COBBLESTONE

COURSE ID 3014

Data Integrity

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Data integrity regulations
- Data Integrity examples

about the course

The purpose of a regulatory inspection is to ensure that your facility is in compliance with FDA rules and regulations. Investigators want to know that product was manufactured appropriately and that the current Good Manufacturing Practices are up to FDA standard. An inspection can be very intimidating to all involved, but it is vital if you want an inspection that results in a satisfactory report.

To this end, in this 90-minute accredited course, we will discuss effective batch record review. Data integrity is the assurance that data records are accurate, complete, intact and maintained within their original context, including their relationship to other data records. This definition applies to data recorded in electronic and paper formats or a hybrid of both. To assure the quality of raw materials, in process materials and finished goods, laboratory data integrity is assuming greater importance in current Good Manufacturing Practices (CGMP) for US Food and Drug Administration (FDA)-regulated industry. Data integrity and security infractions are not only 21 Code of Federal Regulations (CFR) Part 11 issues but also severe CGMP violations. The reasoning behind this complex issue is quite simple: if the integrity of laboratory data is compromised, batches of finished goods may not comply with regulatory authorization terms and, consequently, will not be released for sale.

This training is one part of the 10-course series required for the FDA Inspection Readiness Certification Program. Attend this as a step in the certification process or as a stand-alone course for personal career advancement and training.

who should attend

This course will be valuable to all individuals working within or managing a manufacturing program that supports either the R&D development of a new drug product or the manufacture of commercial drug product released to the market and would be beneficial to professionals in:

• Quality Control	• Quality Assurance
• Contract Manufacturers	• Manufacturing and Filling Operations
• Technical Operations	• Research & Development

Regulatory affairs personnel as well as individuals who are responsible for the review or audit of such inspections and reports would likewise find this course very worthwhile.

learning objectives

Upon completion of this course, you will be able to:

- Describe the current regulatory position on data integrity
- Discover the criteria for data integrity
- Recognize what needs to be addressed to ensure data integrity within a regulated GXP laboratory
- List approaches to improve data integrity in a laboratory environment
- Address Part 11 compliance
- Discuss FDA citations related to data integrity issues

course outline

Review of Learning Objectives

Module 1: Background and Regulations related to Data Integrity

- Regulatory requirements Data Integrity
- Definition of ALCOA
- Review of Manufacturing Data vs. Lab Data

Module 2: Data Integrity Basics

- Identifying Common Issues relating to Data Integrity
- How to Mitigate Issues
- Forms vs. Documents – Control and Reproduction

Module 3: Examples of Proper Data Integrity

- What Regulators look For
- Audit Trails – Importance of Compliance
- Who, What, Where, how?
- Real World Citations about Data Integrity

Assessment Opportunity

course instructor

Danielle DeLucy, MS, is currently an Independent Consultant to the Biologics and Pharmaceutical Industries specializing in the areas of Quality Assurance and Quality Systems. Prior to this role, Danielle has been in the industry for 20 years serving in numerous Quality Management Roles, such as the Director of Product Quality, the oversight of Sterility Assurance practices and provided QA oversight of numerous filling and packaging operations. Danielle began her QA career as a Quality Control Pharmaceutical Microbiologist at a contract laboratory where she performed various tests for their clients. In the years after, she has held positions in the Quality management arena while increasing her responsibility. She has helped to lead many Regulatory Health Inspections and was instrumental in the coaching process of her peers prior to any inspection. Currently, Danielle assists companies who are faced with warning letters and consent decrees establish more robust quality systems so that the company can succeed.

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 1.5 contact hours, or .2 CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)
Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS- established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.