TECHNOLOGY NETWORKS

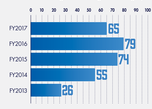
DELIVERING ASSURANCE AND CREDIBILITY

USING MODERN SOFTWARE SYSTEMS TO ENSURE COMPLIANCE

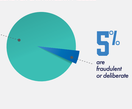
Data integrity is a fundamental element of ensuring compliance in a regulated laboratory and is not a new concept - it dates back decades. However, with computerized laboratory systems now taking the place of paper systems, your compliance strategy must adapt, or you risk difficult regulatory inspections.

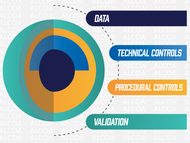
"Data integrity is an important component of industry's responsibility to ensure the safety, efficacy, and quality of drugs, and of FDA's ability to protect the public health"[1]

Total warning letters citing data integrity



REASONS FOR DATA INTEGRITY ISSUES[2]





THE NEED FOR AWARENESS HAS NEVER BEEN GREATER

Companies face the challenge of ensuring that technical and procedural controls are in place to minimize vulnerabilities to their system whilst providing evidence that their analytical results are not fraudulent.

COMPLIANCE FUNDAMENTALS

Chromatography Data Systems provide a platform that presents users with the tools to meet regulatory requirements. However the setup and enforcement of these tools is the responsibility of the user.

Access controls
Prevention of unauthorized changes

Audit trails
Data reconstruction and review

System validation
Fit for intended purpose

Documentation
Procedural and Technical controls

Electronic records
Secure records and signatures

"Chromeleon CDS has moved us away from the inefficient practices of transcribing data into a spreadsheet and helps us to address data integrity within the lab."

- Brian Allistan
Data Integrity Expert and CDS Specialist, Sterling Pharma Solutions

HEAR HOW Sterling Pharma Solutions answered the challenges of CDS data integrity.

"Understanding who did what, when and why is key to maintain data integrity. Electronic signatures provide accountability and traceability. Creation, modification and deletion of records must be captured."

- Katie Harrison
Operations Services Manager, Broughton Laboratories

HEAR HOW Broughton Laboratories have met the regulatory requirements for a CDS involving traceability and audit trails.

SCALABLE INFRASTRUCTURE

Scalability while maintaining compliance and data security is important as a business expands and the demand for efficiency and productivity increases.

Achieve
Paperless Lab - work electronically, reduce manual interventions

Improve
Centralized data storage via a searchable relational database

Maximize
lab efficiency and productivity

QUALITY ASSURANCE

According to the FDA: Invalid or unreliable data is a sign of poor control of operations and equipment, meaning organizations are unable to ensure the expected process quality.

20 – 30%
of time is spent in Quality Assurance and manually checking data[3]

IMPROVING DATA VISIBILITY & ACCESSIBILITY

A survey of over 100 biopharmaceutical companies revealed that development scientists spend several hours a week searching for data...

10 – 20%
of the time data cannot be found[3]

A relational database is fundamental to data security and data retrieval in a networked environment... CAN YOU FIND YOUR DATA?

DATA SECURITY

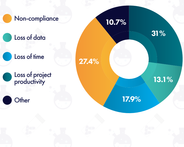
In a regulated environment, such as the pharmaceutical industry, there are a number of reasons why a networked CDS is preferable to a standalone workstation.[4]

Data management is IT driven – secure and encrypted database.

Reduces incidents of data manipulation.[4]

Minimizes potential loss of regulated data.

WHAT ARE THE MAIN CONSEQUENCES OF INADEQUATE DATA EXCHANGE ON A GLOBAL LEVEL WITH LAB SOFTWARE?[5]



FUTURE-PROOFED

Compliant cloud-based services for the pharmaceutical industry are expected to show significant growth as more companies accept and implement the technology.



"Big data is important to the way we carry out regulatory science, which is the science of developing new tools and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products. Through innovative methods such as cloud computing, we are taking advantage of this flood tide of new information to continue to protect and promote the public health."[6]

- Taha A. Kass-Hout, M.D., M.S.
Former Chief Health Informatics Officer, US Food and Drug Administration



CAN YOUR CDS DO IT ALL?

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