



Morf Playbook™ Presents

21 CFR Part 11 Basic Concepts for FDA Regulated Companies from Morf Media, USA.

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Continuous technological innovation and computerized systems provides inherent security and regulation concerns within the industry. This presentation provides an overview of and an historical perspective on the Part 11 regulation, including general, electronic records, and electronic signature requirements.

WHAT YOU WILL LEARN

This comprehensive course provides clear guidance to project managers, IT managers and quality assurance personnel on how to formulate and deliver best practices in regards to Part 11 to their individual teams.

Critical, regulated training provides compliance, improves processes, reduces negative reviews, and improves work consistency.

Provides a clear approach to understanding the history and reasoning behind electronic records and software regulation for project management personnel, IT staff, operations staff and quality assurance personnel.

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 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.

AREAS COVERED

- A comprehensive history and detailed overview of 21 CFR Part 11
• Specifics on Subpart A: General Provisions
• Specifics on Subpart B: Electronic Records
• Specifics on Subpart C: Electronic Signatures
• Complete scope of regulations and their direct applications

LEVEL

Basic & Intermediate

PERFECT CANDIDATES

- Project/Strategic Management
• Quality Assurance staff
• IT staff
• Operations staff

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.