

Beyond the Checklist:

Building a Culture of Quality and Compliance

In the rapidly evolving life sciences ecosystem, where data is the lifeblood of research, development, and patient care, ensuring quality and compliance is paramount and goes far beyond simply ticking boxes on a checklist. A truly effective approach requires building a deeply embedded culture of quality that permeates every level of the organization.

This white paper explores what it means to build a culture of quality, why it matters in a data-centric environment, and how Datavant applies these principles to support the compliance obligations of our life sciences customers.

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Why Quality Matters in a Data-Driven World

At its core, Datavant's commitment to quality is driven by a fundamental purpose: to connect the world's health data to improve patient outcomes.

This overarching goal provides the moral and strategic imperative for prioritizing quality, data integrity, security, and reliability in everything we do. Adherence to regulatory obligations, industry standards, and contractual commitments is non-negotiable and the life sciences industry is governed by rigorous standards and regulations, including 21 CFR Part 11, HIPAA, ICH E6(R3), and GDPR.

"GxP" is a general term encompassing the various "good practice" guidelines within regulated life sciences **ensuring safety, quality, and efficacy**, where the "x" represents different specific practices, including:

- 01 Good Manufacturing Practice (GMP)
- 02 Good Clinical Practice (GCP)
- 03 Good Laboratory Practice (GLP)
- 04 Good Pharmacovigilance Practice (GVP)
- 05 And many more...



Our customers entrust us with their data and their confidence. We honor that trust by holding ourselves to the same rigorous standards and by continuously strengthening our culture of quality.

Datavant's GxP Quality Program is built upon core principles of customer focus, leadership, engagement of people, a systematic process approach, continuous improvement, evidence-based decision making, and relationship management. These principles emphasize that quality is not an isolated function but is integrated into the organization's operations and strategy. Datavant's GxP Quality Program is operationalized through a Quality Management System, which considers the multifaceted nature of our business to create a set of quality processes that improve overall efficiency, reduce errors, and increase customer satisfaction through a focus on continuous improvement.

The Role of the Quality Management System

At Datavant, the **Quality Management System (QMS)** is the foundation of how an organization embeds quality into its day-to-day operations.

Far more than a set of policies and procedures, the QMS integrates people, processes, and technology to ensure consistency, accountability, and traceability across the enterprise. The QMS functions as an interconnected ecosystem reinforcing itself to form a closed loop of governance and accountability. Quality and compliance are not confined to individual functions; they are embedded throughout product development, customer engagement, product delivery and implementation, and operational oversight

Software Development Life Cycle (SDLC)

The foundation begins with the Software Development Life Cycle (SDLC) where **quality and compliance are embedded** into every stage of **product design, development, testing, and release**. From the earliest requirements definition, teams perform risk assessments to guide technical decisions, validation activities, and documentation, ensuring that products are reliable, secure, and compliant with regulatory expectations. For example, if a new data exchange feature is introduced, Datavant's engineers partner with quality and security teams to validate that it maintains **HIPAA compliance and traceability from design through release**.

Customer Audits and Assessments

This structured approach extends to Customer Audits and Assessments, where Datavant views external scrutiny as a vital feedback loop. **Risk-based prioritization** determines which areas warrant the most attention, and findings are systematically tracked through Quality Events. **Issues are identified, triaged, and resolved** through structured root cause analysis and corrective/preventive action planning. Each event is evaluated for risk and impact, enabling Datavant to not only resolve individual issues but also to strengthen processes and prevent recurrence across the organization. Over time, Datavant trends data from multiple customer audits to identify recurring themes—such as requests for greater automation in documentation—and proactively strengthens systems to address those needs before they surface again.

Training and competency

None of these systems can operate effectively without **capable, informed personnel**. Training and competency management form the human backbone of Datavant's QMS. Employees are trained according to **role-specific requirements, with risk-based prioritization** personnel in critical functions receive focused development. Competency is verified and documented, providing assurance that staff are fully capable of executing tasks that affect **quality and compliance**.

Vendor Quality Oversight

Because Datavant operates within a complex network of third-party technologies and partners, Vendor Quality Oversight is another critical system. **Vendors and partners are qualified and periodically reassessed through a risk-based process** that evaluates both operational performance and compliance posture.

Quality Governance and Metrics.

The results of all these interconnected systems are monitored through Quality Governance and Metrics. **Risk indicators, audit results, CAPA effectiveness, and training compliance metrics** are monitored through dashboards and regular management reviews, providing visibility into quality performance and guiding continuous improvement. These governance mechanisms **ensure decisions are data-driven** and tied directly to evidence collected from across the QMS.

Document and Record Control

Finally, Document and Record Control acts as the connective tissue linking all other systems together. **Policies, procedures, technical records, and quality evidence are maintained under controlled conditions** to **ensure accuracy, accessibility, and traceability**. Risk-based controls ensure that critical records, such as validation documents or audit responses, are prioritized and safeguarded.

Together, these systems create a dynamic, self-reinforcing loop. An event in one area—whether a vendor issue, audit finding, or training gap—feeds data and lessons into others. The result is a mature QMS that is both resilient and adaptive, where risks are identified early, improvements are systematically captured, and quality is continuously strengthened across every aspect of Datavant's operations.

What is a Culture of Quality?

A culture of quality is a shared commitment and mindset, baking quality into everything we do. It is critical to efficiently and effectively developing and delivering high quality products and services.



Empower

Building such a culture involves empowering personnel at all levels to understand their roles in maintaining and improving quality.



Resolve

It necessitates encouraging the proactive identification and resolution of potential quality issues, rather than just reacting to problems after they occur.



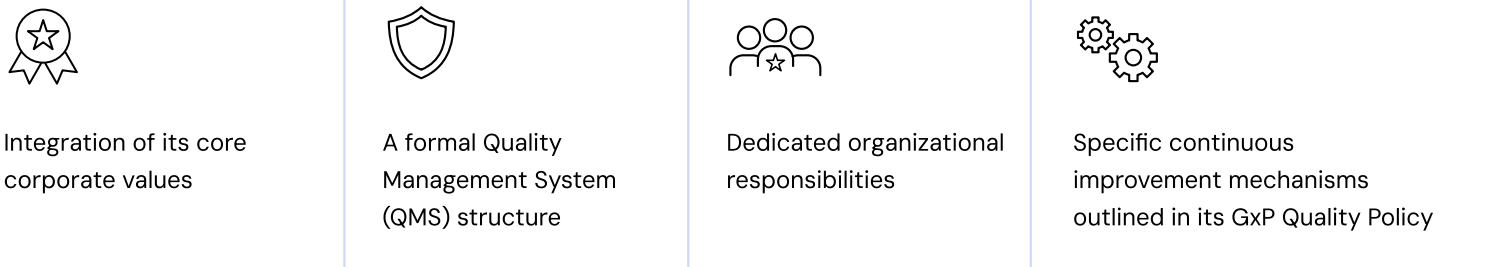
Collaborate

Collaboration across teams ensures that quality goals are shared and challenges are addressed collectively—reflecting Datavant's core value of winning as a team.

Building a culture of quality means moving beyond merely establishing processes and procedures to fostering an environment where quality is a shared responsibility and a proactive endeavor.

How is a Culture of Quality Built?

How Datavant builds a robust culture of quality



Leadership sets the tone for the organization.

Executive management at Datavant consistently emphasizes that **quality is a strategic priority**, not a secondary concern. By incorporating quality into organizational objectives and OKRs, **leadership ensures it is considered in every decision.**

Periodic reviews of the quality management system are conducted and communicated to leadership to assess:

- | | |
|---------------------------------|---|
| 01
Effectiveness | 02
Resource Adequacy |
| 03
Performance Trends | 04
Opportunities for Improvement. |

From Compliance to Excellence

Quality maturity is best understood as a **journey rather than a fixed state**. Organizations typically evolve through distinct stages:

Informal → Repeatable → Managed → Enhanced → Optimized.



At Datavant, this journey reflects the continuous **strengthening of our Quality Management System**, culture of quality, and data-driven decision making.

Each stage represents an **increased level of integration, foresight, and operational control** moving the organization beyond checklist compliance towards **sustained excellence**.

01 Informal

Processes are in place primarily to meet external requirements. Activities may be reactive, with a focus on passing audits and inspections. At this stage, compliance is primarily a checklist exercise focused on satisfying external requirements rather than improving outcomes.

02 Repeatable

Processes are repeatable and monitored, enabling consistent outcomes and improved control. Focus remains on addressing high-risk issues and maintaining compliance rather than driving systemic improvement.

03 Managed

Processes are standardized and well-documented with clear responsibilities, and basic metrics are tracked and performance data is used to set forward-looking quality objectives.

04 Enhanced

Risk-based decision making and data-driven governance guide strategic choices. Continuous improvement is built into every process, and issues are anticipated before they escalate.

05 Optimized

Quality becomes a strategic differentiator. Advanced analytics and predictive tools are used to set new benchmarks for operational excellence and innovation, positioning the organization as a leader within the industry.

Datavant is committed to moving along this maturity journey—continuously strengthening our systems, adopting best practices, and integrating feedback from customers and regulators. Our goal is not just to meet current expectations but to **anticipate and prepare for the evolving demands of a data-driven life sciences ecosystem**.



Building a culture of quality is an ongoing journey, not a one-time project.

In the fast-moving, data-driven life sciences industry, this journey is essential to ensuring trust, compliance, and patient safety.

At Datavant, we view it as a partnership with our customers meeting today's requirements while anticipating tomorrow's challenges.

By embedding quality into both our systems and our culture, Datavant ensures compliance is not a checklist exercise, but a foundation for confidence, innovation, and continuous improvement.

Learn More

www.datavant.com