Morf Playbook™ Presents

Exploring the FDA's Refuse to Accept Policy for FDA Regulated Companies from Morf Media, USA.

NOW ON MOBILE DEVICES

By instituting a Refuse to Accept Policy, the Center for Devices and Radiological Health will be able to focus substantive review ONLY on submissions that are complete. It is expected that 510(K)s that are accepted under this new policy will be reviewed more quickly.

WHAT YOU WILL LEARN

In this course you will learn the expectations of the FDA in regards to 510k submissions and by following the outlined principles you can minimize your risk of submission rejection and increase the potential for a speedy review and approval by the agency.

Extensive Research into the FDA's Refuse to Accept Policy provides background, improves submissions and supplies imperative guidelines for success.

Utilizing a risk-based approach, this course provides context for the FDA's new policy regarding 510(K) submissions, how to avoid immediate rejection and submission guidelines to better expedite the review process.

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

- A complete overview of the FDA's guidance on Refuse to Accept
- Best practices for pre-submission interaction
- A primer on the 510(K) Refuse to Accept Policies and Procedures, including;
  - The 510(K) Checklist
  - The FDA review Clock
  - What to expect in a notification of acceptance
- The Acceptance Review Checklist
- Clear understanding of Traditional vs. Non-Traditional 510(K)s

LEVEL

Basic & Intermediate

PERFECT CANDIDATES

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

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.

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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