ISO 13485 (e)QMS

Implementation & training workshops

For medical device/diagnostics start-ups

2023 dates

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Learn how to implement an ISO 13485 (e)QMS and train on the procedures with our workshops

A QMS consists of procedures that are implemented in clearly structured SOPs (Standard Operating Procedures) and associated templates.

The overarching element of this process landscape is the quality manual.

An ISO 13485 certified QMS helps to obtain a successful product certification. It increases transparency of the various business processes and significantly reduces error and complaint rates and related costs.

Workshops outline

April 17th **01** **Regulatory strategy**
Introduction to medical devices regulations, qualification, classification and insights on conformity assessment (2 hrs)
with Beat Steffen & Barbara Jeroncic

April 19th **02** **QMS**
Quality manual, management responsibilities, document management, human resources, training (2 hrs)
with Martina Coscia & Silvia Scolari

April 21st **03** **QMS**
Design and development, risk management and usability engineering (4hrs)
with Frederike Brühschwein-Mandic & Daniel Meier

April 24th **04** **QMS**
Change management, labeling, clinical evaluation (3 hrs)
with Martina Coscia & Cécile Rod

April 26th **05** **QMS**
Supplier handling, quality agreements, purchasing, incoming inspection, production, storage, packing, distribution, sales (4 hrs)
with Stefano Adami & Mattias Larsson

April 28th **06** **QMS**
Infrastructure and work environment, internal audits, corrective and preventive actions (3 hrs)
with Emilia Berg & Silvia Scolari

May 2nd **07** **QMS**
Complaints, post market surveillance, vigilance, clinical investigation (3 hrs)
with Cécile Rod & Carin Nilsson

May 3rd **08** **QMS**
SW lifecycle process according to IEC 62304, including cybersecurity, machine learning and artificial intelligence (4 hrs)
with Frederike Brühschwein-Mandic, Daniel Meier & Xavier Willemin

May 5th **09** **eQMS**
Demo of eQMS based on Confluence, intro to transition QMS to eQMS, and intro of the validation dossier (2 hrs)
with Xavier Willemin

About
the workshops

Remotely (Microsoft Teams)

English

4-7 start-ups

April 14th - May 5th
Registration deadline: April 1st

Training certificate

Workshops 1 to 7 : CHF 13'300.00 per company
Workshop 8 : CHF 3'600 per company
Workshop 9 : free of charge for participants of worskhops 1 to 7

Key
takeaways

01 Deep understanding of the QMS during the workshops and the implementation

02 Interaction with non-competing companies in the same industry, ompanies can support each other with the implementation

03 Reduced costs compared to a QMS set up by a consultant specifically for one company

04 Training of participating employees

05 Seamless transition from training to practice

06 Discussion of implementation and customization

07 Interaction with experienced consultants and other participants

Participant
profile

- Medical device/diagnostics start-ups (up to 3 participant per start-up)

Instructors

- Beat Steffen, Barbara Jeroncic, Stefano Adami, Mattias Larsson, Cécile Rod, Martina Coscia, Silvia Scolari, Frederike Brühschwein-Mandic, Daniel Meier, Emilia Berg, Carin Nilsson, and Xavier Willemin

Contact

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Registration

- To sign up please fill in the form and send it by email

ISO 13485 (e)QMS

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Registration & questionnaire

01 Company name, address, and contact person:

02 What does your company do? You can attach a brochure or refer to your homepage.

03 When do you want to get your (e)QMS certified?

04 For what kind of medical device do you seek EC certification and when?

05 Please, specify the intended use of your device.

06 How is the device classified according to the European medical device regulation?

07 What do you expect from the Workshop?

08 Which workshop(s) are you interested in?

- QMS without SW part (1st to 7th workshops)
- SW part QMS (8th workshop)
- eQMS introduction (9th workshop)

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Names of participants:

I herewith register for the confinis ISO 13485 QMS development Workshop for Medical Device/IVD Start-Ups.

Place, Date

Name Signature