



Morf Playbook™ Presents

Risk Management and Drug Surveillance for FDA Regulated Companies from Morf Media, USA.

NOW ON MOBILE DEVICES



It is vital to a company's success to be able to recognize risk management and surveillance tools, and evaluation and reporting procedures used in the drug manufacturing industry—information and training that is provided in this course.

WHAT YOU WILL LEARN

This course will show you a clear, effective approach to implementing best practices to align your company with FDA risk management and surveillance processes.

This comprehensive course provides clear guidance to managers and quality assurance personnel on how to follow regulation expectations and formulate their own risk management practices based on existing reporting and surveillance programs.

Expertly formulated risk management processes provide better safety, improve procedures and reduce downtime.

Provides clear information on all important FDA drug-related registration and reporting processes.

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.

AREAS COVERED

- Basic concepts of the drug registration and listing process, including DUNS number
- An overview of the Adverse Drug Experience (ADE) Reporting Program, including the FDA CDER's ADE Training Video
- An introduction into the Drug Quality Reporting System (DQRS)
- Comprehensive risk evaluation and mitigation (REMS) strategies
 - Elements to Assure Safe Use
 - Implementation of REMS
 - Enforcement of REMS
 - Misbranding and Civil Penalties

LEVEL

Basic & Intermediate

PERFECT CANDIDATES

- CEOs
- VPs
- Hospital Administrators
- Doctors and Nurses
- Regulatory, Quality and IT VPs
- Regulatory Affairs professionals
- Quality Managers
- Quality Engineers
- Small business owners
- GxP Personnel
- Consultants

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.