanwhile, those who are on a journey to a single-platform approach to quality management — one likely to be infused with AI capabilities — are likely to prosper, especially in a more complex and exacting world.

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Final thoughts from our QMS experts

Seevaratnam: As we continue automating our QMS, I envision leveraging AI for defect tracking and predictive maintenance on the equipment side. We’re definitely moving in that direction.

Narayanan: Ensure your plans are cost-effective, economically viable, and affordable. Be financially savvy rather than simply chasing technological advancements or rolling out AI for its own sake. Make the rollout customer-centric by fully understanding the business context — know your products and services, your route to market, and identify maturity levels and areas of opportunity.

It’s about developing solutions that optimize resources while keeping patient safety at the forefront.

King: Always begin with the end in mind. Define a clear scope and problem statement to focus on what truly adds value. Secure senior stakeholder alignment and assemble the right team to drive solutioning. Communicate the change and its value, recognizing that in a regulated environment with defined processes and outcomes, you must cost out your solution and select the right AI or digital system for that original problem statement. In healthcare, the ultimate output is patient outcomes.

At the end of the day, we’re people helping people improve global health — and that should guide everything we do.

About IQVIA

IQVIA (NYSE:IQV) is a leading global provider of clinical research services, commercial insights and healthcare intelligence to the life sciences and healthcare industries. IQVIA's portfolio of solutions are powered by IQVIA Connected Intelligence™ to deliver actionable insights and accelerate innovations. With approximately 88,000 employees in over 100 countries, IQVIA is dedicated to accelerating the development and commercialization of innovative medical treatments to help improve patient outcomes and population health worldwide.
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With over 20 years of experience leading global teams in regulatory affairs and quality assurance, Mike King, as Senior Director of Product & Strategy at IQVIA, ensures healthcare solutions meet complex global regulations and oversees platforms like SmartSolve® eQMS and RIM Smart to streamline quality and regulatory compliance processes.

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Sankara Narayanan joined Frost & Sullivan in 2005 and has held research and consulting roles at its Canada and India offices. Sankara has experience in handling industrial cyber security, Quality Management Systems, Manufacturing Analytics, and Smart Manufacturing/ manufacturing software markets. He received a master's degree in Electronics from Sathyabama Institute of Science and Technology. Sankara lives in Toronto, Canada, and enjoys riding his Harley-Davidson Sportster during the summer. In his free time, Sankara likes traveling and exploring different countries.

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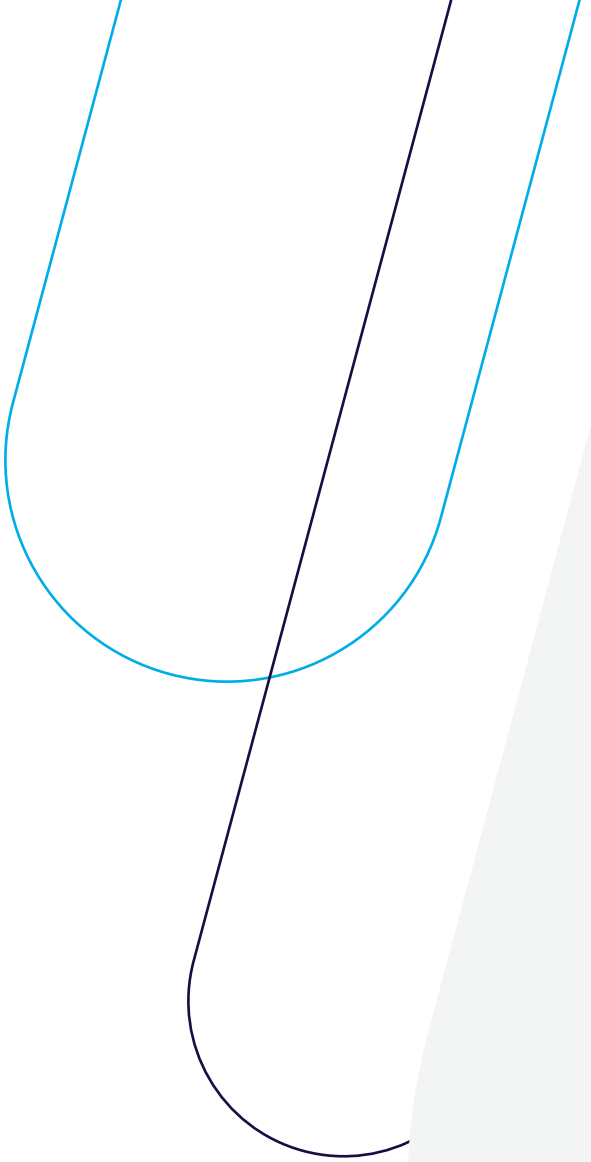
Hannah Seevaratnam has accumulated over 20 years of experience in the healthcare industry, spanning the medical device and pharmaceutical sectors. She has led global projects focused on restructuring Quality and Regulatory organizations, with an emphasis on harmonizing quality processes and systems, evaluating resources, and eliminating redundant roles.Hannah has successfully led multiple remediation workstreams and managed audits to bring a company under a Consent Decree back into compliance. Additionally, she implemented the SmartSolve platform in her previous role and is currently working on its implementation at Robling Medical.



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