COBBLESTONE

COURSE ID 2938

Good Documentation Practices for Laboratory Records

GMP Laboratory Control Professional Certification Program
90 Minute Accredited Webinar

DIRECTED BY

Danielle DeLucy — Owner/Principal ASA Training & Quality Consulting, LLC

90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Paper and Electronic Records
- Best Practices
- What to Avoid
- FDA 483 Examples

about the course

In FDA's Guide to Inspections of Pharmaceutical Quality Control Laboratories (7/93), it is stated "The pharmaceutical quality control laboratory serves one of the most important functions in pharmaceutical production and control. A significant portion of the CGMP regulations (21 CFR 211) pertain to the quality control laboratory and product testing." Good documentation practices are expected to assure they are accurate, legible and traceable to name a few. The lack of such good documentation practices is routinely cited in FDA 483 observations.

This 90-minute accredited course is designed to provide sound training on "good documentation practices" in the laboratory. Good Documentation Practices (GDP) are a "current" industry practice that is reviewed and cited by federal regulators when audited. Pharmaceutical/Biological documents are legal documents that are controlled by all regulatory agencies. The person or persons responsible for filling out these documents accepts the consequences if the documents are not filled out according to good documentation practices. This webinar will cover the basics of what good documentation practices include, along with examples of practices not acceptable to auditors.

This webinar will help attendees review their own procedures and what should be included in applicable training sessions for new employees along with refresher training for those who are more experienced.

This training is one part of the 10-course series required for the GMP Laboratory Control Professional 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 is intended for Lab Analysts, Supervisors and Managers in Pharmaceutical or Biological Laboratories who are responsible for generating, reviewing, evaluating or approving test results for active pharmaceutical ingredients (APIs) or finished pharmaceutical dosage forms in a regulated environment. This course will benefit individuals in:

• R&D	• Quality Assurance
• Quality Control	• Technical Operations

Regulatory affairs personnel responsible for the review of such data will also benefit from this course.

learning objectives

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

- Define good documentation practices (GDP)
- Cite examples of documentation practices that should be avoided.
- Summarize examples of good documentation practices and what they apply to.
- Describe practices for correcting mistakes or when space is limited for comments
- Explain FDA 483 citations given to companies

course outline

Review of Learning Objectives

Module 1: Review of Good Documentation Practices (GDP) – Background

- Examples of laboratory records
- Paper records and Electronic records

Module 2: Data Integrity Basics Regulations Related to GDP

- CFR requirements
- Rules for documentation
- Audit Trails

Module 3: Real World Application

- 483 observations related to GDP
- Case Scenarios

Question and Answer Session

Assessment Opportunity

course instructor

Danielle DeLucy, MS, is currently the owner of ASA Training & Quality Consulting, LLC, an Independent Consultant Agency 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 18 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.