White Paper

Quality by Design, Quality by Process, Quality by Culture

Creating enterprise ownership of quality in the GxP AI Era

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Introduction

Within many healthcare organizations, global quality and regulatory teams are viewed as custodians of compliance. Operating within the bounds of global regulations and standards, such as U.S. 21 CFR, EU MDR, EU IVDR, ISO 13485 and others, they design procedures, maintain records, manage audits and inspections, provide oversight and engage with global regulatory bodies in a range of activities from pre-market to post-market. A core focus of their profession is to ensure healthcare products are developed, manufactured, and distributed in accordance with global regulations and standards to ensure that evidence of their safety, performance, and efficacy is objectively documented and justified. While these responsibilities remain essential, they represent only one aspect of modern enterprise quality management.

Leading healthcare organizations increasingly recognize that quality cannot be delegated solely to a Quality Assurance or Regulatory Affairs department. Product quality, patient safety, regulatory compliance, operational performance, and commercial success are all influenced by decisions made across research and development, manufacturing, supply chains and supplier networks, commercial operations, and executive leadership. The most mature organizations therefore pursue a different objective: enterprise ownership of quality.

This evolution mirrors many of the principles discussed in modern quality management literature, where quality is increasingly positioned as a strategic business capability rather than a compliance function alone. Quality becomes embedded within the design of products, the execution of processes, and the culture of the organization. The result is an operating model that simultaneously strengthens patient outcomes and regulatory performance and drives cost-effective business results.

This paper explores three interconnected dimensions of quality maturity: Quality by Design, Quality by Process, and Quality by Culture, and examines how a single-platform Quality Management System (QMS) and Regulatory Information Management (RIM) environment can support all three.



Quality by Design

The principle of Quality by Design is well established within healthcare and manufacturing. Attributed to the work of Joseph Juran and later adopted across regulated industries, the concept focuses on building quality into products and processes from the outset rather than relying on downstream inspection and correction. This investment in 'the cost of quality' reduces 'the cost of non-quality' and improves product quality while delivering a favorable commercial outcome for an organization.

Within healthcare organizations, Quality by Design extends beyond product development. It encompasses the design of operating models, governance structures, regulatory strategies, and technology ecosystems. Quality becomes a characteristic of a company's operating model and the authority delegated to different departments and roles.

Organizations operating globally must manage differing regulatory requirements, different product classifications, variable market requirements, multiple languages and variations inherent in business units serving different clinical needs that address different clinical needs. As organizational complexity increases, the ability to configure quality and regulatory processes around the organization's specific needs becomes increasingly important.

A modern healthcare Quality Management System (QMS) and Regulatory Information Management (RIM) platform supports this objective by enabling organizations to design controlled processes that reflect the true variability in their operating model, rather than forcing teams to adopt disconnected or inflexible workflows that can come from generic, cross-industry solutions. Design control activities can incorporate global stakeholder inputs from engineering, clinical, manufacturing, quality, and regulatory teams. Strategic regulatory planning can be aligned to product development objectives and global market access goals from the earliest stages of product development.

The value of this approach becomes particularly evident when managing global submission and product registration programs. By including design inputs beyond those of the traditional U.S. and EU markets, and by ensuring companies 'design for registration', the end-to-end product launch activities can be optimized by reducing the need for rework that can occur if products are designed and launched for the U.S. and EU only, and are then taken to markets that require specific technical, toxicological and clinical testing (e.g. China, Russia). Similarly, post-market activities such as adverse event reporting, which involves varying local templates and reporting timelines, post-market surveillance, inspections, and audits benefit from a common framework established at the design stage of a company's activities.

Quality by Design therefore creates the foundation upon which quality and regulatory excellence can scale globally with a positive effect across all company departments.

Quality by Process

If design establishes intent, process determines execution.

Many healthcare organizations continue to operate fragmented quality and regulatory ecosystems consisting of spreadsheets, local databases, standalone technology applications, and manually maintained document repositories. While individual systems may perform effectively in isolation, the interfaces between them often introduce operational risk as professionals must manually connect related quality records and ensure the continuity of traceability through the use of unique identifiers.

Quality and regulatory records rarely exist independently. A product complaint may unearth a systemic issue that leads to a non-conformance investigation, a CAPA, a design change, updated product or process documentation, additional training activities, supplementary supplier actions, updated regulatory submissions, and potentially, field actions or recalls. Maintaining traceability across these activities becomes increasingly difficult when records reside in separate applications with different identifiers, workflows, and reporting models.

Quality by Process focuses on preserving the integrity, traceability, and continuity of those relationships while optimizing the operational efficiency and effectiveness of an organization. Single-platform QMS and RIM environments provide interconnected process architecture that maintains the chain of custody across quality and regulatory activities. Relationships between records are established once and preserved throughout the lifecycle of the activity. This reduces the risks inherent in manually connecting related quality records, removes duplicate data entry, and improves decision making through giving a digital line of sight across related quality records.

An equally important benefit is the reduction of cognitive burden on employees. Quality and regulatory professionals are highly trained specialists whose value lies in scientific judgment, risk assessment, regulatory strategy, and continuous improvement of products, processes and systems. Their productivity is diminished when excessive administrative effort is required simply to navigate multiple systems and manually manage data transfer. A unified user experience, common workflows (accounting for true variation by business unit, country, and process where needed), and standardized reporting reduce operational friction. Teams spend less time performing administrative transactions and more time applying professional expertise to deliver improved patient outcomes and optimized commercial performance.

Modern platforms also extend beyond the boundaries of the quality organization. APIs and integration frameworks enable controlled connectivity with ERP, PLM, MDM and other company systems. Quality processes therefore become part of a broader digital ecosystem while maintaining enterprise governance and traceability.

Quality by Culture

Quality culture is frequently discussed but often poorly defined.

A true culture of quality exists when individuals throughout the enterprise view product quality, patient safety, and regulatory compliance as shared responsibilities rather than departmental obligations. Decision-making becomes aligned around long-term quality outcomes, and employees have both the visibility and accountability required to act proactively in the interests of patients, products and company performance. These three are intertwined and not mutually exclusive.

A key to building a culture of quality is transparency. Single-platform environments create enterprise-wide visibility through common data models, analytics, dashboards, and reporting capabilities. Leaders can identify trends, assess risk, monitor compliance performance, and investigate underlying records from a single source of truth. The discussion shifts from debating which dataset is correct to understanding what actions are required to improve patient, product and business outcomes. Visibility drives accountability, and accountability drives engagement.

Importantly, quality culture is strengthened when technology returns time to employees by optimizing their daily activities. When organizations eliminate redundant work, reduce manual reconciliation, and minimize administrative inefficiency, quality and regulatory professionals gain additional capacity to focus on improvement initiatives, process engineering and new product innovation, which directly contributes to advances in patient safety. This creates a self-reinforcing cycle by allocating time back to Quality by Design.

Quality by Design enables controlled and scalable operating models that account for variances in global regulations, requirements and standards at the outset. Quality by Process ensures those models execute consistently and efficiently across enterprise organizations. Quality by Culture provides the organizational mindset and employee empowerment necessary to continuously improve both.

Together these three principles establish a feedback loop that deepens operational maturity, strengthens management oversight, reduces risk, and supports sustainable commercial growth. The net effect is a significant advance in improving patient safety, product and process quality, and commercial performance.

The GxP AI Era

As Artificial Intelligence (AI) becomes increasingly embedded within healthcare operations, the same principles that govern quality management in healthcare must also govern AI for it to be used safely and effectively in the GxP environment.

Organizations seeking to deploy AI within QMS and RIM applications require clearly defined use cases, identification of applicable regulations and standards, trusted data and AI governance, model oversight, suitable validation approaches and a clear understanding of human accountability. Without these foundations, AI in QMS and RIM could introduce variability and risk, creating operational challenges and potentially resulting in audit observations during inspections. This becomes particularly acute as companies scale from GxP AI pilots into enterprise-wide operational use of AI in QMS and RIM solutions.

In many respects, AI governance is an extension of established quality management principles:

- Quality by Design becomes **AI by Design** through controlled data architecture, intended-use definitions, validation strategies, and risk-based implementation
- Quality by Process becomes **AI by Process** through governed workflows, traceable decision making, documented oversight and vigilance, and controlled interactions between AI components and regulated processes
- Quality by Culture becomes **AI by Culture** through transparency, accountability, continuous learning, feedback mechanisms, and clear understanding of human responsibility for GxP decisions

When these principles are applied consistently, AI can help improve cycle times, enhance decision support, identify previously unseen trends earlier, accelerate knowledge retrieval, and reduce administrative burden while maintaining appropriate oversight in enterprise QMS and RIM solutions.

The future of GxP AI will be defined by the quality systems that enable organizations to deploy AI responsibly and look beyond the technology to understand how it can be utilized to drive cost-effective compliance improvements in business operations and patient outcomes.



Where IQVIA SmartSolve® differentiates

IQVIA SmartSolve was built around the principle that quality and regulatory excellence are inherently connected. The platform combines QMS and RIM capabilities within a single platform, supported by common data structures, integrated workflows, platform-level analytics and AI capabilities.

The award-winning platform supports more than individual quality processes. It enables organizations to establish connected compliance across design, manufacturing, market access, post-market surveillance, regulatory operations, and lifecycle management. Native connectivity between associated processes improves traceability of connected quality records and automates activities that have historically been managed by human effort in disconnected systems.

Through unified reporting, quality intelligence, and AI-enabled capabilities, SmartSolve supports organizations in moving beyond reactive compliance management toward proactive, enterprise quality performance. In effect, SmartSolve embraces Quality by Design, provides Quality by Process, and enables Quality by Culture to support a company in driving a dual focus on global patient outcomes and commercial performance.

Conclusion

Organizations that embed quality within product design, operational processes, and organizational culture create stronger foundations for global regulatory compliance, operational excellence, and sustainable commercial growth. They move from reactive quality compliance toward proactive quality management:

Together, these principles create an environment where patient safety, product quality, and commercial performance are no longer competing objectives. They become complementary outcomes of a mature, connected, and accountable enterprise.

And as the industry embraces the GxP AI Era, these same principles will provide the foundation for trusted AI adoption in QMS and RIM solutions, ensuring that innovation remains aligned with the ultimate objective of healthcare: delivering safe, effective, and accessible products to patients worldwide.



Quality by Design establishes the framework



Quality by Process enables consistent execution



Quality by Culture creates sustainable behaviors

About the author



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Mike King is the Senior Director of Product and Strategy at IQVIA, where he leads global teams across quality assurance and regulatory affairs. With over 20 years of experience in life sciences and enterprise software, Mike drives innovation for IQVIA's SmartSolve® solution including SmartSolve® eQMS, SmartSolve® RIM, and SmartSolve® Fundamentals, helping organizations streamline compliance and accelerate digital transformation. A recognized expert in AI for regulatory and quality functions, he is passionate about improving patient outcomes and empowering professionals to enhance safety and performance across healthcare systems.

About SmartSolve®: SmartSolve is an AI-enabled, Microsoft Azure-based platform that helps Life Sciences organizations streamline and automate global quality management and regulatory compliance. SmartSolve® eQMS centralizes enterprise-wide quality processes, from design and manufacturing to post-market surveillance, while SmartSolve® RIM manages regulatory submissions, product registrations and health authority interactions. Built on industry best practices, SmartSolve connects teams, data, and workflows in a single platform to drive an optimized focus on patient safety, product quality and commercial performance.

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