Morf Playbook™ Presents

Good Documentation Practices for FDA Regulated Companies from Morf Media, USA.

NOW ON MOBILE DEVICES

Good documentation practices are integral to a company's overall Quality Management System (QMS). This comprehensive course provides clear guidance to managers and personnel on how to formulate and deliver best documentation practices to their individual teams.

WHAT YOU WILL LEARN

This course will show you how to meet industry standards of documentation by demonstrating how best to record information as it relates to Good Clinical, Laboratory and Manufacturing Practices (GxP). Good documentation practices are integral to a company's overall quality management system (QMS). While not law, authorities will inspect against these guidelines in addition to the GxP requirements and make comments or observations if departures are seen.

AREAS COVERED

- How to record and round numbers for statistical analysis
- How to be compliant when writing, recording or amending information for documentation used in Good Clinical, Laboratory and Manufacturing Practices (GxP)
- Comprehensive information to ensure records provide documented evidence, traceability and an audit trail that will warrant successful investigations
- How to make documents attributable, legible, contemporaneous, original and accurate.
- Compliance in amending documents or records

LEVEL

Basic & Intermediate

PERFECT CANDIDATES

- Quality Control Personnel
- Supply Chain and Logistics Managers
- Regulatory Affairs Professionals
- Process Development Scientists and Management
- Manufacturing Management and Scientists

Good Documentation Practices describes standards by which documents are created and maintained to ensure successful regulatory agency inspections.

Provides a clear approach to correcting and preventing documentation issues, regulating consistent practices and avoiding negative reviews from the FDA and other agencies.

Clear, step-by-step guidance helps ensure strategy for delivering high-quality products at a profit with consistent operation of all systems.

Provides skill-building and leadership training for regulated industry professionals with RAPS credit — available now on Mobile Devices.

Utilizes an easy, fast and engaging approach to learning using challenges, game theory and social feedback capabilities.

TRAINING FROM INDUSTRY EXPERTS

Ms. Angela Bazigos
Chief Compliance Officer and Head of Life Sciences and Healthcare at Morf Media, USA

Honored by Stanford Who's Who for contributions to the Life Sciences Industry, Ms. Bazigos has more than 40 years of experience working with pharma, biotech, medical device, food safety, and healthcare organizations around the world. She is a Past President of PRCSQA, and is a frequent contributor to industry publications both international and domestic. She co-authored Computerized Systems in Clinical Research/Current Date Quality and Data Integrity Concepts with the FDA and holds a patent in Software Compliance. Ms. Bazigos was recently quoted in the Wall Street Journal on Using Training to Bring Compliance to the Boardroom. Ms. Bazigos additionally served as CCO for Prime Genomics, and held executive roles at Incyte Genomics, Roche and Counsyl among others.

About Morf Playbook™
Morf Playbook is a mobile and social talent development platform that provides compliance training. For more information about Morf Playbook and Morf Media, USA visit www.MorfMedia.com.

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