



Morf Playbook™ Presents

FDA Inspections Bundle for FDA Regulated Companies from Morf Media, USA

NOW ON MOBILE DEVICES



Inspection by the FDA or other foreign regulatory agencies for the purpose of certification is a normal part of the pharma, biotech or medical device manufacturing business. Regulated companies need to know the structure and typical processes of a regulatory agency inspection to ensure a positive outcome. This course bundle was co-developed with former FDA Inspector Larry Spears and contains comprehensive information on all inspection information.

WHAT YOU WILL LEARN

This module bundle clearly presents the facts about expected inspection processes for organizations focused on pharma, biotech and medical device manufacturing.

This bundle trains personnel to meet inspection expectations and avoid pitfalls that often occur due to lack of knowledge or preparation. It is vital to company success for managers and quality assurance personnel to be aware of the requirements of inspection procedures.

AREAS COVERED

- FDA Inspection Program Overview
- Key factors for a successful FDA inspection
- Quality System Readiness
- Information Readiness
- Organization Readiness
- Manage Inspection Outcomes
- Managing Regulatory Risk
- Food Facility Inspections
- Medical Device Inspections
- 21 CFR 11 Inspections
- FDA Quality Metrics
- Corrective and Preventive Action (CAPA)

LEVEL

Basic & Intermediate

PERFECT CANDIDATES

- Senior Management
- Quality Assurance and Control Managers and Personnel
- Supply Chain and Logistics Managers
- Regulatory Affairs Professionals
- Process Development Scientists and Management
- Manufacturing Personnel
- Project Managers in the CMC arena
- Facilities and Engineering Staff
- Internal Auditors
- Legal Departments
- Validation Managers
- Compliance Consultants and Officers

Expert preparation for hosting regulatory inspections provides insight, improves processes, reduces citations and other negative circumstances, and improves work consistency.

Utilizing a risk-based approach, this course provides a comprehensive overview of different inspection expectations in regards to quality system readiness, organization readiness, how to manage inspection outcomes and other important processes.

TRAINING FROM INDUSTRY EXPERTS



Mr. Larry Spears

FDA Consultant for Morf Media, USA

Larry is the Executive VP of Regulatory Affairs/Quality Assurance for Touchstone Technologies Silicon Valley, Inc. "Knowledge is Power". He has deep regulatory expertise from over 35 years experience in government and consulting.

Mr. Spears provides global regulatory strategy consultation to Life Science companies primarily in medical devices/diagnostics and pharmaceuticals with a focus on quality systems gap assessments, FDA mock inspections, quality system development and planning, and remediation for FDA inspection findings including, among others, CAPA and complaints, design controls, supplier controls, production management, and training.



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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