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Webinar on

Scrutinizing Test Method Validation (TMV) To Verify The Performance Of A Medical Device

Learning Objectives

- *Test Method Validation - Overview*
- *Quality System Regulation, 21 CFR Part 820, and ISO 13485 - Overview*
- *When should Methods be Validated?*
- *Qualification vs Validation*
- *Types of Test Method Validations*
- *How to perform successful test method validations*

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- *How to ensure your inspection of verification is effective*
- *Detailing real-life case studies*
- *Understanding global reference standards for test method validation*
- *FDA requirements for TMV*
- *How to prove your inspection method is repeatable and reliable*
- *Recommendations: Some Best Practices and Strategies*

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This webinar will help you better understand Test Method Validations to verify the performance of a Medical Device, global reference standards, the FDA requirements.

PRESENTED BY:

José Mora is a Principal Consultant specializing in Manufacturing Engineering and Quality Systems. For over 30 years he has worked in the medical device and life sciences industry specializing in manufacturing, process development, tooling, and quality systems. Prior to working full time as a consulting partner for Atzari Consulting, José served as Director of Manufacturing Engineering at Boston Scientific and as Quality Systems Manager at Stryker Orthopedics, where he introduced process performance, problem-solving, and quality system methodologies.

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

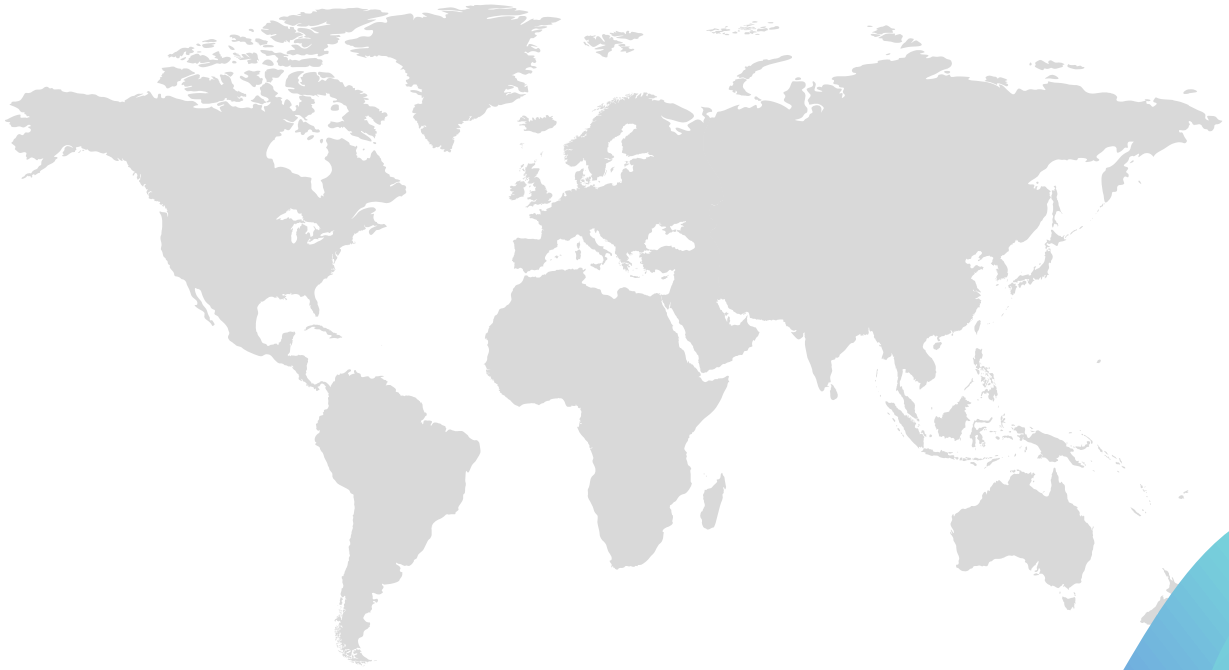
Test method validation is an often-confusing requirement for medical devices. A fundamental issue is the role-reversal between the test method and the product or process it is designed to detect. For example, while a defect-free process is desirable, a test method must be reliable both in detecting defects and in not rejecting acceptable samples. Those who work with process optimization and validation focus on optimizing a process and reducing variability. Those working on Test Method Validation, on the other hand, focus on discerning between process variation and measurement error from the test method itself.

Often, the test method for a new process must be designed specifically for that process, and some of the pitfalls are in confounding the process itself with the test method. This webinar will present case studies to explore how those issues are addressed.

Although the FDA provides guidance on method validation, the Code of Federal Regulations (CFR) Title 21 Part 820: Quality System Regulation (QSR) 21 does not specifically broach the topic of method validation. It alludes to it in equipment qualification, statistical methods, process validation, design controls, and other sections. In numerous warning letters, we have witnessed the significant importance of method validation as an applicable medical device validation activity. Although some traditional methods have been applied to chemical, microbial and laboratory acceptance testing methods, they are generally less utilized in the medical device industry.

Who Should Attend ?

Managers, Supervisors, Directors, and Vice-Presidents in the areas of



Research & Development
Quality Engineers and Auditors
Manufacturing Engineers
Regulatory Affairs Teams
Quality Assurance & Quality Control Teams
Operations Teams
Document Control
Design Assurance Teams
Device Development Teams
Personnel involved in Verification and Validation planning, execution and documentation for devices

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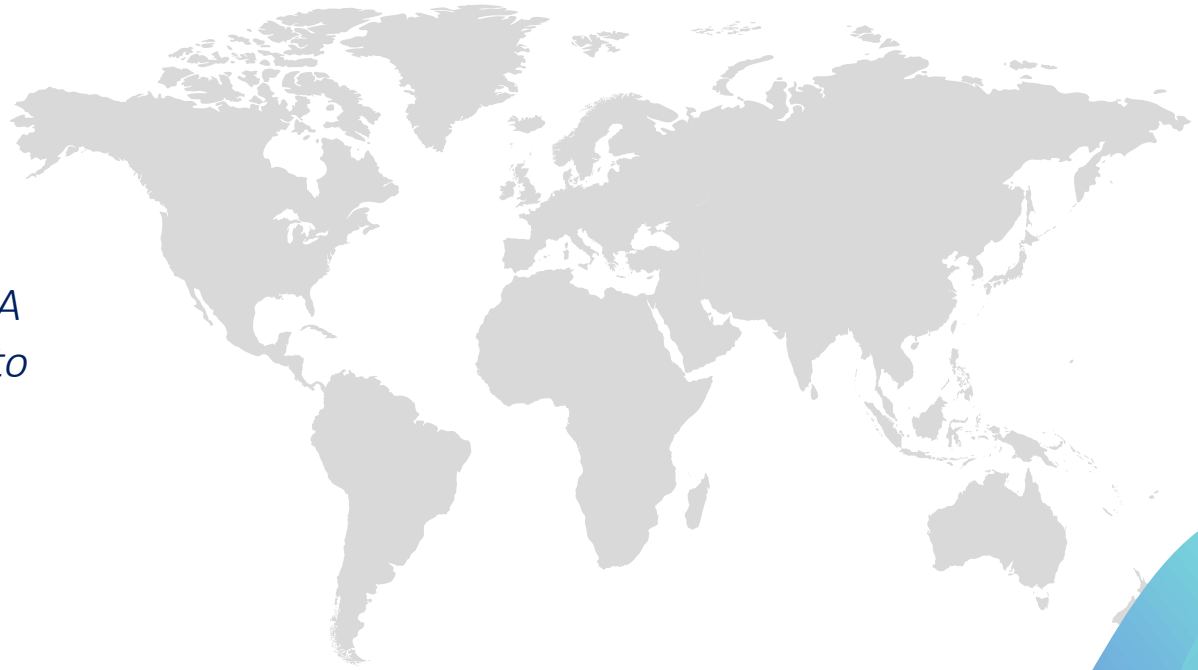
Why Should Attend ?

This webinar will help you better understand Test Method Validations to verify the performance of a Medical Device, global reference standards, the FDA requirements and how to perform successful TMV to ensure your inspection of verification is effective, using detailed real-life case studies.



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