StudyGen 360

StudyGen 360 Reporter
Bioanalytics Standardized Multi-Run Assay Control



Study Reporter

StudyReporter Bioanalytics Assay Control

- Routine quality checks automated
- Manual data review reduced
- Performance compared and trends tracked between runs
- Drift and outliers in key parameters spotted before acceptance criteria are at risk
- Every run judged by the same criteria

Empowering Laboratories with Confident Data Quality Management

In modern bioanalytical laboratories, delivering reliable, high-quality data isn't just a requirement; it's a cornerstone of scientific integrity. Each analytical run represents critical data that influences crucial decisions in drug development and patient care. However, many laboratories face a common challenge: how to ensure consistent data quality while managing increasing sample volumes and complex analytical methods?

Conventional quality management approaches, often based on time-consuming manual checks and isolated data analysis, are no longer sufficient. Integrated run quality management solutions are critical. By automating quality checks, standardizing acceptance criteria, and providing cross-run analysis, these systems not only save time but also improve the reliability of your bioanalytical data. Detecting subtle trends across multiple runs can prevent costly failures and optimize method performance before problems occur.

The impact? Faster decision-making, reduced risk, and more robust data packages for regulatory submissions.

The Hidden Costs of Traditional Quality Management

Traditional quality management approaches often reveal issues only after run completion or, worse, during data reporting. This reactive approach leads to:

- Costly sample re-analysis
- Extended project timelines
- Resource-intensive investigations
- Risk of submitting compromised data packages
- Potential impact on study timelines and product approval

Outliers Using the Example of Retention Time Consistency

Retention time consistency is a fundamental parameter in

chromatographic analysis and a primary indicator of method reliability and system suitability. When evaluating retention time outliers, we're not just looking at individual deviations; we're assessing the overall robustness of our analytical method and device.



Early detection of these outliers, especially in regulated bioanalysis, can prevent:

- False positive/negative results
- Failed analytical runs
- Unnecessary investigations
- Extended instrument downtime

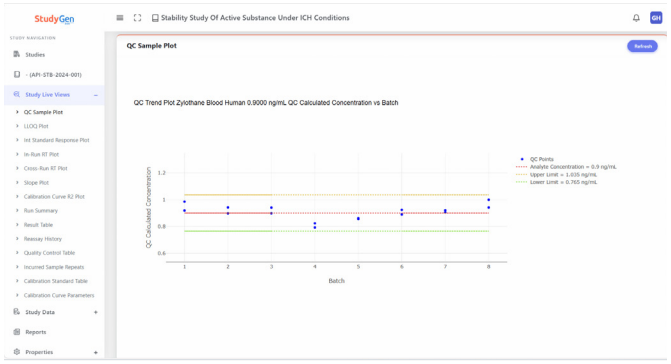
Built Around the Standards You Already Follow

StudyReporter Bioanalytics addresses critical requirements set by the FDA, EMA, and the ICH M10 guidelines for bioanalytical method validation and quality control. The system provides comprehensive standard control charts, including calibration curve trends (slope, R^2), LLOQ-performance, retention time consistency, standard QC-charts, BLANK-after-LLOQ monitoring, and internal standard trends. It also lets you define custom analyses based on raw data parameters.



Catching Drift Before It Becomes a Problem

By automating trend detection and implementing proactive quality measures, laboratories can ensure compliance while significantly reducing operational overhead. Detecting subtle shifts in analytical parameters before they breach acceptance criteria lets scientists focus on method development and optimization rather than reactive troubleshooting and can prevent costly sample re-analysis before it's ever needed.



Stronger Compliance, Leaner Operations

Standardized multi-run assay control also reduces investigation time while strengthening a lab's compliance position through comprehensive trend documentation, protecting study integrity and optimizing resource allocation. Most importantly, preventing quality issues before they affect study data helps safeguard patient safety and data reliability – the operational efficiency and regulatory peace of mind a proactive approach to quality management is meant to deliver.

At a Glance

- Run recurring data quality checks automatically
- Cut down on manual data review effort
- Follow parameter trends across multiple runs
- Spot QC drift early, before acceptance criteria are at risk
- Standardized evaluation criteria across all runs
- Standard control charts, plus custom analyses defined from raw data parameters
- Early detection of outliers in key run parameters

Ready to Experience the Power and Efficiency of StudyGen 360?