From 25/05/2021

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

To 18/06/2021

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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.

Up to 8 meetings of

2 - 4 hours.

Location to be determined (during the last workshops we were alternating between the locations of the different Start-Ups and Berne: depending on the COVID situation the meetings could be performed remotely).

If you would like to sign up, please fill in the attached questionnaire and send it by email (see below).

Deadline for registration: **21 May 2021**

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Eight workshops (2-4 hours each) are at the core of this initiative. They are conducted by one of our experts and together with various Start-Ups. Prior to each workshop, the respective documents, SOPs and templates are provided in an electronic format. The participants then study the material and prepare for the workshops (e.g. relevant questions for their specific needs / field of application). The interaction with our experienced consultants (which present the documents and SOPs during the workshops) and the other participants ensures seamless transition into practice and training at the same time. During each workshop there will be enough time to discuss questions regarding the implementation (customization). You will meet our senior consultants: **Beat Steffen**, **Viky Verna**, **Barbara Jeroncic**, **Stefano Adami**, **Andrea Biasiucci, Mattias Larsson, and Martina Coscia.**

We have successfully conducted this workshop with **11 Start-Up companies** in the previous editions. All parties considered it a great success.

The **advantages** for each participating company are :

- 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.

The series of workshops will be conducted starting from 4 participants (4 Start-Ups). The maximum number of Start-Ups is limited to 7.

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

Dates

25.05.2021 1st Workshop:	Regulatory strategy: introduction to medical devices regulations, qualification, classification and insights on conformity assessment (2 hours).
28.05.2021 2nd Workshop:	QMS: quality manual, management responsibilities, document management, human resources, training (3 hours).
01.06.2021 3rd Workshop:	QMS: design and development, risk management and usability engineering (4 hours).
04.06.2021 4th Workshop:	QMS: change management, labeling, clinical evaluation (4 hours).
08.06.2021 5th Workshop:	QMS: supplier handling, quality agreements, purchasing, incoming Inspection, production, storage, packing, distribution, sales (4 hours).
11.06.2021 6th Workshop:	QMS: infrastructure and work environment, internal audits, corrective and preventive actions (3 hours).
15.06.2021 7th Workshop:	QMS: complaints, post market surveillance, vigilance (3 hours).
18.06.2021 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.