GRCEDUCATORS Axons Technology and Solutions

Webinar on

# **Cleaning Validation Guidelines**

## **Learning Objectives**

Cleaning Validation Guidance

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



This webinar discusses global Cleaning Validation Guidelines as they are currently available for pharmaceutical and biopharmaceutic

al 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.



On-Demand Webinar Duration : 90 Minutes Price: \$200

### **Webinar Description**

This webinar discusses global Cleaning Validation Guidelines as they are currently available for pharmaceutical and biopharmaceutical industries. In addition, it describes the use of QRM (quality risk management) in Cleaning Validation and the growing trend of applying this approach to lifecycle of the product manufacturing process. Establishing of health-based Cleaning Validation limits also discussed in this session. Additionally, recommendations on the complaint and sustainable program will also be covered, as well as the 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.



# Who Should Attend ?

Validation

Quality Assurance

R & D

Production

Quality Control

Microbiology

Engineering



# 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 discuss Cleaning Validation Guidelines 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.



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