

Actions Affecting Quality and Data Integrity

Six Quality Disciplines That Enable Predictable, Inspection-Ready Bioanalysis

In regulated bioanalysis, quality is not a checkpoint — it's the foundation that keeps programs moving. When quality systems are embedded into daily workflows, teams reduce rework, avoid delays and deliver inspection-ready data on predictable timelines.

Here are six quality principles that enable predictable, inspection-ready bioanalysis.



Audit Finding Reductions

Proactive evaluation reduces errors and promotes continued process improvement



Deviation Control

Clear procedures and training minimize deviations.



QC Effectiveness

Consistent, timely QC review protects data integrity without slowing throughput.



Training & Readiness

Role-based training and competency assessments reduce errors and variability.



CAPA Prevention

Identification of early adverse quality trends prevents CAPAs



QA - Lab Integration

Embedded QA collaboration enables faster resolution and stronger compliance.



Chris Tudan, PhD
Director
Biochemistry & QA

Q&A with QA

Q: Why do delays still happen in regulated BioA?

A: Most delays stem from rework, unclear processes or late identification of quality issues — not analytical science itself.

Q: What actually keeps timelines predictable?

A: Quality systems that are integrated and embedded into daily operations, not enforced after the fact.

Q: What should sponsors look for in a BioA partner?

A: Low audit findings, reduced deviations, effective QC, strong training, and clear QA-lab collaboration.

**Quality isn't a checkpoint.
It's the engine that keeps programs moving.**

Scan the QR code to explore how Velocity applies these quality disciplines to deliver defensible, inspection-ready data and predictable timelines without sacrificing speed.

