Data Integrity

Quality & Compliance Essentials

"We need to educate GxP employees on the issue of data integrity and what it means to record accurate and true information."

"We want to focus this education on key job functions, including clinical, QA and our QC lab personnel."

Regulatory agencies expect all areas of GxP, including clinical trials, QC labs, and the manufacturing process to be in a "state of control" and this control includes how data is recorded. The FDA requires companies to validate any application that's part of the overall quality system.

As the US FDA has stated: "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."

UL's new Data Integrity program, written by industry-leading subject matter experts, enables companies to build awareness to the entire GxP audience, including QA, QC Lab and IT professionals.

The program includes two full-length courses, which each takes about 40 minutes to complete, as well as three "short courses" targeted to professionals within QA, QC Lab and Clinical, so they gain an understanding of how to ensure data integrity within their specific job functions.

QA teams can deliver these courses to as many learners as possible, to stretch their training budget and eliminate the need to develop this regulatory training content on their own, without sacrificing the quality of the training content.

The Data Integrity program includes these five courses:

- Introduction to Data Integrity
- Auditing of Computer System Validation to Ensure Data Integrity
- Data Integrity for QA
- Data Integrity in the QC Labs
- Data Integrity in Clinical Trials

Introduction to Data Integrity — DATA01

This course provides foundational knowledge of the concepts of data integrity and quality, and was developed for all GxP employees.

Key concepts of data integrity and quality are introduced, as well as important definitions and roles around data integrity, including the stages of the data life cycle.

The course also explains management's responsibility for ensuring data integrity.

Auditing of Computer System Validation to Ensure Data Integrity — DATA02

Auditing computer systems for compliance with FDA rules and international standards requires that the IT knows what to look for in validation documentation.

This course helps IT and Quality Systems professionals understand data integrity and governance, validation, documentation deliverables, design and configuration, maintenance and more.

Data Integrity for QA — DATA03

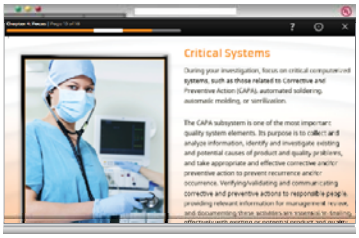
This "short" course explains how Quality Assurance can implement QMS controls to ensure data integrity.

The course provides examples of QMS controls such as quality management system governance, quality assurance infrastructure, CAPA, supplier oversight and QMS auditing.

Data Integrity in the QC Lab — DATA04

This "short" course explains how to promote data integrity in the Quality Control (QC) laboratory. The course also examines the types of data integrity issues found by FDA investigators globally, and explains possible consequences of data integrity non-compliance.

This short course also outlines strategies for remediation of data integrity issues.



Data Integrity in Clinical Trials — DATA05

This "short" course explains the role of management responsibility to ensure technical and procedural controls are utilized throughout clinical trials to assure data integrity.

This short course helps clinical managent professionals understand that confidentiality of information and data that may identify trial subjects must be protected.

An Engaging Learning Experience

To ensure the learners retain the material, each course contains "interactive quizzes" that must be completed before learners can move to the next chapter. Learners can take these quizzes as often as possible to achieve the 80% passing score. These attempts are not reflected in their qualification record.

In addition, courses contain a number of interactive activities that engage learners. These interactions also "chunk" critical information, which has been proven to improve retention in adult learners.

Affordable Pricing

Pricing for the set is based on an organization's employee size. For a firm with 1,000 employees, for example, the subscription cost works out to approximately $20 per learner. Courses can be delivered in one of three methods:

- SCORM: Course files are provided in SCORM, so they can be delivered via your organization's SCORM-compliant learning management system. Optional maintenance fees are available, in the event that the courses are updated to reflect new regulations.
- AICC: Course files are delivered as AICC, so they can be delivered via your organization's AICC-compliant learning management system.
- ComplianceWire®: Courses can be delivered through UL Compliance to Performance's ComplianceWire learning management system for an additional fee.

Get Started

To learn more about the Data Integrity courses, or view a preview, please contact Pat Thunell at pat.thunell@ul.com.