

*Webinar on*

# **Equipment Validation, Tracking, Calibration and Preventive Maintenance**

# Learning Objectives

- Types of Validation*
- The Validation Sequence*
- Calibration Frequency and How to Reduce It*
- Understanding of Calibration Traceability*
- Benefits of Equipment Calibration Outsourcing*
- Calibration Remediation Requirements*



# Areas Covered

- Equipment Validation
  - Installation Qualification
  - Operation Qualification
  - Performance Qualification
- Equipment Calibration
- Use of Calibration Standards for Efficiency and Accuracy
- Equipment Maintenance
- Remedial Action for Out-of-Calibration Equipment
- Calibration vs. Maintenance: Which One?
  - Equipment Maintenance



This webinar includes Equipment Validation and Calibration, Use of Calibration Standards for Efficiency and Accuracy, Remedial Action for Out-of-Calibration Equipment.

**PRESENTED BY:**

*Jeff Kasoff, RAC, CMQ/OE, LBB, has more than 30 years in Quality and Regulatory management. Over that time, Jeff has implemented and overseen quality system operations and assured compliance, at all sizes of company, from startup to more than \$100 million in revenue. Jeff has the following certifications: Manager of Quality and Organizational Excellence certification from ASQ, Regulatory Affairs Certification from RAPS, and Lean Black Belt from IIE.*

On-Demand Webinar

Duration : 60 Minutes

Price: \$200

# Webinar Description

FDA and EU regulations require that firms have a program for the calibration and maintenance of test and measurement equipment. The program must include intervals, scheduling, specific procedures, limits of accuracy/precision, and remedial action in the event that the equipment does not meet established requirements. Prior to use, however, this equipment must be validated to make sure it produces a product that meets its specifications. There are ways, though, to validate equipment already in use.

This session will review the regulatory requirements for validation, including a detailed review of IQ, OQ, and PQ. A sample validation process will be followed through each phase. Documentation requirements for both protocol and results will be reviewed, as well as a list of pitfalls to avoid in documenting your validation. The importance of the Master Validation Plan will be discussed too. Preventive maintenance will be covered, including how to assure it does not adversely impact validated processes. A cost-effective equipment calibration program will be featured as well.



# Who Should Attend ?

*QA management, Quality Engineering staff*

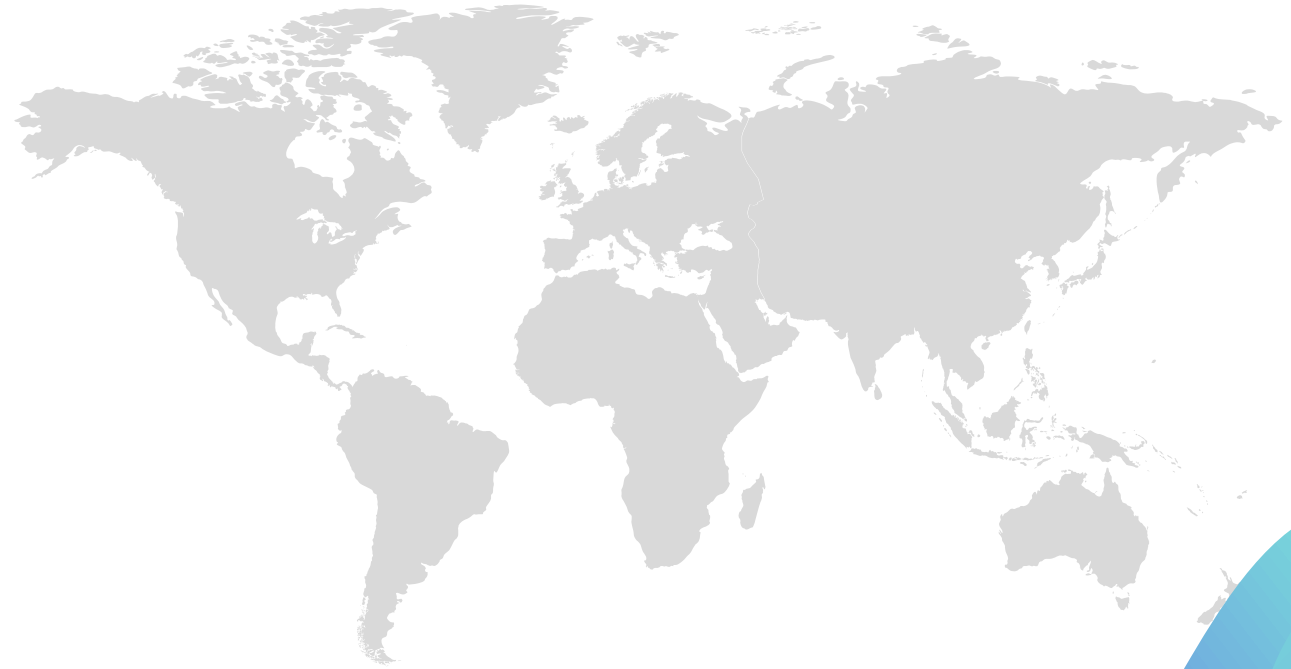
*R&D management, Engineering management*

*Production management*

*Manufacturing Engineering staff*

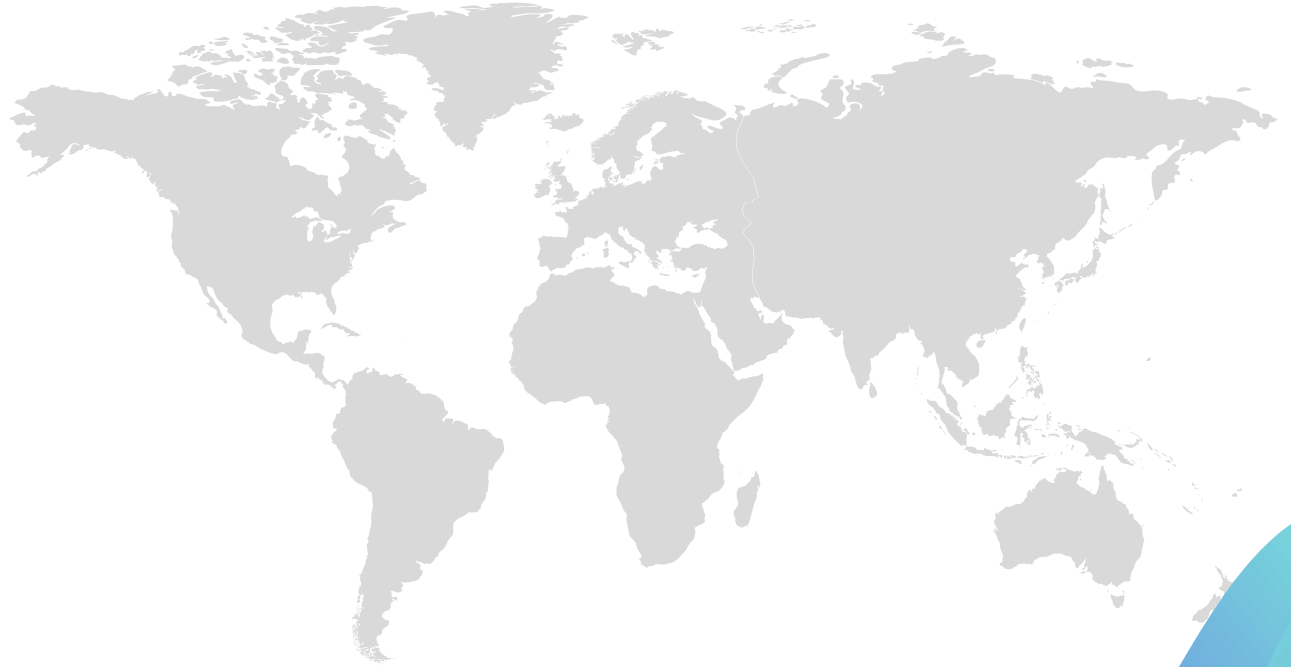
*Design engineers, Reliability engineers*

*Calibration technicians, Maintenance personnel*



# Why Should Attend ?

*Medical devices and pharmaceutical products must be safe and effective. Equipment used in assembly, test, or measurement must be able to be used for its intended purpose and result in a product that meets its required specifications. It is not cost effective to routinely measure product to evaluate conformance to all specifications. It is, therefore, critical to have an in-depth understanding of the methods for establishing equipment and corresponding processes that assure product output on a routine basis.*



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