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Webinar on

Writing World Class Compliance Documentation

Learning Objectives

- *The true purpose and function of regulatory documentation*
- *What is the value add?*
- *The pitfalls associated with writing regulated documentation*
- *The documentation hierarchy*
- *Documentation Formats*
- *Gathering the technical information you need*
- *Using Subject Matter Experts*
- *Documentation writing tips*
- *Managing technical document reviews*
- *Writing effective compliance documentation*

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This webinar will present the methodology to make Standard Operating Procedures and Work Instructions a valuable component of the operational strategies of any regulated organization.

PRESENTED BY:

Carolyn Troiano has more than 35 years of experience in computer system validation in the pharmaceutical, medical device, animal health, tobacco, e-cigarette/e-liquid, and other FDA-regulated industries. She is currently an independent consultant, advising companies on computer system validation and large-scale IT system implementation projects.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

Standard operating procedures and work instructions can be an effective tool in the control and standardization of operations, the conduct of training, the meeting of all regulatory requirements, and as user support tools to guide individual performance and to manage the execution of that performance. The key is in knowing how to apply the proper techniques to their creation.

Standard Operating Procedures and Work Instructions – the documentation required by regulation – is essential to the effective and compliant running of any regulated business. Unfortunately, many individuals in those businesses miss the valuable opportunities that properly developed Standard Operating Procedures/Work Instructions can provide. Regulated documentation can serve a variety of purposes other than meeting a regulatory requirement – as training materials, to standardize operations, to manage individual and group performance, to identify the sources of deviations, etc. The key is to know how to write those documents to properly meet those needs.

This webinar will present the methodology to make Standard Operating Procedures and Work Instructions a valuable component of the operational strategies of any regulated organization.

Who Should Attend ?

Engineering

Marketing

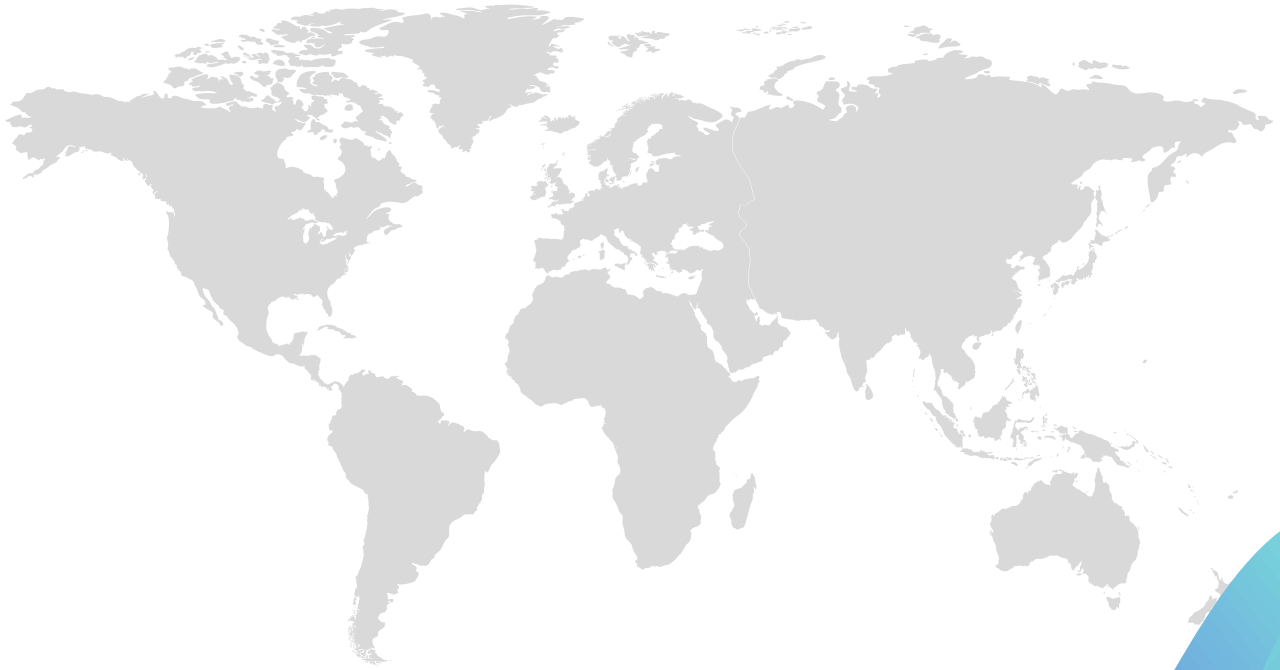
Regulatory documentation

Research & development professionals in the Pharma

Biologics, and Medical Devices

Directors

Managers, and associates



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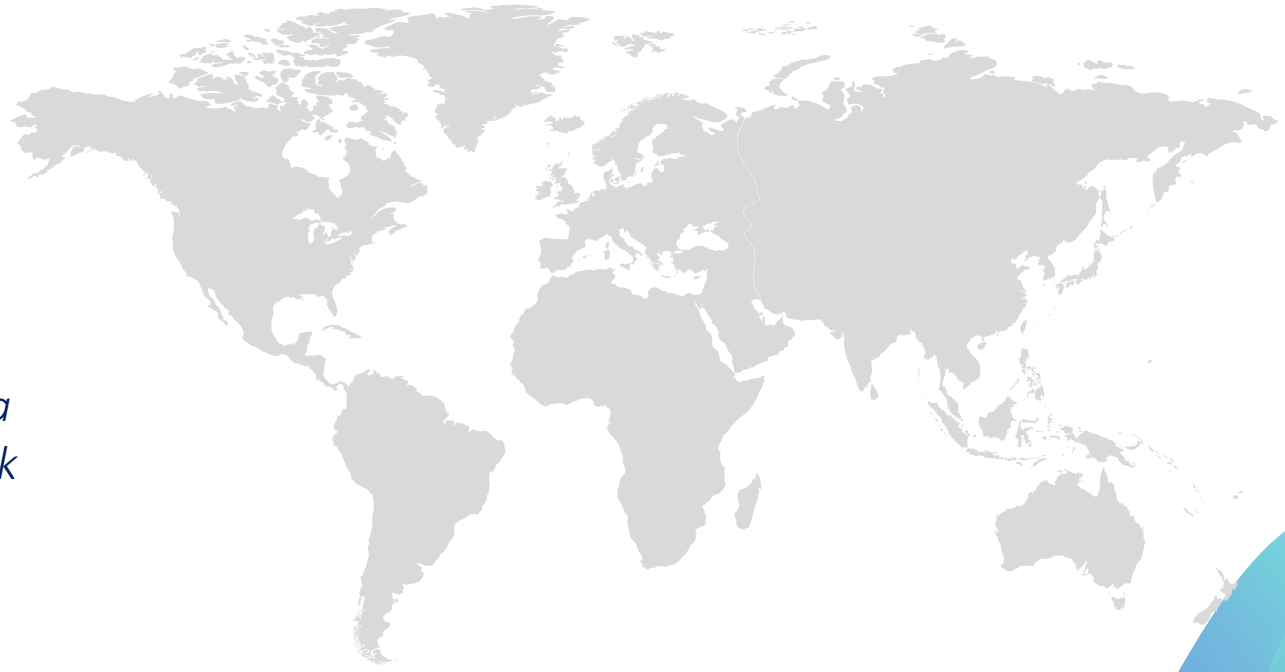
Why Should Attend ?

Writing effective compliance documentation is not intuitive, it is not a skill that is often taught in our universities, and it can be a difficult and cumbersome task to execute. Knowing the most effective and efficient processes for gathering, organizing, and writing technical documentation is absolutely critical to providing significant value to a dreaded, avoided, and seemingly unimportant work task.

These documents are critical to regulatory compliance but they are also critical to effective business operations. Because the process of effectively developing these documents is not intuitive, it is imperative that everyone tasked with creating these documents have basic foundational knowledge of how to create effective documents with a minimum of effort.



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