Die Unternehmen der
Medizintechnologie :
www.bvmed.de

Online seminar
03. and 04. September 2024

Quality Management according to EN ISO 13485

How to successfully set up and maintain a process-oriented quality management system

The seminar will be held in English

BVMed AKADEMIE

Quality Management according to EN ISO 13485

03. and 04. September 2024 | online seminar

Topic

EN ISO 13485 is based on the principles of ISO 9001 and the PDCA (Plan-Do-Check-Act) cycle. Nevertheless, EN ISO 13485 places far more requirements on a complete quality management system, which also increases the amount of documentation required.

Learn about the structure and contents of EN ISO 13485 and find out how to set up, maintain and optimise your quality management system with the help of many practical examples.

Targetgroup

The seminar is aimed at Manufacturers of medical devices, Suppliers, subcontractors and sub-suppliers, Employees from quality assurance / quality management, Management, Process owners, auditors and Employees of authorities.

Speaker

> **Timo Bohnhoff**
Senior RA and QM Manager
qtec services GmbH | Lübeck

Moderation

> **Christopher Kipp**
Regulatory Affairs Manager
Bundesverband Medizintechnologie e.V. (BVMed) | Berlin

Seminar Manager

> **Heike Bullendorf**
Head of BVMed Academy
Bundesverband Medizintechnologie e. V. (BVMed) | Berlin

Contents and Objectives

03. September 2024

09.15 a.m. *CheckIn / Registration*

09.30 a.m. Christopher Kipp
Welcome and Opening

09.35 a.m. Timo Bohnhoff
- **Introduction to quality management**
- **Regulatory requirements for medical devices**
- **Areas of application**
- **Documentation requirements**
- **Management responsibility and commitment**
- **Internal communication**
- **Quality policy**
- **Quality objectives**

04.00 p.m. *End of Day 1*

04. September 2024

09.15 a.m. *CheckIn*

09.30 a.m. Christopher Kipp
- **Reflection on seminar day 1**

09.35 a.m. Timo Bohnhoff
- **Management assessment, human resources, infrastructure**
- **Product realization**
- **Development requirements**
- **Procurement**
- **Measurement, analysis and improvement**
- **Practical examples/workshops: Implementing EN ISO 13485 in your own company**

04.00 p.m. *End of seminar*

Break times | per day
11.30 – 11.45 a.m. | coffee break
01.00 – 02.00 p.m. | lunch break

Registration until 02.09.2024 | 03.00 p.m.
online | **www.bvmed.de/qms-en-24**

Registration is required for participation, for which you will receive a registration confirmation by e-mail.

Dial-in data
Participants will receive the dial-in details by e-mail at least two days before the seminar.

Cancellation
Cancellation free of charge is possible up to 5 working days before the start of the seminar. Thereafter, the full participation fee is due even in the event of non-participation.

Participation fee
Seminar documents and certificate of attendance are included.

BVMed members
895,00 Euro | plus VAT | per person
1.065,05 Euro | incl. VAT | per person

Non-members
995.00 Euro | plus VAT | per person
1.184,05 Euro | incl. VAT | per person

Invoices will be issued after the seminar has been held, due after receipt of the invoice without any deductions.

Changes/Adjustments
The BVMed Academy reserves the right to change lecturers and/or postpone or change the program. If an event has to be canceled for reasons for which the BVMed Academy is responsible, only participation fees already paid will be refunded. Further claims are excluded.

Organizer
BVMed-Akademie
c/o Bundesverband Medizintechnologie e. V.
Georgenstraße 25, 10117 Berlin
Phone | +49 30 246255-0
info@bvmed-akademie.de
www.bvmed-akademie.de