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Webinar on

EU Medical Devices Regulation: CE Mark Expiration and the EU Refusal of Your Exports

Learning Objectives

- *Identify the significant MDR requirements that apply*
- *Benefit/Risk analysis*
- *Understand "Substantial Equivalence" for premarket authorization*
- *Highlight post market requirements for reports, procedures, and records*
- *Identify the U.S. Export consequences*

The webinar will cover an overview of the changes in the EU's device regulatory requirements.

PRESENTED BY:

Casper (Cap) Uldriks brings over 32 years of experience from the FDA. He specializes in the FDA's medical device program as a field investigator, served as a senior manager in the Office of Compliance and an Associate Center Director for the Center for Devices and Radiological Health.

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On-Demand Webinar

Duration : 60 Minutes

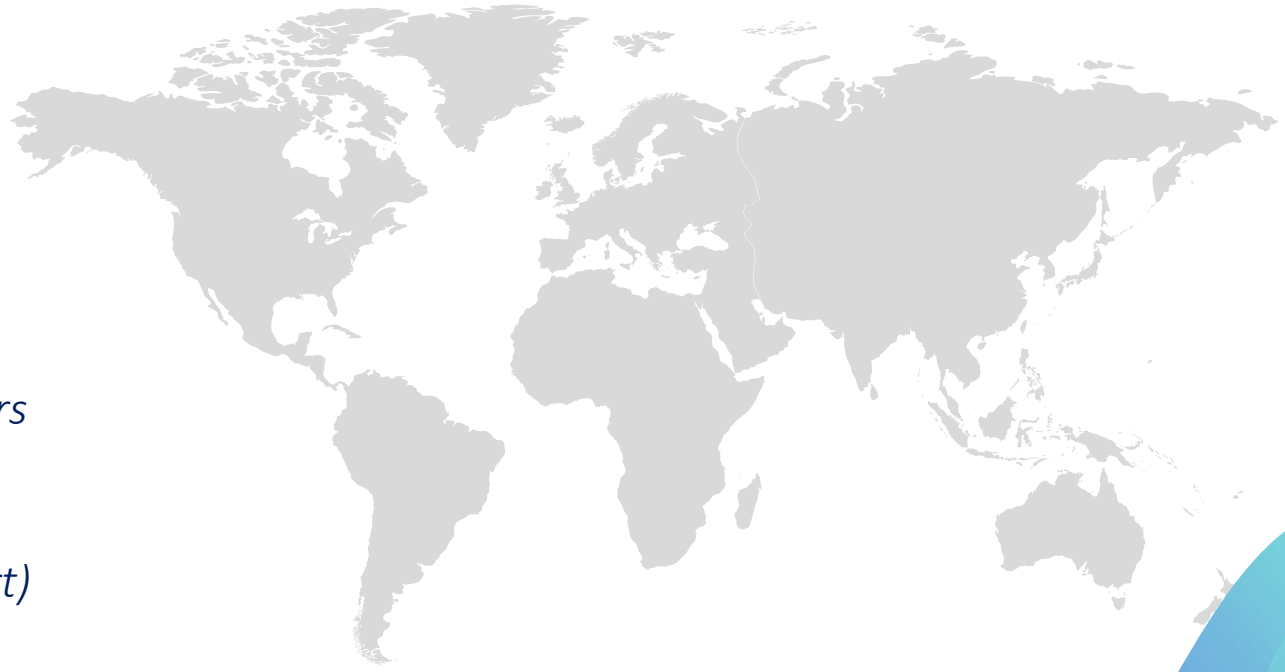
Price: $200

Webinar Description

FDA and the EU have tried to harmonize device regulatory requirements for over 25 years. Major differences between the FDA and the EUincludepremarket authorization (CE Mark), complaint investigations, post market surveillance, and reports. The EU's new Medical Devices Regulation (MDR) incorporates more rigorous regulatory requirements for those areas and in some cases outpaces the FDA's requirements. The FDA gold standard may take a back seat. Corporations, manufacturers, distributors, importers and Notified Bodies now have specific requirements that must be met in order to market products with a CE mark. The requirements are more extensive than FDA's in critical areas. This means you need to upgrade and implement your Quality System regulation program before 2020.

Who Should Attend ?

Device Manufacturers
Device Exports / Importers
FDA Consultants
Device Specification Developers
Forensic Engineers
Regulatory Program and Procedures Developers
Quality Assurance Managers and Consultants
Regulatory Affairs Directors
International Logistics Manager (Export/Import)
Three-year business plan developers
Device design/specification developers
Postmarket surveillance managers



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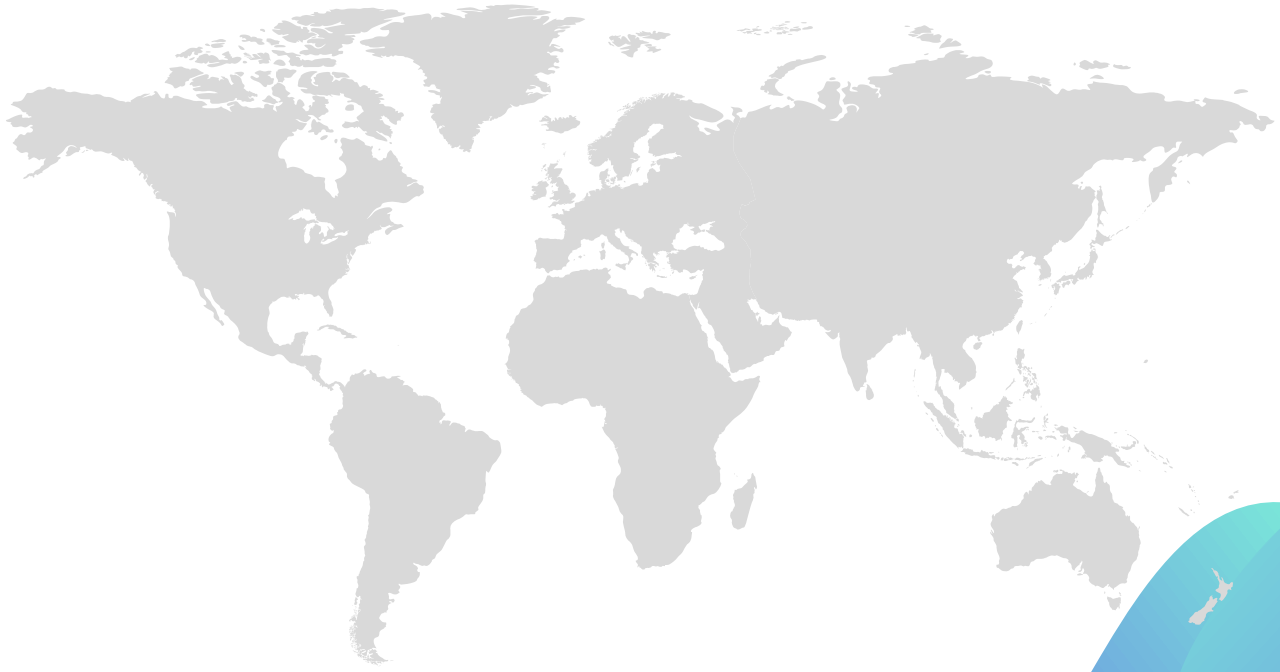
The webinar will cover an overview of the changes in the EU's device regulatory requirements. Compliance is required. Firms may be dismayed at the new requirements. The economic burden will be significant. A CE mark is maybe withdrawn for currently marketed devices that have predicates relying on technology for over ten years. Devices that do not meet the new CE mark requirements are subject to refusal by the foreign country and therefore do not meet the FDA's legal requirements for export status. This means your device has no market in the EU and will not be permitted back into the U.S.

Firms need to review their FDA regulatory program to identify where some requirements may need to be revised so device design, production, CAPA and the use of a Total Product Life Cycle Paradigm conform to FDA's and the EU's requirements.

The topics of the webinar will include the following:

- *How their products are now defined under MDR*
- *New compliance requirements*
- *The impact of new CE mark qualification*
- *Legal impact on U.S. exports*



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