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Webinar on

Quality By Design (QbD) For Analytical Methods

Learning Objectives

- *Understanding uncertainty within the steps of an SOP*
- *Knowing how to choose critical steps that can cause a non-compliance*
- *Knowing how to choose a monitoring variable*
- *Understanding Control Charts*
- *Understanding Nelson's Rules*
- *Being able to have a trigger for a preventive action*

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This Webinar will highlight the use of statistical tools to monitor operations for a proactive operation.

PRESENTED BY:

John C. Fetzer, Ph.D., has had over 30 years of experience in HPLC methods development. He has authored or co-authored over 50 peer-reviewed papers on liquid chromatography, has served on the editorial advisory boards of the Journal of Chromatography, Analytical Chemistry, and Analytical and Bioanalytical Chemistry.

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

Webinar Description

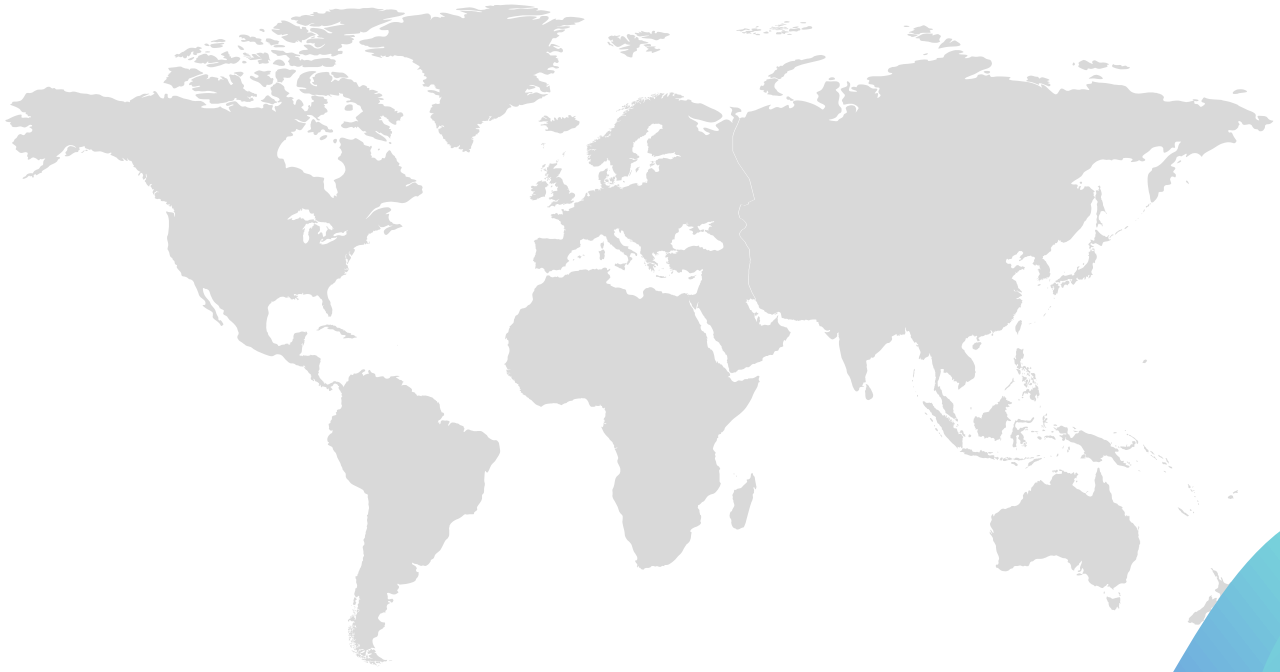
This 60-minute presentation will highlight the use of statistical tools to monitor operations for a proactive operation.

There are always certain steps in a method where control is critical either because this step contributes a lot to the overall uncertainty or its uncertainty is more likely to change from common causes. These critical points can be assessed and a monitoring program instituted. This data is then collected and plotted on a control chart. Using Nelson's rules of statistical use of control charts, the individual uncertainties are monitored. This allows for early observation and intervention before non-compliance occurs.

By looking through a method SOP and with knowledge of the chemistry and instrumentation, certain critical factors can be found. Others may be known from past non-compliances. Each of these factors can be assessed as a way to monitor steady and acceptable performance or times in which changes occur. This is done by measurement of a specific parameter and following that over time by using a control chart. Critical warning factors based upon Nelson's rule, which themselves are based on statistical probabilities, determine acceptable behavior or a likely deviation. These deviations then are signs that a preventive action is done before there is a non-compliance.

Who Should Attend ?

Any laboratory that is using GLP or ISO 17025 for compliance – any laboratory doing samples in pharmaceutical, biomedical, environmental testing, or assuring compliance with regulations.



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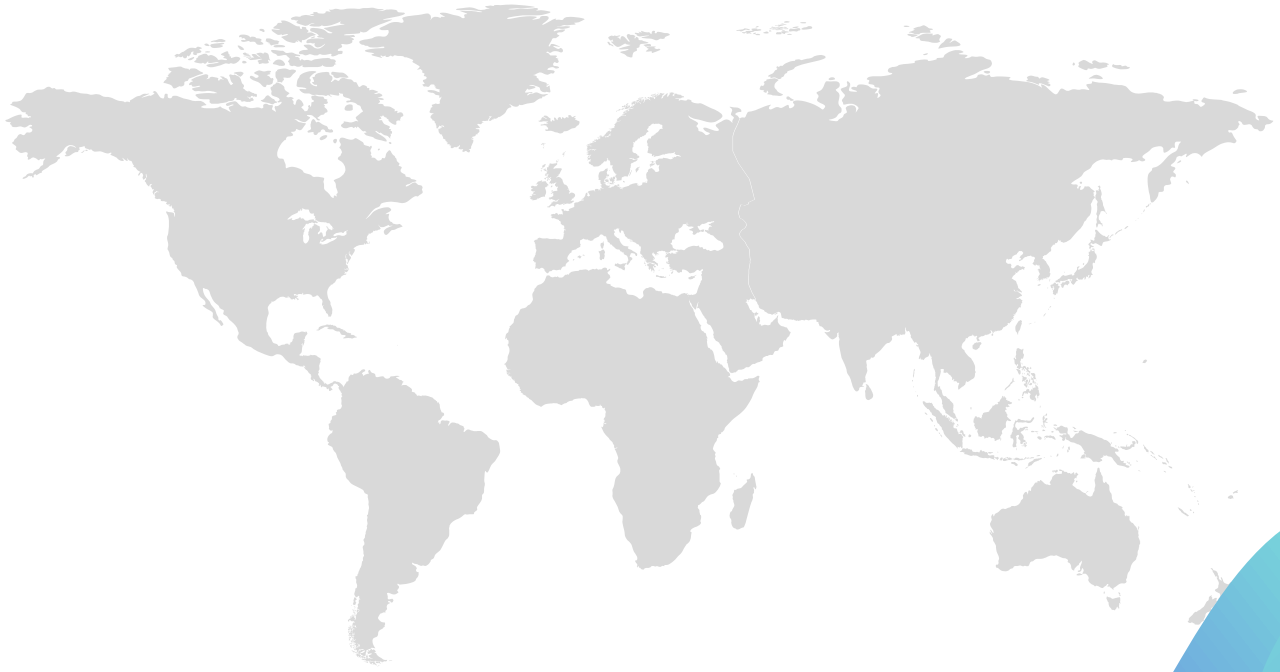
Why Should Attend ?

A non-compliance, when results are outside of +/- 3 σ, is a catastrophe that must be avoided. Using knowledge of a method allows for monitoring and preventive actions that can make a non-compliance very, very rare.



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