confinis
regulatory compliance worldwide

ISO 13485 (e)QMS implementation and training

for Medical Device/ Diagnostics Start-Ups

29th Nov — 21st Dec

Up to 9 online qualifying sessions with our senior consultants

Location: remotely (Microsoft Teams).

The objective of the workshop is to implement an EN ISO 13485:2021 (e)QMS and train on the procedures.

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: November 21st 2022

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Format

- ◊ 9 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 start-ups.

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 **18 start-ups** in the previous editions. All parties considered it a great success.

Our senior consultants and trainers for this workshop: Beat Steffen, Barbara Jeroncic, Stefano Adami, Mattias Larsson, Cécile Rod, Martina Coscia, Silvia Scolari, Begoña Campos, Frederike Brühschwein-Mandic, Daniel Meier, Emilia Berg, Carin Nilsson, and Xavier Willemin.

Dates

29.11.2022 1st Workshop:	Regulatory strategy: introduction to medical devices regulations, qualification, classification and insights on conformity assessment (2 hours).
05.12.2022 2nd Workshop:	QMS: quality manual, management responsibilities, document management, human resources, training (2 hours).
07.12.2022 3rd Workshop:	QMS: design and development, risk management and usability engineering (4 hours).
09.12.2022 4th Workshop:	QMS: change management, labeling, clinical evaluation (3 hours).
12.12.2022 5th Workshop:	QMS: supplier handling, quality agreements, purchasing, incoming Inspection, production, storage, packing, distribution, sales (4 hours).
14.12.2022 6th Workshop:	QMS: infrastructure and work environment, internal audits, corrective and preventive actions (3 hours).
16.12.2022 7th Workshop:	QMS: complaints, post market surveillance, vigilance, clinical investigation (3 hours).
19.12.2022 8th Workshop:	QMS: SW lifecycle process according to IEC 62304, with references to cybersecurity, machine learning and artificial intelligence (4 hours).
21.12.2022 9th Workshop:	eQMS: demo of eQMS based on Confluence, intro to transition QMS to eQMS, and intro of the validation dossier (2 hours).

Costs

- ◊ CHF 13'300.00 per company for 1st - 7th workshops.
- ◊ CHF 3'600.00 per company for 8th workshop.
- ◊ 9th workshop bonus (for free).

CHF 1'000.00 will be invoiced at the time of reservation, the remaining cost before the beginning of the 1st workshop. Max. 3 participants per company. Additional support with the implementation of the QMS/eQMS on a 1:1 basis, will be quoted and charged separately.