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Webinar on

Risk Based Design Control – The New Paradigm For Medical Device Design

Areas Covered

- *The 2019 approach to design control*
- *What do FDA and ISO say about it?*
- *How do you present it to management?*
- *What are the key steps in risk-based design control?*
- *How to implement risk-based design control in our company*

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FDA Design Control has been around since 1996 when the FDA published the design control regulations as 21 CFR Part 820.30.

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.

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On-Demand Webinar

Duration : 60 Minutes

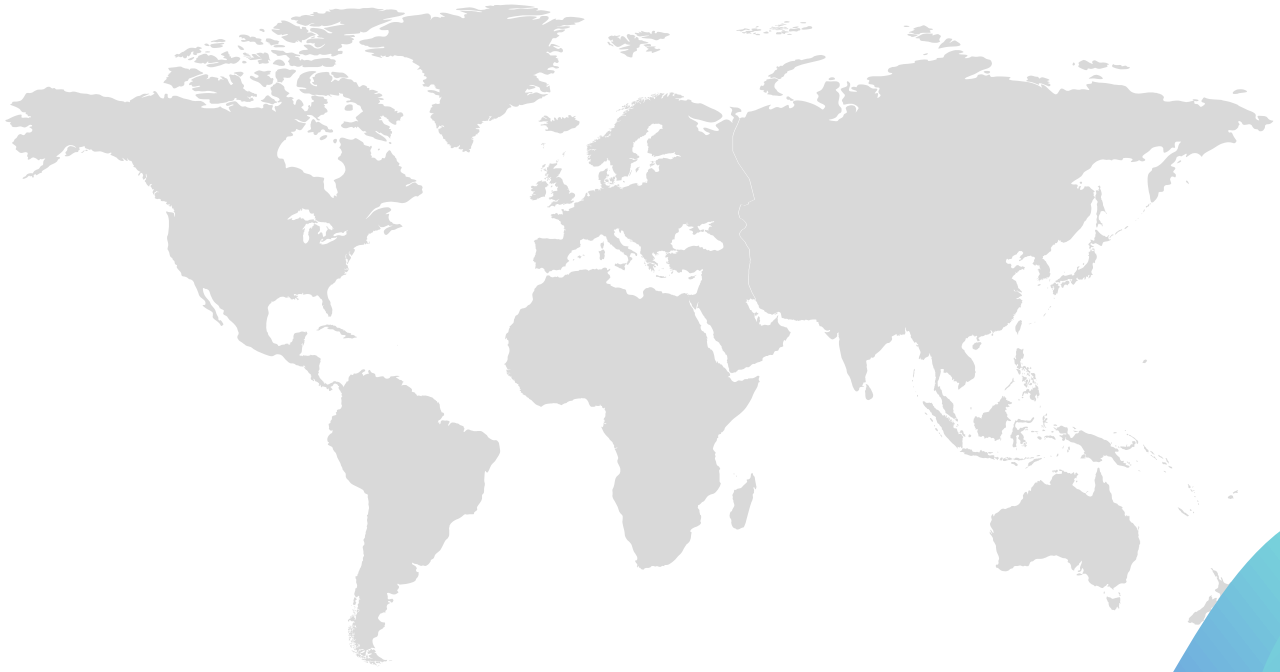
Price: $200

Webinar Description

Design Control is essentially a quality assurance program for the Research and Development department. The VP or Director of R&D owns the design control effort. Over the years many companies have included the design control requirements into their project plans and build the Design History File as part of the development process. Nothing has changed in these basics, but FDA's and ISO's expectations are now that risk management is built into the design and development process. Thus, the emergence of risk-based design control. This approach will be discussed in detail during this webinar.

Who Should Attend ?

VP, Directors, Managers of R&D, Project Managers in R&D, VP, Directors, and Managers of QA, Internal Quality Auditors, QA Consultants to the medical device industry



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Why Should Attend ?

We must be prepared for quality audits. The MDSAP, ISO 13485:2016 certification, FDA PAI, and routine QSIT inspections. If these acronyms are familiar to you, then this is a webinar you should attend.

FDA Design Control has been around since 1996 when the FDA published the design control regulations as 21 CFR Part 820.30.

For many years establishing a design control SOP that included all the sections of Part 802.30 was all FDA expected. But things have changed, and FDA now expects a risk-based approach in addition to the basics.

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