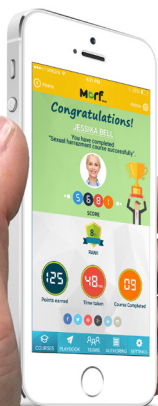




## Morf Playbook™ Presents

# Writing Effective SOPs for FDA and CLIA Regulated Companies from Morf Media, USA

NOW ON MOBILE DEVICES



Standard Operating Procedures (SOPs) are required by law for companies that are regulated by the Code of Federal Regulations such as Title 21 and Title 42. Yet there is no guidance on how to write, organize and maintain SOPs. Consequently, SOPs are frequently written in a way that makes compliance difficult or seemingly impossible. This often leads to regulatory errors that come to light during a FDA audit.

Every FDA and CLIA inspection starts with a review of SOPs. Thirty to forty percent (30%-40%) of adverse inspection issues are a result of poorly written SOPs.

### WHAT YOU WILL LEARN

This course will show you how to write, organize, and maintain SOPs and train personnel in a way that will ensure compliance in a way that is concise, reproducible and easy to follow.

You will also gain a strategic view of how SOPs help streamline operations and create efficiencies, while ensuring regulatory compliance.

### AREAS COVERED

- SOPs and their relation to the regulations
- SOPs as part of the company's regulatory infrastructure
- Best Practices for writing SOPs to ensure conciseness, efficiency and ease of use
- Risk Based approach for writing SOPs
- Training on SOPs
- Tools for tracking SOPs life-cycle and when validation is required
- What an inspector looks for in SOPs during an inspection

### LEVEL

Basic & Intermediate

### PERFECT CANDIDATES

- CEOs
- Regulatory VPs / Quality VPs / IT VPs
- Regulatory Affairs Professionals
- Quality Managers
- Quality Engineers
- Small Business Owners
- GxP Personnel
- Consultants

**Well-written Standard Operating Procedures (SOPs)** provide direction, improve communication, reduce training time, and improve work consistency.

**SOPs used in combination with planned training and regular performance feedback** lead to an effective and motivated workforce.

**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).

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