

Overcoming the Documentation Nightmare

Purpose

This program provides a most interesting review of proper documentation practices for both paper-based and electronic record environments. Allan brings to this program the dynamic presentation style clients have come to expect. Actual plant video engages the learner. Interactive and LMS versions include quizzes and a final exam.

Objectives

At the completion of the class, managers and executives will be able to:

1. Properly enter information into records.
2. Properly correct entry errors.
3. Identify unacceptable documentation practices.
4. Properly complete rounding number operations.
5. Explain basic electronic record requirements.

Who should attend this course?

This class is targeted to all employees with documentation responsibilities, from completing documents to review and approval.

Intent of the class

This course is intended for training purposes only and is not a substitute for technical recommendations, regulatory or legal advice. These materials are intended to raise compliance issues for further discussion at your company. It is recommended that you consult appropriate authorities for specific recommendations and advice.

Class Length: *This time does not include testing time.*

40 Minutes in 11 segments

On-site Options

This class can be taught with a live instructor at your company. Call for details.

Topics Covered

Introduction

1. 483 Observations related to documentation practices

Documentation Practices

1. Entry
2. Error correction
3. Unacceptable practices
4. Prohibited practices
5. Falsification

Data Handling - Rounding

Electronic Records

1. General requirements
2. Reliability

Electronic Record Access

1. Biometrics
2. Authority checks
3. Access controls

Electronic Record Security

1. System breach
2. Time out

Electronic Record Integrity

1. Audit trail
2. Record protection
3. Record integrity

FDA and Documentation

1. Request for documents
2. Record retrieval
3. Retention time