DATA INTEGRITY CERTIFICATION

What is Data Integrity?

Data Integrity is a global mandatory requirement for the regulated healthcare industry. Developing a medical product and bringing it to market involves different players and activities. A fundamental step is linked to the robustness and accuracy of the data submitted by manufacturers to regulatory authorities. That data must be comprehensive, complete, accurate and, true to assure the quality of studies supporting applications for medical products to be placed on the market. Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA). It also must comply with good manufacturing practices (GMP), good clinical practices (GCP), and good laboratory practices (GLP).

Data Integrity is a basic element of good documentation practices, one of the most fundamental pillars of any quality management system, including current good manufacturing practices.

Learning Objectives

This three-day training (21 contact hours) will cover the following elements, among others:

- Data Integrity – Why it is important?
- Risk-Based Approach to Preventing & Detecting Data Integrity Failures
- EU Annex 11, MHRA, WHO, and FDA Data Integrity Guidances
- Typical documentation and data integrity failures and how to avoid them
- Good Documentation Practices (ALCOA)
- Data Integrity Compliance Plans and Accountability Structures
- Techniques to Identify and Investigate Aberrant Data Patterns
- Update on Current Enforcement, including FDA 483s and Warning Letters
- Data Integrity in the Manufacturing and Laboratory Environments
- Data Type and Recording Media
- Information Technology and Data Integrity, how to work with it?
- Validation for Data Integrity and requirements
- 21 CFR Part 11: Electronic Records, Electronic Signatures
- Electronic Spreadsheets
- Reviewing electronic data and meta data: audit trails
- Document control of blank and template forms
- Quality Unit Responsibilities

Background

There has been a dramatic escalation in the number of U.S. Food and Drug Administration (FDA) warning letters, World Health Organization (WHO) notices of concern, and EU statements of noncompliance in which false or misleading information has been identified during inspections. Failure to properly manage data integrity applies equally to paper and electronic data. It can arise either from poor systematic control of the data management systems due to a lack of knowledge, human error or from intentionally hidden, falsified or misleading data.

Recently, a string of FDA-issued warning letters for data integrity violations has been published on the agency's website. Specifically, from January 2015 to May 15, 2016, 21 out of 28 warning letters given to drug manufacturers involved data integrity issues.

Between 2015 and 2016, major regulatory bodies, such as the European Medicines Agency (EMA), the FDA, the WHO, and the Pharmaceutical Inspection Co-operation Scheme (PIC/S), published guidance documents on the topic of data integrity and data management.

Target Audience

Data Integrity three-days certification will benefit Managers and staff from Manufacturing, QC/QA and Analytical Development Laboratories of pharmaceuticals, medical device and API manufacturers. Auditors responsible for performing self-inspections or external audits will also benefit from this certification.

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"Passion for Quality"

BEC, Inc. is authorized by IACET to offer 2.1 CEUs for this program. FULL attendance to the learning event is mandatory to receive CEUs.

OUR INSTRUCTORS

Guillermo Candelario is a Chemist with a master degree in chemistry and 30+ years of experience in QC laboratories operations and QA areas. Guillermo is currently a GMP consultant and laboratory system expert for Business Excellence Consulting. He has been head of laboratory operations at several major pharmaceutical companies.

William Velez is an Electrical Engineer with a minor on Electronics and Controls, and is a Master Engineering in Manufacturing Engineering focused on Industrial Automation. He has 10+ years of experience in automation and CSV for the medical devices and pharmaceutical industry. He is currently a GMP consultant and CSV expert for Business Excellence Consulting.

Program

Day 1

- Introduction
- Regulatory actions and Requirements
- Define raw data and metadata
- ALCOA definition and principles
- Other definitions
- Data Governance and lifecycle
- Pitfalls to avoid on data records
- How to assure spreadsheets compliance in a regulated environment
- Electronic records compliance requirements
- Red flags for fraud related to data integrity
- Risk based approach to Computerized System Validation (CSV)
- Triggers for Data Integrity Loss

Day 2

- Validation elements of computerized system for GxP environment
- QC Laboratory as an intensive generator of data.
- Discussion of the applicable standards for laboratory operation
- How to preserve sample representativeness/integrity
- Requirements of computerized systems to assure data integrity
- Laboratory controls
- Laboratory records issuance and control
- Calibration records requirements
- Good Documentation Guidelines for laboratory operations – New USP General Chapter
- Analysis of FDA 483 and Warning Letters citations for Data Integrity in the QC Laboratory

Day 3

- Production and process controls
- Manufacturing equipment controls
- Materials Management
- Requirements for Document Management for preserving the integrity of the data
- Records requirements for production
- Good Documentation Practices
- Analysis of FDA 483 and Warning Letters citations for Data Integrity in production
- Document controls
- Document retention
- Responsibility of the Quality Unit with respect to Data Integrity
- Data Integrity Policy
- Data Integrity Gap Analysis
- FDA expectations on Data Integrity remediation

Training Effectiveness Evaluation

A very comprehensive training effectiveness evaluation system will be conducted using the Kirkpatrick model. A pre-test prior to the beginning of the training, plus a post-test at the end of the training will be completed. A minimum grade of 70% in the post-test is required to pass the certification.

Materials

Each participant will receive:

- MS PowerPoint Presentation
- Guidelines, warning letters and supplemental information
- IACET Certificate for 2.1 CEUs

With more than 60 courses and workshops, BEC, Inc. is a leading worldwide regulatory and compliance training provider. Since May 2015, BEC, Inc. has been accredited by the International Association for Continuing Education and Training (IACET). Last year more than 6,000 professionals were trained by BEC, Inc. in 14 countries.