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Webinar on

Software Validation Utilizing Principles of Lean Documents and Lean Configuration

Date : July 15, 2021

Areas Covered

- *Software configuration*
- *General setup, Organization*
- *User Management*
- *Rights Groups, Roles, and Actors*
- *Products, Processes*
- *Failure Modes, Process Signals, Task*
- *Screens, menus, and modules*
- *Process validation steps*

This webinar is an overview of the coming changes and their implications, using a new approach yet is based upon solid principles and proven practices.

PRESENTED BY:

Jose Ignacio 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. José worked for 10 years at Cordis Corporation.

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Date : July 15, 2021

Time : 01: 00 PM EST

Duration : 90 Minutes

Price: $179

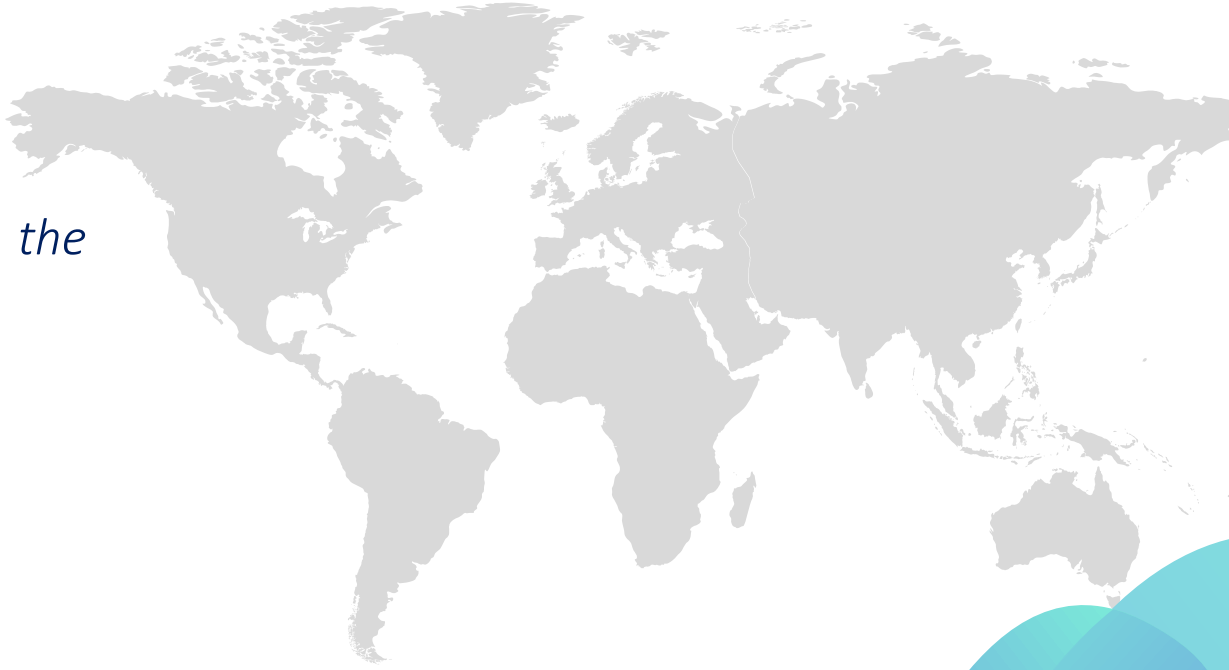
Webinar Description

All life science businesses are required to maintain their Quality Management System (QMS) processes in a state of control, via controlled documents and objective evidence in the form of records. New approaches to software validation will help avoid many of the structural costs with a major endeavor by removing legacy methods that applied to paper systems. This will also set the stage for further integration with other software systems and modules.

With the increased need to automate many Quality Management System (QMS) and manufacturing processes, as well as medical devices themselves, software validation has continued to come to the forefront in terms of design controls, process controls, supply chain management, and almost every process currently involved in medical devices. This is happening while AI and robots continue to also proliferate in the general business, marketing, and sales arena.

One the trend is that often controlled documentation is embedded into the the software itself and these may not have received the scrutiny of their paper document counterparts in terms of controls and review. With the increased burden on software from every direction, the traditional ways of configuring information are becoming obsolete artifacts of a paper-based era. A new approach to software configuration and validation is needed to set the stage for this new era of information and the internet of things (IoT).

Who Should Attend ?



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

- *R&D*
- *Manufacturing Engineering*
- *Design Assurance*
- *Quality Assurance*
- *Operations*
- *Document Control*

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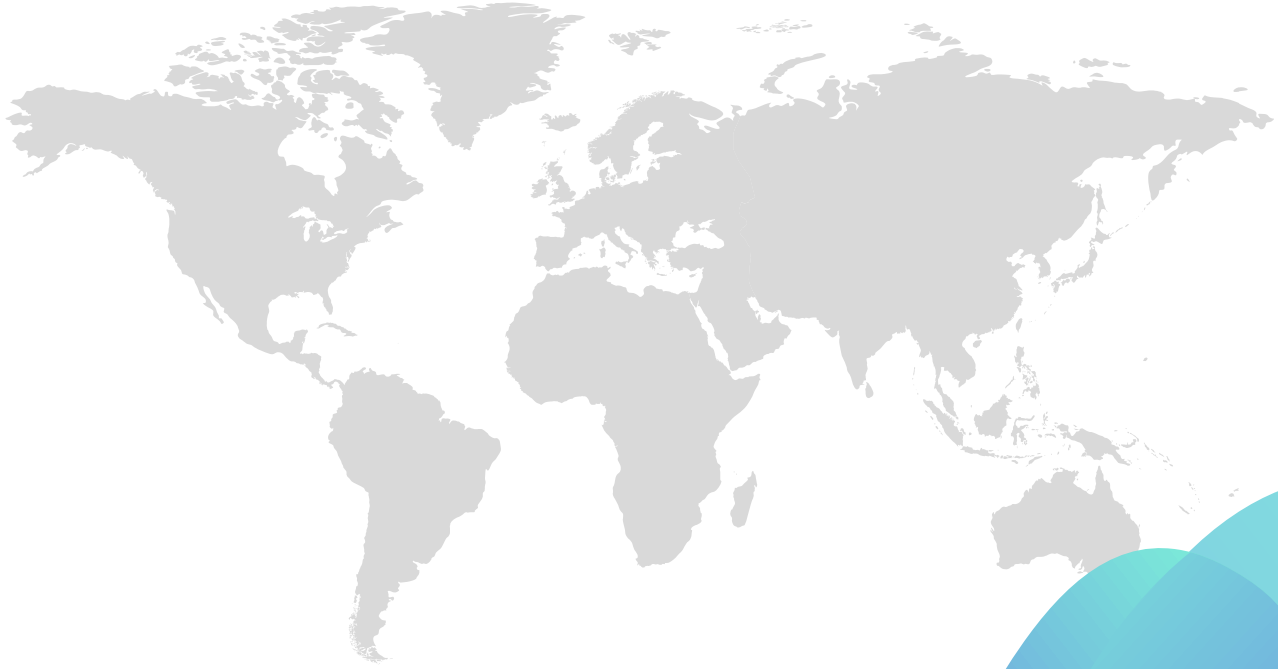
Why Should You Attend ?

You will soon be overwhelmed by continuing to apply paper document methods and approaches to software configuration and validation. Rather than wait to be surprised by unexpected situations, or to implement requirements haphazardly, it is better to understand the hands-on challenges of dynamic requirements as they push the boundaries of technology and new applications.



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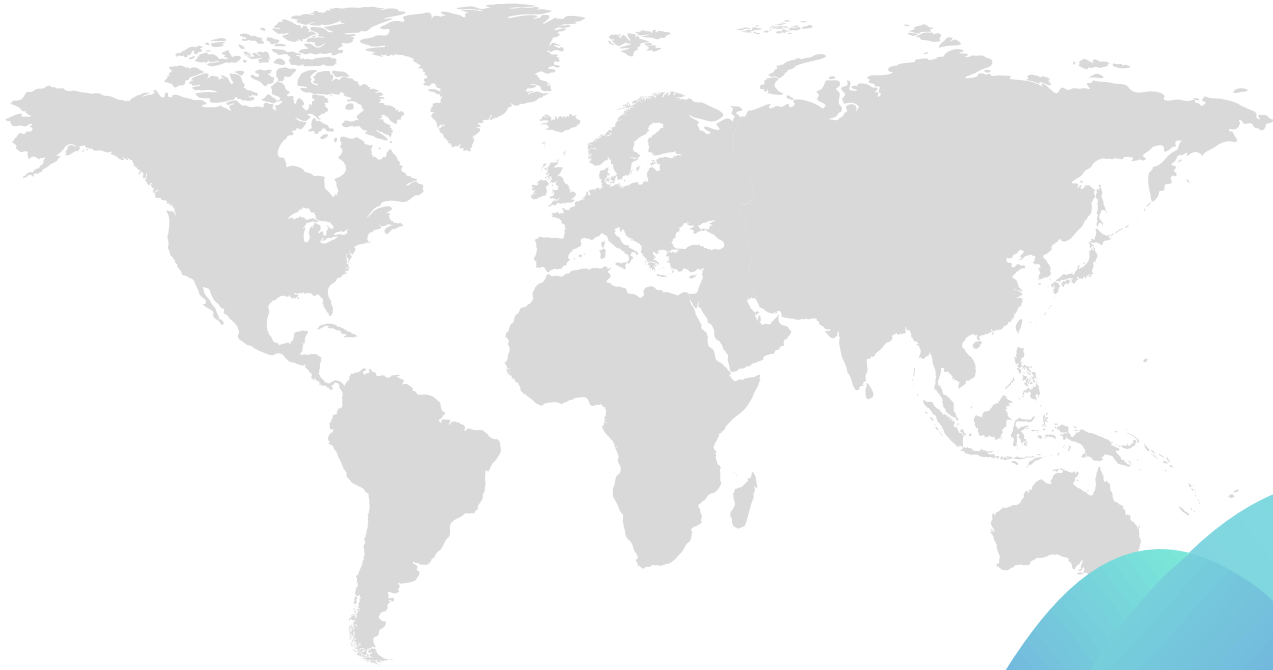
If you are already constantly struggling to create, manage, and maintain all of the information found in controlled documents, all of which are often redundant, repetitive, and clustered together in an awkward manner, and now realize a different way is needed, this webinar is something that will give you a different perspective and a very different approach that you can use. This webinar is an overview of the coming changes and their implications, using a new approach yet is based upon solid principles and proven practices.



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