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*Webinar on*

# Best Practices for Implementing an Effective Cleaning Validation (using principles of upcoming ASTM E3106)

# Learning Objectives

- *Cleaning Validation Guidance*
- *Establishing Health Based Limits*
- *Quality Risk Management*
- *Lifecycle Approach*
- *Cleaning Verification*
- *Continued Validation Monitoring*
- *Cleaning Analytical and Microbial Methods*

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This webinar discusses the implementation of Cleaning Validation programs based on global Cleaning Validation Guidelines as they are currently available for pharmaceutical and biopharmaceutical industries.

**PRESENTED BY:**

*Igor Gorsky has been a pharmaceutical industry professional for over 30 years. He held multiple positions with increasing responsibility at Alpharma, Wyeth and Shire. He worked in Production, Quality Assurance, Technical Services and Validation including an Associate Director of Global Pharmaceutical Technology at Shire Pharmaceuticals.*

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

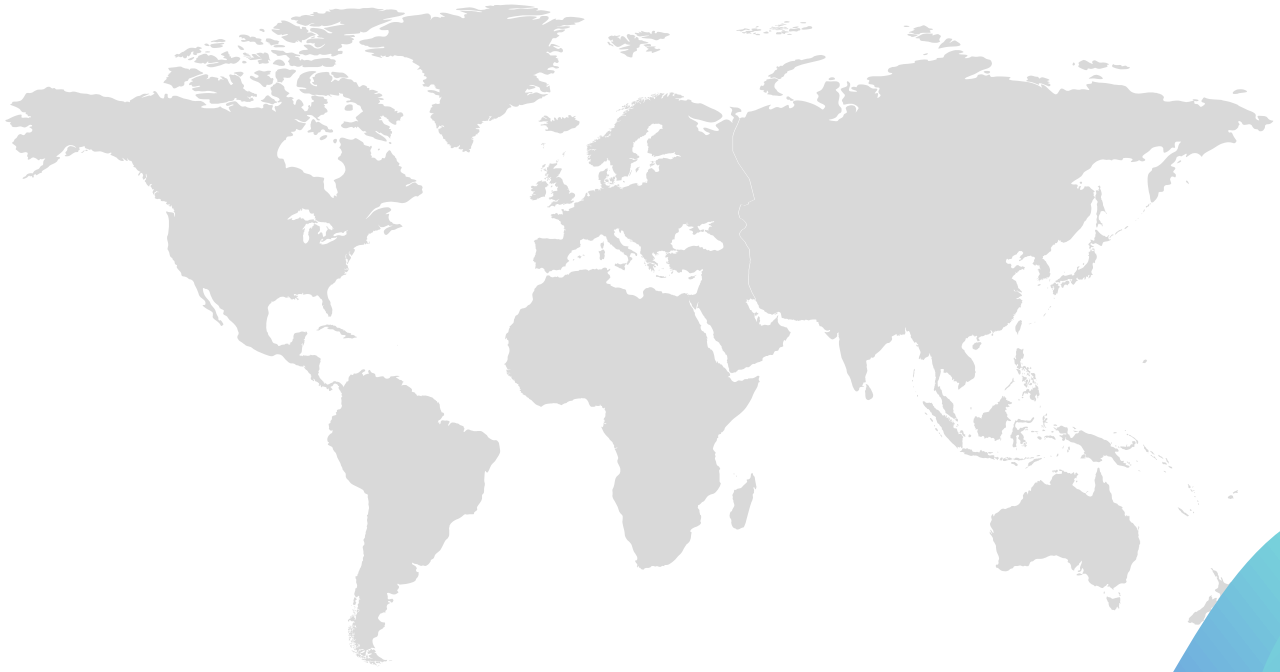
# Webinar Description

This webinar discusses the implementation of Cleaning Validation programs based on global Cleaning Validation Guidelines as they are currently available for pharmaceutical and biopharmaceutical industries. What makes this webinar special and unique is a very rare glimpse into upcoming ASTM E3106 for Cleaning Validation. This is a Risk-Based Science-Based Lifecycle approach guidance document that was fully vetted with industry as well as with the FDA. It is a first guidance document in the last 25 years (since the FDA Guidance of 1993) and its based-on elements of ICH Q8-11 and Process Validation Guidance. In addition, this webinar describes use of QRM (quality risk management) in Cleaning Validation and growing trend of applying this approach to lifecycle of a product manufacturing process. Establishing of health-based Cleaning Validation limits also discussed in this session. Additionally, recommendations on a compliant and sustainable program will also be covered, as well as regulator's expectation for these programs.

Cleaning Validation is a regulatory requirement as well as expectation. In addition, robust and compliant cleaning validation program makes perfect business sense for successful manufacturing facilities. Additionally, attendees and delegates will be provided glimpses of ASTM E3106 concepts.

# Who Should Attend ?

*Validation*
*Quality Assurance*
*R & D*
*Production*
*Quality Control*
*Microbiology*
*Engineering*
*Risk Management*



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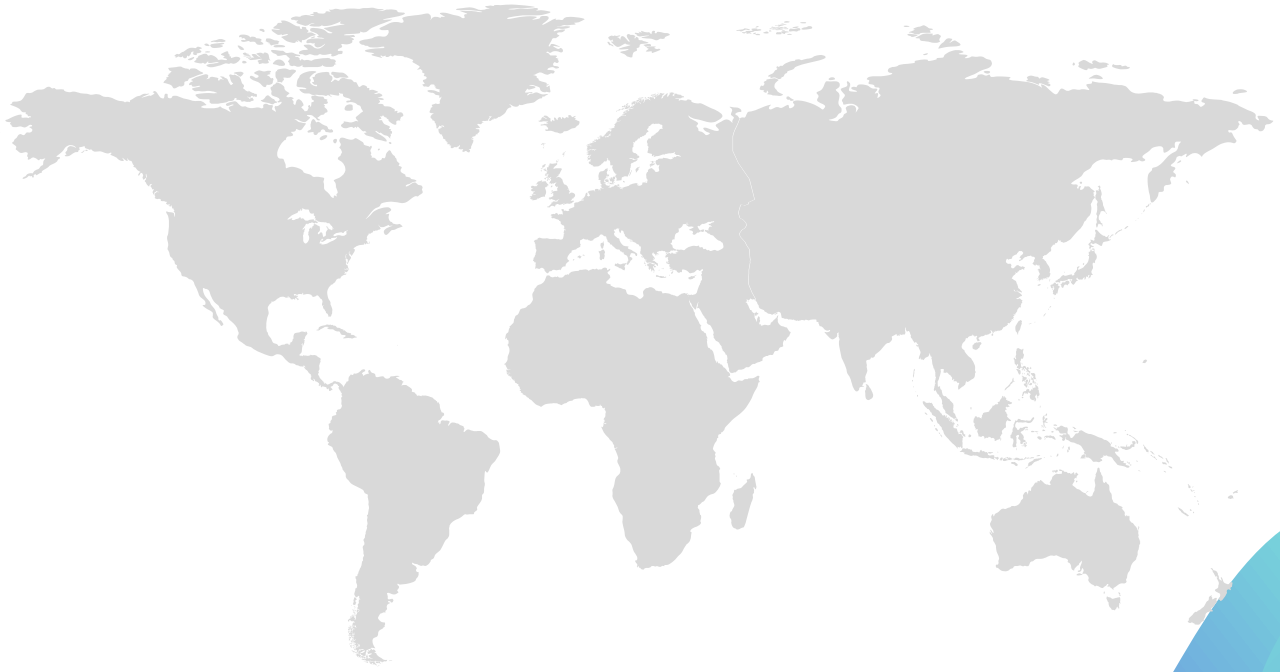
# Why Should Attend ?

*If you are a professional who is involved in the development of pharmaceutical and biopharmaceutical products and processes' cleaning procedures throughout the continuous lifecycle of drug products this webinar is definitely for you. During this session, we will Best Practices for Implementing an Effective Cleaning Validation that include the development of cleaning process programs and cleaning verification and validation programs. We will discuss regulatory validation guidance and show how quality risk management should be utilized in the implementation of a risk-based lifecycle approach to cleaning validation. We will also touch upon the use of statistics in cleaning validation process and talk about continued verification/monitoring. We will concentrate on a risk-based approach as it is a cornerstone of cleaning process validation principals and practice using principles of upcoming ASTM E3106.*



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