

Die Unternehmen der
Medizintechnologie :
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Online seminar
10. and 12. Dezember 2024

Risk Management for Medical Devices

EN ISO 14971 and Medical Device Regulation (MDR)
Regulatory requirements for risk management



The seminar will be held in **English**

Risk Management for Medical Devices

10. and 12. Dezember 2024 | online

Topic

In this interactive seminar, you will learn how to implement and document a professional risk management process according to ISO 14971, consider the influences on interfaces such as Technical Documentation including Clinical Evaluation and Usability for Use, and derive necessary measures for risk control.

Many illustrative examples and concrete tips will help you to apply the requirements to your company and your products.

Targetgroup

This seminar is aimed at Manufacturers of medical devices, Risk managers and members of a risk management team, Regulatory affairs managers, Quality management officers and Auditors.

Speaker

- > **Dr. Claudia Rampf**
Senior RA and QM Manager
qtec services GmbH | Lübeck

Moderation

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

Seminar manager

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

Contents and Objectives

10. Dezember 2024

09.15 a.m. *CheckIn / Registration*

09.30 a.m. Christopher Kipp
Welcome and Opening

09.35 a.m. Dr. Claudia Rampf
> **Introduction into Risk Management**
> **Risk Management according to ISO 14971:2019**
> **Risk Management Process – Part 1**

- Risk Management planning
- Risk analysis – Hazard identification
- Risk management tools

04.00 p.m. *End of Day 1*

12. Dezember 2024

09.15 a.m. *CheckIn*

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

09.35 a.m. Dr. Claudia Rampf
> **Risk Management Process – Part 2**

- Risk analysis – Risk assessment
- Risk evaluation – Acceptance criteria
- Risk control – Manage the risk
- Risk management review

> **Risk Management Documentation, Data flow, Interfaces**

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 09.12.2024 | 03.00 p.m.
online | www.bvmed.de/rms-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

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