



Actions Affecting Quality and Data Integrity

Six Quality Disciplines That Enable Predictable, Inspection-Ready Bioanalysis



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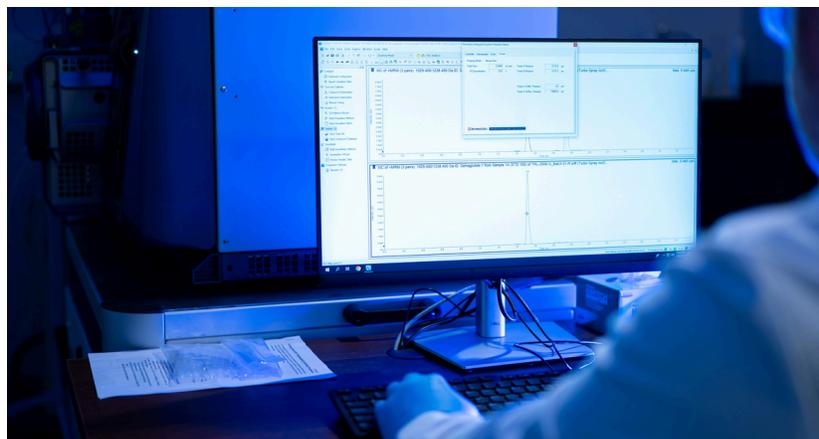
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INTRODUCTION: QUALITY AS AN ENABLER OF SPEED

In regulated bioanalysis, quality and data integrity are not separate from speed. Instead, they're the prerequisites for it. As development timelines compress and regulatory expectations remain well-defined, bioanalytical laboratories are under pressure to deliver results faster without introducing friction through rework, deviations, audit findings or corrective actions.

Across the industry, delays are rarely caused by analytical science alone. More often, they stem from breakdowns in quality discipline: unclear processes, insufficient training, ineffective quality controls or late identification of systemic issues. When quality systems function as downstream checkpoints rather than integrated workflows, timelines become unpredictable and sponsor confidence erodes.

Here we outline six quality disciplines that most directly affect quality and data integrity in bioanalytical laboratories. Together, they form a practical framework for evaluating whether quality systems are enabling progress — or quietly becoming a bottleneck.



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THE SIX DISCIPLINES THAT MOST AFFECT QUALITY AND DATA INTEGRITY



Reducing Audit Findings Through Proactive Trend Management

Audit findings are often treated as isolated events, but in practice they are indicators of broader system performance. High-performing laboratories track audit findings by type, severity and recurrence, using trend analysis to identify root causes before they escalate into systemic issues.

Regular review of audit metrics (paired with cross-functional discussion between quality and operations) enables organizations to address gaps through targeted training, procedural updates or workflow adjustments. Over time, this approach reduces both the frequency and impact of future audit findings, while improving inspection readiness and sponsor confidence.



How Velocity applies this principle

We evaluate audit findings by type and responsible scientist, and review them during monthly quality improvement meetings that include QA leadership and lab operations. Identified patterns are translated into focused training, procedural refinements and shared learnings across weekly operational team meetings to support continual improvement.



Reducing Deviations to Prevent Delays

Deviations are an inherent risk in complex laboratory environments, but high deviation rates often signal gaps in the understanding or application of SOPs and bioanalytical protocols. Left unaddressed, recurring deviations introduce downstream consequences, including additional documentation, investigation cycles and potential delays to data delivery.

Laboratories that focus on reducing deviations at the source through clear procedures, effective training and consistent execution minimize operational delays and preserve momentum. Sustained deviation reduction improves consistency, reduces administrative burden and supports predictable timelines.



How Velocity applies this principle

Any deviations are reviewed with a focus on identifying gaps in procedural understanding or execution. Leadership forums that include principal investigators examine deviation types and contributing factors to inform targeted training, procedural clarification and executed alignment, supporting ongoing reduction in deviation frequency over time.



QC Effectiveness as a Driver of Both Quality and Throughput

Quality control review is one of the most critical, and most misunderstood, aspects of bioanalysis. Ineffective or inconsistent QC review increases the risk of audit findings and rework, while delayed QC review directly slows data delivery.

High-performing laboratories invest in structured QC review processes, clear accountability and ongoing reviewer training to ensure consistency. When QC review is timely and predictable, analytical integrity improves without sacrificing efficiency.



How Velocity applies this principle

We document and track all QC review activities and conduct annual QC training to promote consistency across reviewers.

QC effectiveness is monitored continuously as part of broader quality improvement initiatives, supporting both data integrity and turnaround time.



Training and Competency as Foundations of Productivity

Training is often discussed as a compliance requirement, but in practice it is a primary driver of productivity and consistency. Laboratories with structured, role-based onboarding, targeted training aligned to responsibilities and competency assessments reduce procedural errors, analytical repetition and variability between analysts.

Training ensures that scientific staff apply procedures consistently while adapting appropriately to assay-specific requirements and analyte complexity.



How Velocity applies this principle

We emphasize role-based training modules delivered during onboarding and as responsibilities change, paired with documentation and competency assessments for scientific personnel. Training is aligned to specific SOPs, assay types and analytical responsibilities to ensure consistent execution across complex bioanalytical workflows.

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Preventing CAPAs by Addressing Trends Early

Corrective and Preventive Actions (CAPAs) consume significant time and resources and often indicate that process breakdowns were identified too late. Laboratories that proactively monitor trends in deviations, audit findings and QC outcomes reduce the likelihood that issues escalate into formal CAPAs.

By addressing inefficiencies early, organizations preserve operational uptime and minimize disruption to ongoing studies — a critical factor for sponsors operating against tight development milestones.



How Velocity applies this principle

By emphasizing early identification of quality signals and cross-functional review, we have not, to date, required a formal CAPA, allowing teams to focus on scientific execution rather than remediation.



Integrating QA and Lab Operations

In most organizations, quality assurance operates independently from laboratory operations, which can create delays and an adversarial dynamic. Ideally, high-performing bioanalytical laboratories integrate QA and operations, embedding quality into daily workflows rather than enforcing it after the fact.

When QA and lab operations collaborate closely, issues are identified earlier, resolved faster and communicated more clearly, helping strengthen both compliance and efficiency.



How Velocity applies this principle

At Velocity Labs, QA is treated as an extension of lab operations. QA leadership participates in operational discussions and works alongside scientific teams to embed quality into workflows, rather than acting solely as a downstream checkpoint.

QUALITY AS AN ENABLER, NOT A CONSTRAINT

The effectiveness of quality systems, and the degree of cooperation between the QA team and Lab Operations, ultimately determines whether bioanalytical labs accelerate or delay developmental timelines. The six quality disciplines outlined here can distinguish laboratories that deliver predictable, inspection-ready results from those that struggle with rework, inefficiencies and avoidable delays.

These disciplines must be supported by intentional workflows, clear ownership and systems (including our electronic lab system, VELO) designed to reinforce quality in daily execution. We apply these principles as part of our commitment to speed with substance, quality discipline that supports both rigor and momentum.

Reach out to our team today to learn how our systems-driven approach to quality can strengthen data integrity and keep your timelines predictable.

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ABOUT VELOCITY LABS

Velocity Labs is a bioanalytical CRO built for programs that need speed with substance. We deliver non-regulated, GLP and GCP-aligned LC-MS/MS bioanalysis across discovery, preclinical and clinical phases—producing high-quality data aligned to ICH M10.

Our scientists support a wide range of modalities—small molecules, peptides (including GLP-1 receptor agonists), proteins and ADCs—through phase-appropriate, fit-for-purpose methods built to streamline the path into GLP validation. We're also experts in microsampling and patient-centric sampling devices.

Velocity supports programs across human and animal health—from emerging biotechs to global pharma — with rapid turnaround times and clear communication supported by robust QA and documentation.

We help teams accelerate the development of life-changing therapeutics—treating disease one sample at a time while moving at the speed of bioanalysis!

Learn more at [velocitylabs.com](https://www.velocitylabs.com).