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Webinar on

The New ISO 14971 - How to Create a Risk File for Medical Devices

Learning Objectives

- *What is the Medical Device Single Audit Program (MDSAP)?*
- *Which Companies must have MDSAP?*
- *Which Companies should have MDSAP?*
- *Which Companies should postpone MDSAP?*
- *What are the requirements of MDSAP?*
- *How to implement MDSAP in a smart way into an quality management system according to ISO 13485, 21 CFR 820 (QSR) or any other regulatory framework?*
- *How the MDSAP-Audit is working?*
- *What is the difference between MDSAP and European Notified Body Audits?*

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The course will give you an overview of the requirements and how a smart implementation of these requirements in your product documentation is possible and finally what are the expectations of the European Notified Bodies.

PRESENTED BY:

Prof. Dr. Dr. h.c. Frank Stein, medical engineer, medical engineering experience since 25 years, clinical and research experience in cardiac surgery and cardiology, industrial experience in ophthalmology, neurology, traumatology and dental implants, active implants, active devices, international project and regulatory consulting experience in Europe, North-America, Asia, Australia, Arabic Countries, Latin-America.

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On-Demand Webinar

Duration : 90 Minutes

Price: $200

Webinar Description

This course will give an introduction into the new ISO 14971 and how to create a risk management file according to the ISO 14971. The course will give you an overview of the requirements and how a smart implementation of these requirements in your product documentation is possible and finally what are the expectations of the European Notified Bodies.

Who Should Attend ?

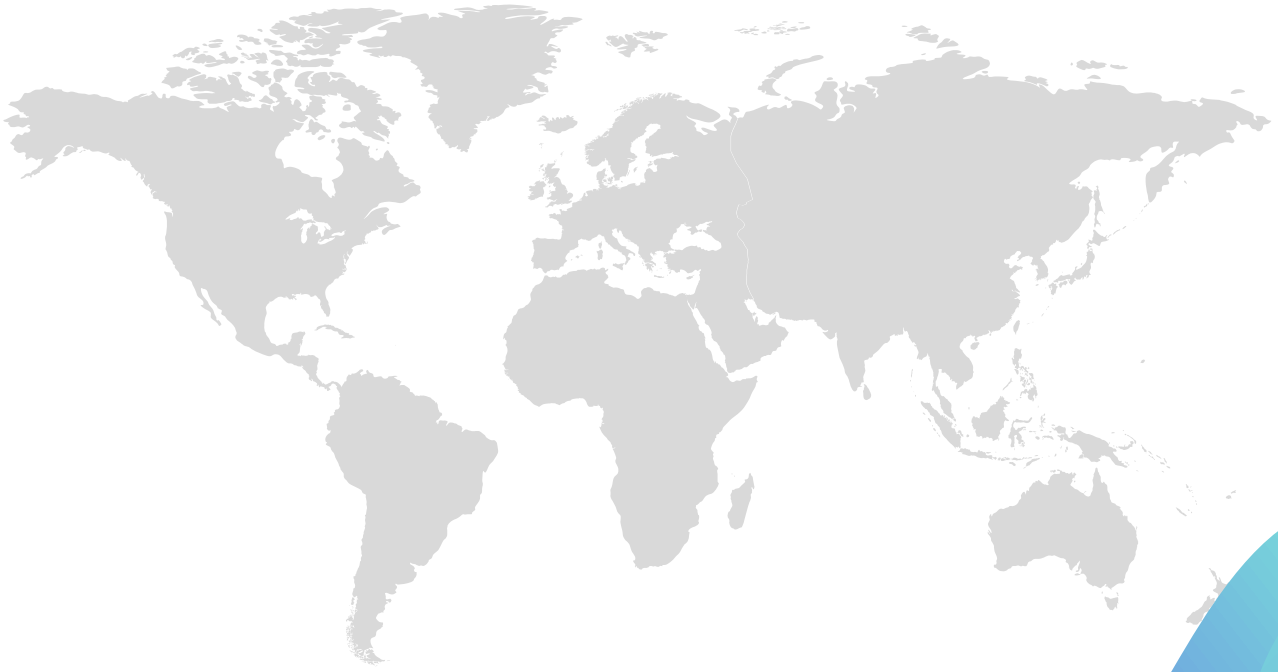
CEO's of companies, which sell to Australia, Brazil, Canada, Japan or US

Regulatory Affairs Managers of Companies, which sell to Australia, Brazil, Canada, Japan or US

Quality Managers of Companies, which sell to to Australia, Brazil, Canada, Japan or US

Quality Representatives of Companies, which sell to Australia, Brazil, Canada, Japan or US

Other managers, which need to deal with regulatory or quality guidelines



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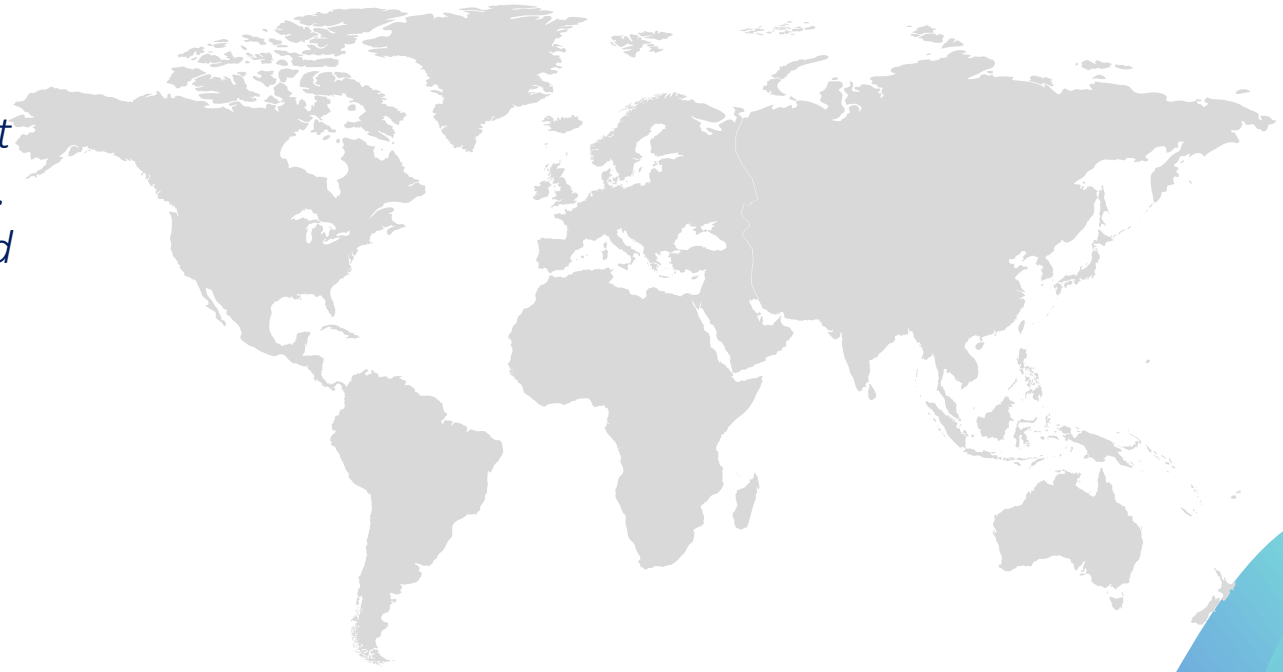
Why Should Attend ?

You should attend this webinar to understand, what is the ISO 14971 and how is the ISO 14971 working. Your implementation time should be short and need smart ideas to reach the right level of a risk management file according ISO 14971.



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