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Webinar on

Avoiding 483s Throughout Your Organization – Strategies, Risk, and Mitigating Approaches

Date : July 23, 2021

Areas Covered

- *Understanding the regulations that pertain to your industry and your business throughout each level and function of your organization*
- *Defining your critical processes and why that is important*
- *The benefits of developing sound regulatory documentation*
- *Why harmonizing your processes is critical to consistency in operations and regulatory compliance*

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- *Why technical training is essential to every aspect of business operations to include meeting and exceeding regulating requirements*
- *Institute a sound and effective complaint and investigations handling process*
- *Performance management – the glue that holds everything together and guarantees acceptable performance throughout the organization*

This webinar will provide the approach and framework that you need to follow to make your compliance program a valuable ingredient in the process of running your business with the significant benefit of avoiding 483s.

PRESENTED BY:

Charles H. Paul - is the President of C. H. Paul Consulting, Inc. - a regulatory, Lean Manufacturing, training, and technical documentation consulting firm. Charles is a management consultant, instructional designer, and regulatory consultant and has led C. H. Paul Consulting, Inc.The firm works globally completing projects throughout the EU, UK, South America, and Asia.

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Date : July 23, 2021

Time : 01: 00 PM EST

Duration : 60 Minutes

Price: $179

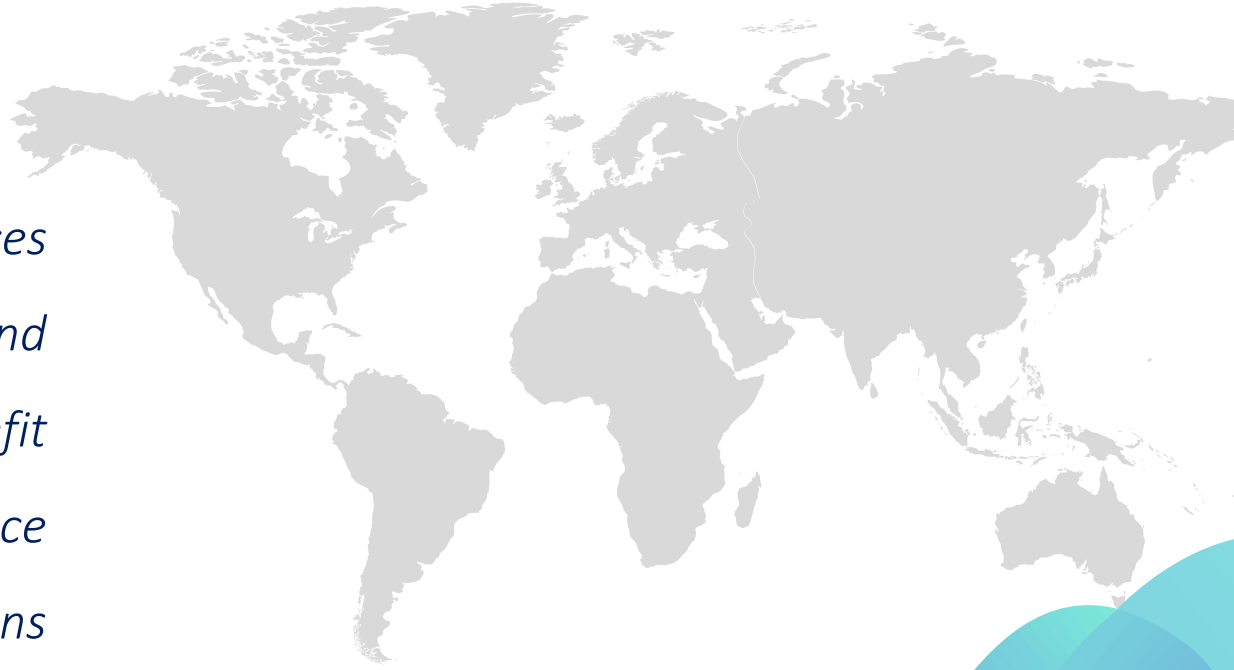
Webinar Description

Certainly, the most simplistic solution to achieving compliance excellence and 483 avoidance is “to do the right things right!” But what does this really mean?

I have distilled the “doing the right things right” solution into 7 separate individual keys or actions that will provide a solid foundation for the establishment of any 483 avoidance program. Why should you attend this Webinar? Because as much as we try, most regulated industries don’t have a set approach for developing a compliance program that is integrated into the fabric of their organization that is targeted to avoiding 483s, that also serves real valuable functions to improve operations, improve and maintain human competence, and enhance competitiveness. Compliance and regulatory affairs are viewed in many cases as a “non-value add” that is an expense and not an asset, that is a “check-the-box” to be completed in the event that there is a regulatory audit or issue and because it is required.

It is not bad to standardize your operations. It is not bad to build your operations around safety and efficacy. It is not bad to structure an organization that exceeds your regulatory responsibilities while at the same time optimizing every function within the company that the regulatory processes touch. This webinar will provide the approach and framework that you need to follow to make your compliance program a valuable ingredient in the process of running your business with the significant benefit of avoiding 483s and other adverse regulatory reporting while at the same time achieving a measure of operational excellence.

Who Should Attend ?



This webinar is applicable to the entire life sciences industry – pharmaceuticals, medical devices, and biologics. Position titles that this webinar will benefit include Associates, Managers, Directors, and Vice Presidents, quality assurance associates, operations personnel. The following positions are more descriptive of those applicable positions.

- *Operations Managers & Directors*
- *Compliance Managers & Directors*
- *Training Managers & Directors*
- *Quality Assurance Managers & Directors*

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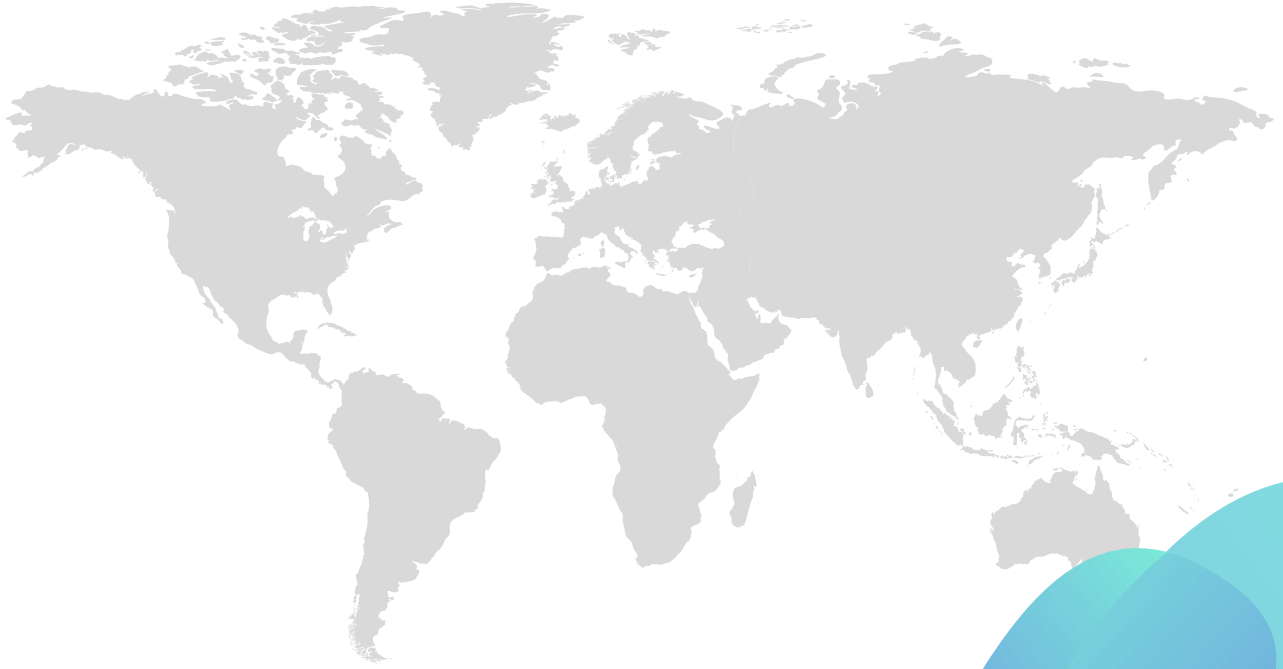
Why Should You Attend ?

483's can occur in any life science organization. The primary cause……not meeting regulatory requirements in practice. Avoiding 483's and adverse findings if the strategies are executed properly, will also significantly contribute to achieving operational excellence. The cost of a 483 is significant but unique to each company. In general, those costs include – reputation damage, competitor leverage, loss of business, lost stockholder confidence, and diversion from the job at hand, none of which a life sciences company can afford in today's competitive environment.



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