

Webinar on

Building a Compliant Laboratory – From Foundation to Business Excellence

Areas Covered

- Laws, Regulations, and guidance applicable to laboratory operations*
- It's not just about meet the regulations, it's getting the processes to achieve business needs*
- Process mapping approach to designing a sample executable laboratory operations SOP*
- Steps necessary to ensure existing laboratory and new laboratories have processes implemented that ensure compliance*



Learn how to build a compliant laboratory from starting with a good foundation to implementing for Business Excellence.

PRESENTED BY:

Over 30 years of diverse international industry experience in Quality Assurance, Quality Control, and Regulatory Affairs. Last 18 years as a consultant to biopharma, pharma and device industries.

On-Demand Webinar

Duration : 60 Minutes

Price: \$200

Webinar Description

Compliance in laboratory settings has been a topic for the FDA and other regulators for decades. With the increased focus on data integrity and continued focus on laboratory investigations, it is critical more than ever to ensure you have designed your laboratory operations system to meet the compliance needs of your business. In this presentation, I will define compliance, provide a translation of regulations and guidance into user requirements and then using those user requirements to show how one can design a laboratory system. Finally, I will provide a roadmap for implementation whether an existing laboratory or a new laboratory.

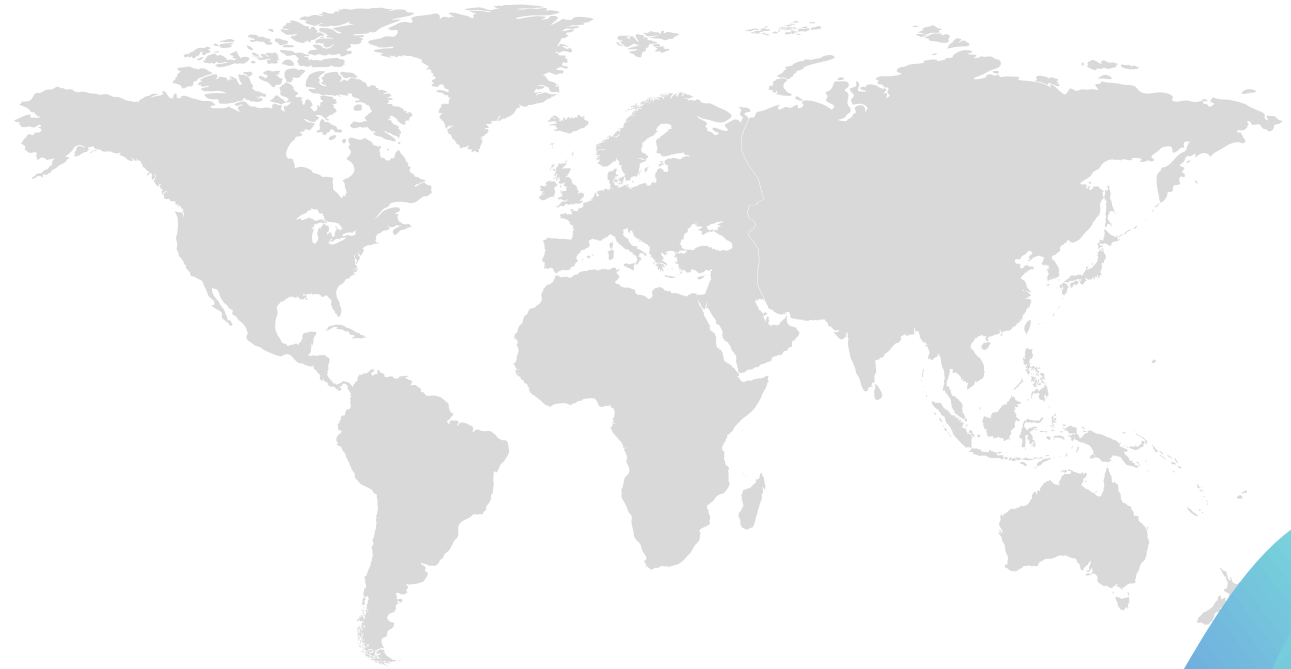


- Compare what Compliance means in the Pharmaceutical, Biotechnology, and Medical Device Laboratory and how that differs from Business Excellence
- Understanding how to translate the thou shalt of regulatory guidance and stakeholder needs into user requirements and then into system execution steps
- Understanding stakeholders needs and translating requirements into the design to achieve business excellence
- Process mapping approach to designing the laboratory operations system
 - a. Organize the processes into meaningful systems
 - b. Evaluate for efficiency
 - c. Develop Performance Metrics
 - d. Create a process map for each system
 - e. Identify key linkages to other systems – augment maps
 - f. Develop the map into standard operating procedures
- Presentation of a Process map for one laboratory operations system
- Receive a sample SOP for laboratory operation that can be translated to your operation



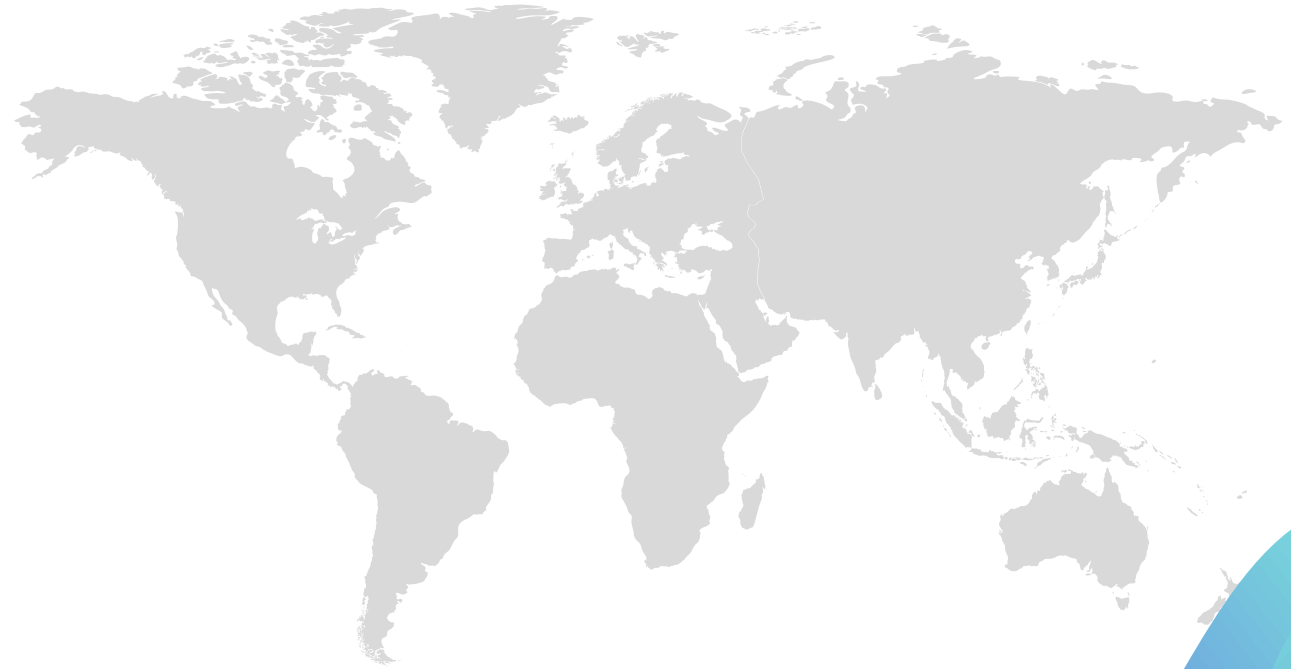
Who Should Attend ?

*Laboratory operations management.
Quality Assurance Management.
Designers of laboratories.*



Why Should You Attend ?

Everyone struggles with getting their laboratory into compliance. Learn how to build a compliant laboratory from starting with a good foundation to implementing for Business Excellence. Dr. Husman's presentation will walk you through the process and steps needed to ensure a compliant laboratory is built or rebuilt for business excellence.



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