Ensure Data Integrity in Your Analytical Lab

Agilent OpenLab

Use this checklist to make sure that your lab is doing everything it can to stay compliant and maintain data integrity.

Preventive controls

- ☐ Create and adopt strong **quality agreements** with all contract manufacturing organizations (CMOs).
- ☐ Use **data and business flow diagrams** to help identify security vulnerabilities.
- ☐ **Develop clear SOPs** and keep them up to date.
- ☐ **Train all users** in your data review procedures—including all SOPs.
- ☐ Have **controlled systems in place for validating changes** in laboratory operations. This includes changes to application configuration and functionality, as well as system updates and patches.
- ☐ **Involve QA** in your overall process.
- ☐ When **validating system configuration**, always validate changes against predefined configurations, as well as functional and user specifications.
- ☐ **Keep method development** consistent with ICH and FDA guidelines. Methods developed by sponsor companies should be transferred to the CMO and the CMO must revalidate before QA/QC production begins.
- ☐ Make sure that **analytical records are complete**, and all tests and results summaries are validated.

Agilent
Trusted Answers

- ☐ Create a **controlled sample tracking mechanism** to ensure that samples are tested and tracked through completion.
- ☐ **Document and thoroughly investigate** unexpected discrepancies.
- ☐ Be sure that results summaries are **traceable** to the raw data.
- ☐ Adhere to **out-of-specification (OOS) procedures**, including timely completion of the investigation.
- ☐ **Retain raw data** (such as chromatograms) throughout its life cycle, and have controls in place to prevent deletion and overriding of raw data.
- ☐ Maintain a strong **stability testing** program with stability test methods for assays and impurities. Demonstrate accuracy, specificity, range, ruggedness, robustness, and system suitability.

Detective controls

- ☐ Review data and associated metadata in the **source system** before each batch release.
- ☐ Review **instrument error logs**.
- ☐ Establish a **recipe or a method management system**.
- ☐ Implement data **monitoring mechanisms** to flag anomalies.
- ☐ Be certain that **instrument error alarms** notify the appropriate users.

Learn more about the paradigm shift in regulatory audits and what it means for analytical laboratories. View the on-demand webinar: *Addressing the Paradigm Shift in Regulatory Inspection*
www.agilent.com/chem/regulatory-inspections-webinar

Learn more about keeping your data consistent, accurate, and protected.
www.agilent.com/chem/openlab-cds-data-integrity

Published in the USA, October 1, 2018
5994-0294EN

Agilent
Trusted Answers