



### Morf Playbook™ Presents

# FDA Quality Metrics—Latest Advances for FDA Regulated Companies from Morf Media, USA

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Recent increases in field alert reports, recalls and drug shortages has mandated the attention of the industry. The FDA has been accused of focusing solely on modernizing plant controls and systems instead of properly regulating product quality.

To address issues and concerns, the FDA established the Office of Pharmaceutical Quality. This office exists to improve the scrutiny of brand-name, generic, and over-the-counter drugs, and is asking the industry to offer up better metrics for field investigations.

### WHAT YOU WILL LEARN

This course will show you the context, the impact and the best practices related to the FDA's New July 2015 "Request for Quality Metrics Guidance for Industry" & Safety and Innovation Act (FDASIA). 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 summary of the FDA centers that are involved in Quality Metrics
- An explanation of the current quality control issues
- A step-by-step overview and guide focused on the FDA's request to the industry for quality metrics
- Comprehensive insights on the most frequent citations from 21 CFR 210/211
- A primer on the FDA public meeting and its results
- Complete references

### LEVEL

Basic & Intermediate

### PERFECT CANDIDATES

- Quality Managers
- Quality Engineers
- Small business owners
- GxP Personnel
- Consultants
- Quality VPs
- IT VPs

**Expertly formulated Quality Metrics** provide context, improve overall product quality, reduce recalls and shortages, and improve manufacturing consistency.

**Utilizing a risk-based approach**, this course provides context for the FDA's new July 2015 "Re-request for Quality Metrics Guidance for Industry" & Safety and Innovation Act (FDASIA).

**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. 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](http://www.MorfMedia.com).