Morf Playbook™ Presents

FDA Overview of Regulatory Requirements for Medical Devices from Morf Media, USA.

NOW ON MOBILE DEVICES

The FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms that manufacture, repackage, relabel, and/or import medical devices sold in the United States.

Medical devices are classified within Classes I-III and regulatory control increases with each class. The device classification regulation defines the regulatory requirements for a general device type, as well as all premarket requirements and expectations. This course is intended to provide a vital overview of the regulatory requirements for medical devices or, as it is sometimes called, Devices 101.

WHAT YOU WILL LEARN

This course will provide you with a comprehensive overview of what products are regulated as medical devices, how to determine the classification of your devices, how to ensure that your establishment is registered correctly, and other information on medical device manufacturing regulations.

AREAS COVERED

- Comprehensive overview of the Center for Medical Devices & Radiological Health (CDRH)
- The complete Medical Device Classification system and details
- An overview of medical devices and their individual regulations
- A primer on medical device controls
- All Establishment Registration information, including premarket notification specifics, exemptions, and Pre-Market Approval (PMA)

LEVEL

Basic & Intermediate

PERFECT CANDIDATES

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

Expertly formulated device manufacturing and labelling provides regulatory assurance, improves overall product quality, reduces recalls and shortages, and improves manufacturing consistency.

Utilizing a risk-based approach, this course provides the background and full view of the FDA's Center for Devices and Radiological Health (CDRH) as it applies to regulations and requirements for medical devices.

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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