Morf Playbook™ Presents

Medical Device and User Free Act III Overview for FDA Regulated Companies from Morf Media, USA.

NOW ON MOBILE DEVICES

The MDUFA III took effect in 2012 and instituted new guidelines for medical device submission and rejection. Changes like these could cause companies to suffer unnecessarily due to ignorance and/or inability to adapt. This course clearly presents the facts about the new changes to regulation as they apply to medical device manufacturers and clinical trials, and comprehensive methods of properly implementing them.

WHAT YOU WILL LEARN

This course is designed to aid physicians, managers and quality assurance personnel in the formation of new procedures and processes to reduce the negative impact of regulatory changes and help your company prepare both strategically and tactically for regulatory interactions in the next five years.

AREAS COVERED

- The history and context of the FDA's MDUFA I to MDUFA III
- An overview of the FDA Safety & Innovation Act (FDASIA)
- A primer on process & policy improvements
- A full list of updated quantitative goals
- Projected MDUFA III review dates and times
- Key Highlights of the new regulation
- How best to implement all of the expected new processes
- A guide to hiring the best team to fulfill expectations

LEVEL

Basic & Intermediate

PERFECT CANDIDATES

- Clinical Trial Physician / Doctor
- Manager to Senior Director of;
- Regulatory Affairs
- Quality Assurance
- Clinical Research
- Data Management
- Data Monitoring
- Institutional Review Board

Expertly formulated review and submission processes speed approval timelines, improve approval rates and reduce instant rejection.

Utilizing a risk-based approach, this course provides context for the MDUFA III and how companies can best incorporate new practices with reduced negative impacts on the company.

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 inter- national 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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