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Entwicklung, Zulassung und Qualitätsmanagement für Medizinprodukte

ONLINE-CERTIFICATE PROGRAM: MEDICAL SOFTWARE SPECIALIST

Your start into the world of Medical Software & Apps!

On April 26, 2024 our practice-oriented certificate program will start on all regulatory requirements for medical software and applications in a compact online course.

DEVELOPMENT AND APPROVAL OF SOFTWARE AS MEDICAL DEVICES with focus on EUROPE

The use of software in medical devices or of software as a medical device offers many new possibilities for more precise diagnoses and more efficient therapies. For example, it is much easier to link data for a diagnosis or to implement new treatment and diagnostic procedures.

Software that is designed for this purpose is also subject to the analogous regulatory requirements and standards that apply, for example, to ventilators or implants. However, software is particularly difficult to classify within this regulatory framework and is often a matter of interpretation. Often it comes down to the so-called intended purpose.

YOUR ADVANCE AS A MEDICAL SOFTWARE SPECIALIST

This certificate program introduces you to the world of regulatory terminology and explains why the intended purpose is of fundamental importance from the outset for anyone developing software in connection with the diagnosis or treatment of diseases. And why proper classification is as important as the product idea itself.

In our online courses to become a Medical Software Specialist, you will gain the knowledge you need to navigate this complex environment step by step. This includes sound knowledge of the relevant laws, standards and regulations, as well as how the software lifecycle is integrated into the quality management and risk management systems.

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The developers of software for or as medical devices are ultimately more than just software developers. They create software products that, in addition to a clinically proven benefit for patients, must not pose an unacceptable risk. Therefore, they must fulfill all legal requirements for medical devices.

Manufacturers of software for or as medical devices therefore need specialists who have sound technical knowledge as well as regulatory and clinical expertise. These specialists are very much in demand! The medical device market is one of the most innovative and fastest growing markets of the last years.

CERTIFICATE PROGRAM – CONTENT

Module 1	Introduction to the development of software for medical devices	April 26, 2024 9am – 4.30pm
Module 2	Implementation of IEC 62304 and IEC 82304-1 for medical device software manufacturers	May 8, 2024 9am – 4.30pm
Module 3	Risk management for medical device software – ISO 14971	May 24, 2024 9am – 4.30pm
Module 4	UX and Usability for Medical Software and Apps – IEC 62366-1	June 3, 2024 9am – 4.30pm
Module 5	Cybersecurity – IT security for medical devices	June 7, 2024 9am – 4.30pm

Single modules also available!

OUR MEDICAL SOFTWARE EXPERTS

DI Martin Schmid
Managing Director and
Senior-Consultant
en.co.tec Schmid KG

Trainer at the modules 1, 2 and 3

Nilaykumar Patel MSc
Chief Quality Officer
contextflow GmbH and
Co-Auditor with en.co.tec

Trainer at the module „Cybersecurity“

Dipl.-Inf. Michael Engler
Senior Consultant
Benkana Interfaces GmbH
& Co. KG

Trainer at the module „Usability“

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TARGET GROUP - PARTICIPANTS

- Medical device manufacturers whose products contain software or are software products in their own right, from the areas of regulatory affairs, quality management, systems and software engineering, usability engineering, requirements engineering, project management, risk management, product management, IT, management,
- Service provider / supplier in the medical technology,
- Consultants for medical software
- Newcomer & Start-Ups

COSTS

- Early bird (until March 29, 2024): Euro 2.350,- (excl. VAT)
- Standard (starting with March 30, 2024): Euro 2.590,- (excl. VAT)
- incl. seminar documents as PDF and a certificate of participation

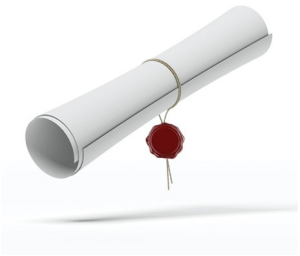
DISCOUNTS

10% discount for

- Cluster members (Standortagentur Tirol, Forum Medtech Pharma, Human.technology Styria, LISAvienna, MTC Upper Austria)
- from the 2nd participant of a company/organization
- for returning visitors
- The discounts cannot be combined.

CONCLUSION OF THE ONLINE CERTIFICATE PROGRAM

The certificate program concludes with an online exam (multiple choice) and an individual discussion of the content of all modules. After successfully passing the exam, you will receive your personal certificate.



With this recognized certificate, you can prove your qualification and competence in the field of medical software:

- You have the necessary knowledge about the desired functions and possible risks of software.
- You will be able to take into account the legal and normative requirements during the software development process.
- Your know-how will ensure usability and risk minimization.

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ONLINE-Trainings:

All you need for the ONLINE modules is a laptop with camera and microphone. Our eLearning platform works on all operating systems in a web browser (e.g. Firefox, Safari or Chrome). You will receive the course materials in PDF format and the link to the virtual classroom via email. Each module is designed to be interactive, similar to a face-to-face seminar: you can ask the instructor questions, there will be practice examples, and you will have the opportunity to interact with other participants.

Book now and click here for online registration

If you have any questions, we are happy to help:

Mag. (FH) Christa Bachinger-Hauk
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Everything you need to know about the Online-Certificate Program:
www.encotec.at