COBBLESTONE

COURSE ID 2723

Avoiding Pharmaceutical and Biopharmaceutical Data Integrity Problems

Focus on FDA Data Integrity Guidance

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- FDA's Newest Guidance Documents on Data Integrity
- ALCOA
- Critical Do's and Don'ts
- How to Solve Data Integrity Issues

about the course

"In recent years," states the Agency, "FDA has increasingly observed CGMP violations involving data integrity during CGMP inspections." While a few of these situations may actually involve intentional fraud, others may occur where simply inadequate controls have been put into place to prevent data manipulation. Whether intentional or not, FDA views these situations as unacceptable.

The primary objective of this 90-minute accredited online training course is to equip you with the necessary skills to identify, evaluate, and remedy potential Data Integrity problems in your organization. Additionally, you will learn how to present to the FDA that your CGMP data satisfy the ALCOA principles - Attributable, Legible, contemporaneously recorded, Original or a true copy, and Accurate. Our training program will focus on a recently issued Draft Guidance for Industry by the FDA, which outlines the agency's latest perspective on this critical topic.

who should attend

This timely online training course will benefit professionals in the following FDA-regulated industries: Pharmaceuticals, Biopharmaceuticals, Vaccines, Cellular and Tissue Therapies and other Biologics, PET Drugs.

This online training course will be of benefit to all persons whose span of responsibility includes compliance with the U.S. Food and Drug Administration's (FDA's) Current Good Manufacturing and Good Tissue Practice Regulations (CGMPs and CGTPs) including, but not limited to, scientists and other professionals in:

• Quality Assurance	• Quality Control
• Compliance	• Development
• Auditing	• Manufacturing and Production
• Regulatory Affairs	

The course will also benefit senior management staff of FDA-regulated companies.

learning objectives

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

- Explain why data integrity is of crucial importance to your firm and to the FDA
- Spot potential data integrity issues at your firm
- List some essential activities to perform and other activities to avoid that help prevent data integrity issues during FDA inspections of your electronic and paper CGMP records and documents

course outline

Review of Learning Objectives
Module 1

- Background and recent History of Data Integrity (DI) Issues
- Special Definition of Terms, Acronyms and Abbreviations in the context of DI
- FDA's new Guidance Document for Industry:
- Data Integrity and Compliance with CGMP status, importance, and why you must know its contents.

Module 2

- Sections of 21 CFR Parts 211 and 212 with Data Integrity-related requirements
- Review of DI Issues in FDA Warning Letters
- Other important rules, policies, and guidance, including 21 CFR Part 11, FDA's Application
- Integrity Policy; FDA's OOS Guide, and more

Module 3

- Critical Do's and Don'ts of DI Compliance
- Examples of how to solve DI issues
- Summary and Conclusions

Question and Answer Session

Assessment Opportunity

course instructor

Rachel Monsef is a consultant to the biopharmaceutical and pharmaceutical industry for analytical and quality control. She has 21 years' experience working with many types of assays for all stages of drug development. She has been responsible for method development, method qualification, method validation, assay transfers, characterization work and stability studies. With these responsibilities she has been responsible for working within quality systems and maintaining data integrity. She has previously worked for Seagen and Lundbeck (formerly Alder) and is currently consulting for both companies.

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.