confinis

regulatory compliance worldwide

ISO 13485 QMS development Workshop for Medical Device/IVD Start-Ups

15 Nov — 09 Dec

Up to 8 meetings of 2 - 4 hours

Location: remotely (Microsoft Teams).

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 not only obtain a successful product certification but guarantees an increase in transparency of the various business processes and thereby significantly reduces error and complaint rates and related costs.

To sign up, please fill in the attached questionnaire and send it by email (see below).

Deadline for registration: 8th November 2021

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Format

- ◊ 8 workshops
- ◊ Conducted by one of our experts together with other start-ups
- ◊ Documents, SOPs, templates provided electronically in advance to be studied and to prepare questions
- ◊ Interaction with experienced consultants and other participants based on the documents received
- ◊ Seamless transition into practice and training at the same time
- ◊ Enough time during workshops to discuss questions regarding implementation (customization)
- ◊ 4 - 7 participants

Advantages for participants

- ◊ Reduced costs compared to a QMS set up by a consultant specifically for one company
- ◊ Companies gain deep understanding of the QMS during the workshops and implementation
- ◊ Participating employees are trained (training certificate will be provided)
- ◊ Interaction with non-competing companies in the same industry, and companies can support each other with the implementation

We have successfully conducted this workshop with **15 start-ups** in the previous editions. All parties considered it a great success.

Our senior consultants and trainers for this workshop: Beat Steffen, Viky Verna, Barbara Jeroncic, Stefano Adami, Andrea Biasiucci, Mattias Larsson, Cécile Rod, Adrian Gammeter, and Martina Coscia.

Objective **Each participating company implements an ISO 13485:2016 QMS and receives training on the procedures.**

Dates

15.11.2021 1st Workshop:	Regulatory strategy: introduction to medical devices regulations, qualification, classification and insights on conformity assessment (2 hours).
17.11.2021 2nd Workshop:	QMS: quality manual, management responsibilities, document management, human resources, training (3 hours).
22.11.2021 3rd Workshop:	QMS: design and development, risk management and usability engineering (4 hours).
25.11.2021 4th Workshop:	QMS: change management, labeling, clinical evaluation (4 hours).
29.11.2021 5th Workshop:	QMS: supplier handling, quality agreements, purchasing, incoming Inspection, production, storage, packing, distribution, sales (4 hours).
02.12.2021 6th Workshop:	QMS: infrastructure and work environment, internal audits, corrective and preventive actions (3 hours).
06.12.2021 7th Workshop:	QMS: complaints, post market surveillance, vigilance (3 hours).
09.12.2021 8th Workshop:	QMS: SW lifecycle process IEC 62304, with references to cybersecurity, machine learning and artificial intelligence (4 hours).

Costs

- ◊ CHF 12'200.00 per company for 1st - 7th workshops.
- ◊ CHF 3'600.00 per company for 8th workshop.

CHF 1'000.00 will be invoiced at the time of reservation, the remaining cost before the beginning of the 1st workshop. Max. 2 participants per company. Additional support with the implementation of the QMS on a 1:1 basis, will be quoted and charged separately.