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Webinar on

STED - File: How to Improve Your Technical File

Learning Objectives

- *Quality management processes additional to the SO 13485:2016 quality management standard for medical device companies*
- *Requirements in comprehensive product documentation in a global market e.g. Canada, Australia, Europe*
- *Maintenance of a STED-File*
- *First Setup of a STED-File*

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This course will give an introduction to the creation and maintenance of technical documentation according to the STED format.

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

The STED-File with the special format as technical documentation covers a lot of countries and help to have technical documentation in global acting companies. A STED-File collect all the data's and can help you to keep the overview to deal with this format regarding the several requirements in countries, which required STED-Format e.g. Australia, Canada, etc. Another topic is how to deal with the STED-Format regarding the new EU MDR File Format in Europe and how to convert or work with a mapping table to be prepared for technical file submissions beginning this summer 2019 in Europe. This webinar will show, how to plan and conduct a gap-analysis, an action plan and how to be on track with first setup and maintenance of the file. A STED-File connect the quality management department and the regulatory affairs department. The STED-File-Format requires activities in both areas. Technical documentation and quality management are strong connected e.g. in the processes post-market surveillance, post-market clinical follow-up, clinical evaluation, risk management, technical documentation, complaint management, vigilance.

This course will give an introduction to the creation and maintenance of technical documentation according to the STED format. This format is mandatory for technical file submissions in several countries e.g. Canada, Australia and you can use this format with a matching table for the European Union, which requires starting in summer 2019 the EU MDR format. The introduction will give an overview about the structure, term definitions, the requirements for the quality management system and the technical documentation, how a smart implementation of these requirements in the quality management system and the technical documentation is possible and finally how to prepare your technical file reviews by authorities and how to work with several formats by several countries.

Who Should Attend ?

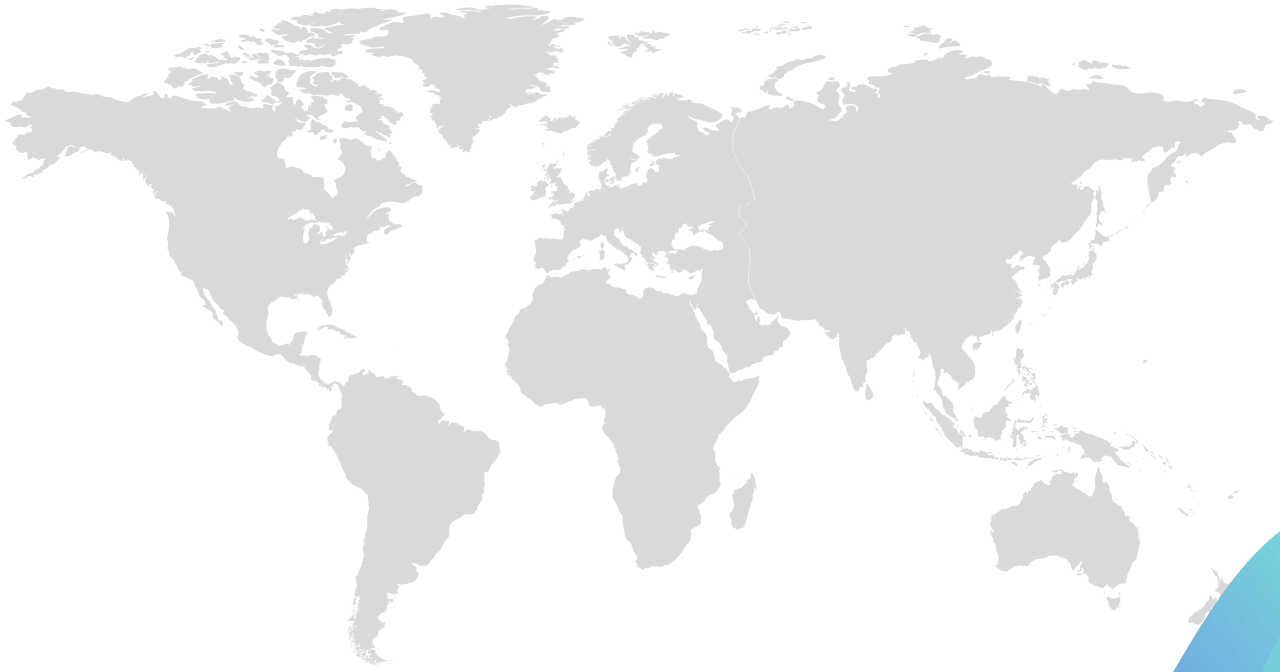
CEO's of companies

Regulatory Affairs Managers of Companies

Quality Managers of Companies

Quality Representatives of Companies

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



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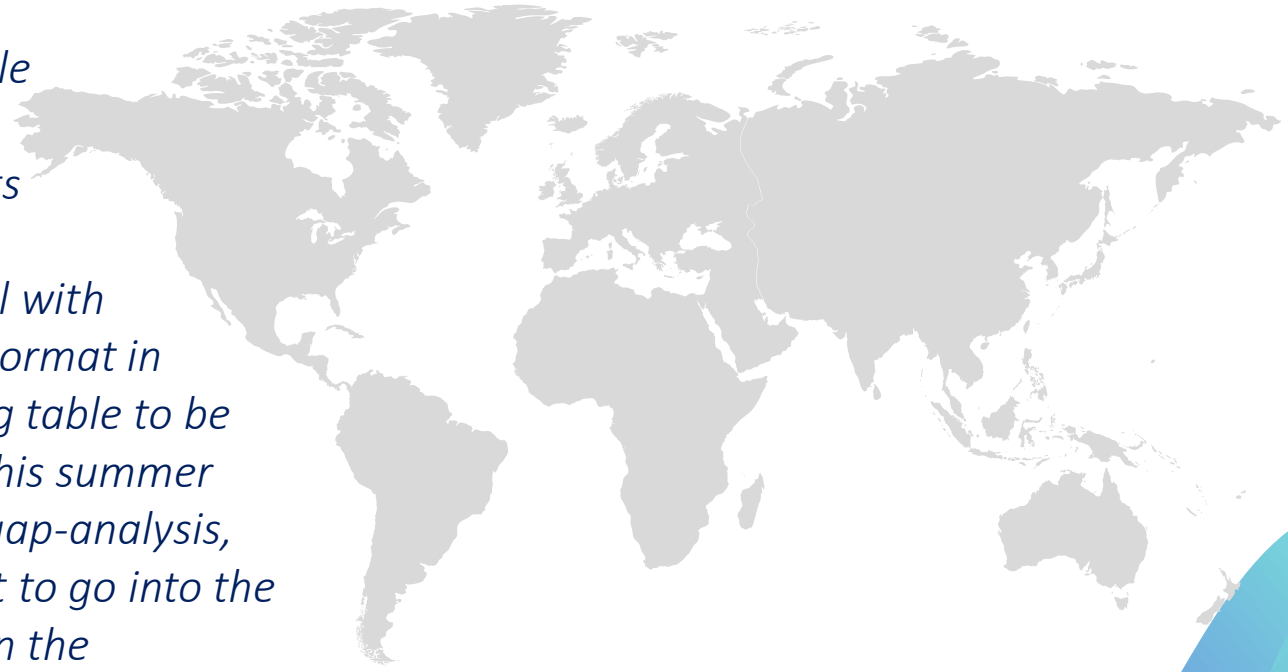
Why Should Attend ?

You should attend to learn more about the STED-File as technical documentation and how to deal with this format regarding the several requirements in countries, which required STED-Format e.g. Australia, Canada, etc. Another topic is how to deal with the STED-Format regarding the new EU MDR File Format in Europe and how to convert or work with a mapping table to be prepared for technical file submissions beginning this summer 2019 in Europe. Learn how to plan and conduct a gap-analysis, an action plan and how to be on track. Learn, what to go into the quality management department and what to do in the regulatory affairs department. The STED-File-Format requires activities in both areas. Technical documentation and quality management are strong connected e.g. in the processes post-market surveillance, post-market clinical follow-up, clinical evaluation, risk management, technical documentation, complaint management, vigilance.



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