Morf Playbook™ Presents

Medical Device Establishment Registration and Listing for FDA Regulated Companies from Morf Media, USA.

NOW ON MOBILE DEVICES

This presentation will provide the basic information needed to fulfill the FDA requirements for Medical Device Establishment Registration and Listing based on requirements and changes enacted with the legislation of 2012.

WHAT YOU WILL LEARN

This course will show you the context, the impact and the best practices related to the FDA's 2012 legislation on medical device registration and listing. It is designed to aid managers and quality control personnel in the formation of new expectations and streamlined processes, based on information directly from the FDA.

AREAS COVERED

- A primer on regulatory requirements
- The full list of who is required to follow medical device registration and listing requirements and what exemptions may exist
- Specifics on when to register and list
- An overview of registration and listing information
- Complete FURLS information, including;
  - FURLS Accounts and Passwords
  - Owner Operator Account
  - Official Correspondent Account
  - Creating Multiple Accounts
- A list of User Fees
- Step-by-step instructions on how to follow regulations

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
- Regulators

Expertly formulated registration and listing procedures provide speed, improve overall product processes, reduce negative FDA reactions, and help build a positive reputation.

Utilizing a risk-based approach, this course provides context for the FDA's 2012 legislation for medical devices and how to implement best practices based on those revisions.

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.

morfmedia.com