Kursuskatalog 2024

MedTech Academy

Viden der styrker dine kompetencer

MEDICO INDUSTRIEN
MEDTECH DENMARK

Indhold

Anvendte fotos er AI genererede.

Introduktion

Danmarks største udbyder af kurser til medicobranchen

Medicoindustrien tilbyder en bred vifte af spændende og højaktuelle uddannelsestilbud, som er målrettet dig, der sætter læring og kompetenceudvikling i fokus.

Vores uddannelsesprogram for 2024 afspejler de krav til kompetenceudvikling og opdatering på den nyeste viden, som vores medlemmer efterspørger. Du vil møde engagerede og kompetente undervisere, som er specialiserede inden for hvert deres fagfelt. Vores mål er hele tiden at være på forkant med virksomhedernes behov for læring og udbyde de kurser og seminarer, som branchen efterspørger.

Med venlig hilsen

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Kursusoversigt

Udvikling og produktion af medicinsk udstyr

Regulatoriske forhold

Salg og markedsføring af medicinsk udstyr

Øvrige kurser

Uddannelser

Virksomhedsinterne kurser

Online kurser med WMDO

Udvikling og produktion af medicinsk udstyr

Brugervejledninger til medicinsk udstyr

Kursets overordnede formål er at give dig praktiske redskaber til at udarbejde robuste brugervejledninger, som lever op til de gængse lovkrav omkring indhold, samtidig med at de er letforståelige og minimerer risiko for brugerfejl. På kurset vil du få en metodisk introduktion til, hvordan du kan finde, udarbejde og implementere de krav, som lovgivning og interessenter typisk sætter til indhold i brugsvejledninger relateret til medicinsk udstyr.

Du vil også blive introduceret til Human Factors arbejdsredskaber og viden, som sætter dig i stand til at identificere og optimere på de design elementer (tekst, billeder og komposition/opsætning) i brugsvejledningerne, som kan forårsage usikkerhed og fejlsituationer i anvendelsesøjeblikket.

"Godt med undervisere med meget praktisk erfaring." Deltager, 2020

Dato
22.-23. januar 2023

Varighed
2 dage

Medlemspris/ ikke-medlemspris
12.040 kr./18.520 kr.

Sprog
Dansk

Introduktion til UDI (Unique Device Identification) – identifikation og mærkning af medicinsk udstyr

Formålet med kurset er at give deltagerne en fuld forståelse af og overblik over de krav og elementer, der indgår i EU-kommissionens forordning for medicinsk udstyr omkring UDI og øvrige myndigheders (herunder FDA) tilsvarende tiltag.

Målgruppen for kurset er primært medarbejdere, der beskæftiger sig med logistiske processer inden for mærkning, pakning, kvalitet, produktion, indkøb, grafik, lager, regulatoriske områder o.lign.

"Godt materiale, god underviser - jeg fik det med mig, som jeg havde håbet på." Deltager, 2023

Dato
22. januar 2023
27. september 2023

Varighed
1 dag

Medlemspris/ ikke-medlemspris
6.020 kr./9.260 kr.

Sprog
Dansk

Statistik for procesvalidering

De seneste års trend inden for procesvalidering er at flytte fokus fra at prøve at dokumentere, man kan holde verden fast til at dokumentere, man har tilstrækkelig procesforståelse til at justere sin proces for at modvirke udefrakommende ændringer.

Dette kursus klæder deltagerne på til at komme i gang med at bruge statistiske værktøjer og få viden om, hvad der er "best practice". Kurset vil bringe kursusdeltagere i stand til at gennemføre grundlæggende statistisk analyse i relation til validering og frigivelse. De samme værktøjer kan bruges til optimering af udbytte. Herved vil man både sikre en bedre produktionsøkonomi og fremtidig compliance.

"En meget energisk og kompetent underviser, der kan lære fra sig og gøre teorien spændende og relevant." Deltager

Dato
29 februar -
1. marts 2024

Varighed
2 dage

Medlemspris/ ikke-medlemspris
12.040 kr./18.520 kr.

Sprog
Dansk

Clinical Evaluation for Medical Devices in Europe and International Approach

With the new Medical Device Regulations in place, it brings a whole new challenge for many companies to update their approach to gather the necessary clinical data for CE-mark. As there is no grandfathering of existing products on the market, all medical devices CE or not CE-marked are concerned about the Medical Device Regulation's requirements immediately.

With these new regulations, many companies which may not have thought about the need for clinical investigations, now face an additional challenge in conducting prospective clinical investigations. Along with MDR, ISO 14155 has undergone a significant update.

This two-day course will provide you with an in-depth review of how to interpret the many changes in the clinical evaluation/investigation requirements and how to discuss aspects of clinical evaluation and investigations with the Notified Bodies.

"Very competent trainer. Furthermore she was very "present" and interesting to listen to." Participant, 2023

Date
18-19 April 2024
5-6 November 2024

Duration
2 days

Member price/ non member price
12.040 kr./18.520 kr.

Language
English

Design Control

The course is focused on the development process for new medical devices and maintaining them in an organisation where design control requirements apply. The course addresses what level of documentation is required according to both EU MDR and FDA 21CFR and provides tools on how to work successfully and efficiently with design control. Since standards play a significant role in design control and development of medical devices, the course will reference the most commonly used standards that apply to medical devices. This includes ISO 14971 on risk management, IEC 62366 on usability engineering, IEC 60601 on electrical safety and IEC 62304 on medical device software. You will also learn about the most common pitfalls in medical device product development.

"The course gave a very good overview of the essentials within medical device design control." Participant, 2023

Date
29-30 April 2024
28-29 October 2024

Duration
2 days

Member price/ non member price
12.040 kr./18.520 kr.

Language
English

Process Validation

Since process validation sets the stage for ongoing defect-free production of medical devices, many departments are involved. Manufacturing and engineering have major roles to play, but personnel from QA and R&D are generally involved. Anyone who is involved in these activities or is responsible for auditing this function will benefit from this practical approach of performing validations as well as providing documentation as proof of compliance.

The goal of the course is to provide a clear understanding of what must be validated, when it needs to be done and particularly how to do it.

"Well organized, clear agenda, to the point." Participant, 2023

Date
2-3 May 2024
7-8 November 2024

Duration
2 days

Member price/ non member price
12.040 kr./18.520 kr.

Language
English

Project Management for Product Development of Medical Devices

The course is focused on how to manage the development process for new medical devices and maintaining them in an organization where design control requirements apply.

The course combines several of the key project management tools with the design control process. This gives you a unique opportunity to know how to manage development projects in the medical device business and at the same time get a detailed knowledge of the different design control documents required by the authorities. One of the challenging issues for all development projects in the medical device industry is how to manage all the different stakeholders and project team members in a very regulated area. The course introduces a unique tool for ensuring a sufficient maturity of the device development and at the same time ensure the necessary progress of the project.

"Very knowlegable instructor, great comprehensive content and excersises." Participant, 2023

Date
13-15 May 2024
18-20 November 2024

Duration
3 days

Member price/ non member price
18.060 kr./27.780 kr.

Language
English

Praktisk gennemførelse af risikoanalyser ved produktudvikling

Dette kursus henvender sig til personer, der skal medvirke ved gennemførsel af risikoanalyser, og som har behov for et detaljeret kendskab til analyseteknikkerne FMEA/FMECA og HAZOP.

Kurset giver deltagerne et grundigt kendskab til planlægning, gennemførelse af de nævnte teknikker og rapportering af risikoanalyser. Det er et godt udgangspunkt at have et grundlæggende kendskab til ISO 14971: Håndtering af risikostyring for medicinsk udstyr.

"Gode undervisere, godt materiale, fine øvelser, god struktur og overordnet et rigtigt godt kursus." Deltager, 2022

Dato
12.-13. juni 2024

Varighed
2 dage

Medlemspris/ ikke-medlemspris
12.040 kr./18.520 kr.

Sprog
Dansk

Hold dig opdateret om nye kurser, seminarer og uddannelser

Tilmeld dig nyhedsbrevet “KursusNyt” på www.medicoindustrien.dk eller scan QR-koden og få nye kurser og uddannelser direkte i din indbakke

Regulatoriske forhold

IVDD to IVDR Transition

BSI will give you an overview of the significant changes to the regulatory requirements for IVD manufacturers. The changes include a new rule-based classification system, increased scrutiny of technical documentation, and improved traceability of devices through the supply chain.

This course has been designed to introduce IVD manufacturers and other Economic Operators in the supply chain to the key changes to requirements for CE marking following the publication of the new IVD Regulation (IVDR).

Date
15-16 January 2024

Duration
2 days

Member price/ non member price
10.820 kr./16.660 kr.

Language
English

Online

Patenter, forretningshemmeligheder og forskningssamarbejder i medicobranchen

For en medicovirksomhed er det helt afgørende, at viden og produkter sikres mod kopiering og andre krænkelser, og at virksomheden ikke selv krænker andres rettigheder. Det er derfor lige så afgørende at forstå, hvad der kan patentbeskyttes og hvad der kan beskyttes som forretningshemmeligheder/ know-how. Kurset giver dig et overblik over disse emner, bl.a. via konkrete eksempler og cases om medicinsk udstyr.

På kurset gennemgår vi også de centrale spørgsmål i forbindelse med regulering af patenter og forretningshemmeligheder i forskningssamarbejder, både med private virksomheder og med universiteter, hospitaler og andre offentlige institutioner.

Dato
17. januar 2024

Varighed
1 dag

Medlemspris/ ikke-medlemspris
6.020 kr./9.260 kr.

Sprog
Dansk

Implementation of the IVDR for CE Marking

BSI will teach you how to implement the requirements of the European In Vitro Diagnostic Device Regulation (IVDR 2017/746) and how to obtain and maintain the CE mark for your product. Gain confidence with the IVD classification rules and the conformity assessment routes. Learn the importance of the General Safety and Performance Requirements in product development, and of scientifically robust performance evaluation and clinical evidence.

Explore the role of risk management during product development and in post market follow up. Develop an understanding of the interface and interaction with Notified Bodies, economic operators (importers, distributors, EU Representatives) and subcontractors/ suppliers, according to their obligations under the IVDR.

Date
29-31 January 2024

Duration
3 days

Member price/ non member price
16.230 kr./24.990 kr.

Language
English

Online

Implementation of the MDR for CE Marking

The objective of this course is to help implement the requirements of European Medical Device Regulation (MDR) to obtain and maintain CE marks for your product. The CE mark gives access to a market with 500+ million people. Find out best practice for assembling Technical Documentation and QMS when placing medical devices on the European Union market. The course will also review the requirements of, and relationship between, the legal manufacturer, subcontractors/suppliers, Notified Bodies (e.g. auditing), and economic operators (importers, distributors, EU Representatives) according to their obligations by MDR.

This course aims to offer guidance on implementation of the requirements stipulated in the MDR. The course focuses on enabling you to draw up a clear concept or project plan, and how to integrate the requirements into your business and your documentation. Moreover, you should gain confidence and expertise to evaluate and implement more specific requirements on your own.

"I highly appreciated that the instructor very well managed a very interactive training course to assure that participants got the most out of the time." Participant

Date
29-31 January 2024

Duration
3 days

Member price/ non member price
16.230 kr./24.990 kr.

Language
English

Online

Technical Documentation for Medical Devices According to the MDR

BSI enables greater understanding of the key requirements for technical documentation for medical devices, in line with the European Medical Device Regulation (MDR) requirements in Europe. The aim of the course is to enable manufacturers to create robust technical documentation to demonstrate compliance to the MDR and better understand regulatory requirements and Notified Body expectation, to prevent unnecessary delays to the certification process.

"The teacher had deep expert knowledge, and I liked the activities involving students." Participant, 2022

Date
2 February 2024
13 September 2024

Duration
1 day

Member price/ non member price
5.410 kr./8.330 kr.

Language
English

Online

Person Responsible for Regulatory Compliance according to MDR and IVDR

This one-day course will provide a background on Person Responsible for Regulatory Compliance duties and how this concept is translated into the Medical Device and IVD world, and will cover some of the practical aspects of the implementation of this new requirement for manufacturers.

"The course was very well conducted and to the point." Participant 2023

Date
6 February 2024
10 September 2024

Duration
1 day

Member price/ non member price
6.020 kr./9.260 kr.

Language
English

MDD to MDR Transition

The course introduces the most important changes of the Medical Device Directive (MDD) to the new Medical Devices Regulation (MDR). You will be able to understand the key changes in the transition from the MDD to the new MDR. You will also be able to communicate the impact to your organization of the key changes introduced by the MDR, and the transition arrangements defined within the MDR. Finally, you will be able to identify the next steps for your organization to meet the MDR requirements.

"The trainer gave a good overall insight to MDR." Participant, 2023

Date
26-27 February 2024

Duration
2 days

Member price/ non member price
12.040 kr./18.520 kr.

Language
English

MDR Auditing - Training of Internal Auditors in Relation to MDR

Gain knowledge about the MDR requirements not covered by ISO 13485 and understand the MDR requirements related to the QMS and their impact. Learn what to look for when auditing a QMS against the MDR requirements.

"Detailed information and useful comments about pitfalls and many useful links and documents." Participant, 2023

Date
4 March 2024
28 October

Duration
1 day

Member price/ non member price
5.410 kr./8.330 kr.

Language
English

Online

Salg til det offentlige uden udbud

Kurset fokuserer på de situationer, hvor salg kan ske til det offentlige, uden at der forudgående er gennemført et EU-udbud.

Kurset starter med en kort introduktion til udbudsloven og EU's udbudsregler, hvorefter du lærer hvad gælder for indkøb, som er under tærskelværdien for EU-udbud, og hvad er det nu lige tærskelværdien er, og hvordan beregnes den?

Kurset vil også komme nærmere ind på, i hvilke tilfælde indkøb kan ske uden EU-udbud, fordi der kun er én mulig leverandør, eller fordi der foreligger force majeure eller lignende særlige omstændigheder.

Dato
13. marts 2024

Varighed
1/2 dag, formiddag

Medlemspris/ ikke-medlemspris
3.010 kr./4.630 kr.

Sprog
Dansk

Tips & tricks i forbindelse med afgivelse af tilbud i EU-udbud

På kurset får du de bedste praktiske råd, når man skal afgive et tilbud i EU-udbud. Kurset fokuserer på nogle af de praktiske spørgsmål, der melder sig, når man som tilbudsgiver ønsker at søge prækvalifikation til at deltage i et EU-udbud eller skal afgive tilbud i et EU-udbud.

Hvornår skal og kan man gå sammen med andre selskaber, og hvad er det nu, der gælder om brug af støttende enheder og underleverandører? Hvordan udfyldes et ESPD, og hvilke regler gælder om serviceattest og støtteerklæringer?

Dato
13. marts 2024

Varighed
1/2 dag, eftermiddag

Medlemspris/ ikke-medlemspris
3.010 kr./4.630 kr.

Sprog
Dansk

IEC 60601 - How to Apply Safety and Risk Management to Medical Electrical Equipment and Systems

The objective of this course is to create a general understanding of the IEC 60601-series, which is the product standard series for electrical medical devices and systems. The course will cover the structure of the series, how to use and interpret it in a proper way and the major news that have been introduced in the latest edition. It will also cover the relation to the European market and other important markets around the world. Hands-on training sessions will be applied throughout the course. The course is based on a practical rather than theoretical viewpoint.

"Fine structure and content; overview of the standard and lectures on the specific topics worked well." Participant, 2022

Date
25-26 March 2024
3-4 October 2024

Duration
2 days

Member price/ non member price
12.040 kr./18.520 kr.

Language
English

New Constructing and Structuring a Cybersecurity Framework

After completing the course, you will understand the key concepts behind using a centralized framework to provide one-to-many requirements coverage, you will become familiar with some of the official standards and requirements for cybersecurity frameworks and you will have a plan for how to implement the plan in your organization.

The framework is meant to document how security by design is applied end-to-end, from organizational awareness to a common thread through documentation, showing how threat modelling, risk management, postmarket vigilance and security architecture is performed.

Date
3-5 April 2024

Duration
3 days

Member price/ non member price
18.060 kr./27.780 kr.

Language
English

Software as Medical Device and Quality Management

The course introduces regulatory requirements that are particularly affecting software as medical device and how they can be addressed effectively, also in an agile development model and when developing Artificial Intelligence solutions.

Gain knowledge about how to classify and qualify your digital health solutions/medical device software and how to evaluate the technical documentation.

The course is focused on the practical implementation of quality procedures for development of software as medical device (SaMD) and medical device software (MDSW) when having inhouse development or having outsourced the software development activities.

"The content of the course was a good fit with my need and the trainer was interesting and a good presenter." Participant, 2023

Date
15-16 April 2024

Duration
2 days

Member price/ non member price
12.040 kr./18.520 kr.

Language
English

New Introduction to Cybersecurity Risk Management for TIR57 Compliance

The course will help build threat modelling concepts for an organization and will cover how to do security risk management using the AAMI TIR57 standard. The course will introduce a model which can manage the relations between cyber security risk management and safety management.

We will look at the threat models introduced in TIR57, orienting security observation from different pivoting perspectives, such as threat sources, asset management and known device vulnerabilities. The course will demonstrate these concepts through a case study on a fictive product.

"I liked the trainer's willingness to adapt the used examples to fit participant requests". Participant, 2023

Date
22-23 April 2024

Duration
2 days

Member price/ non member price
12.040 kr./18.520 kr.

Language
English

Nyt Bliv klar til den nye cyberregulering, NIS2 - krav om obligatorisk uddannelse af ledelsen

Langt størstedelen af medicobranchen bliver direkte omfattet af EU's cybersikkerhedsdirektiv, NIS2, der får virkning i Danmark - og bliver håndhævet af myndighederne allerede til oktober 2024.

Ledelsen, herunder bestyrelsen og direktionen, i omfattede organisationer skal blandt andet følge relevante kurser og uddannelse for at opnå og styrke kompetencerne til at overvåge og identificere risici, forstå deres påvirkning af organisationen samt prioritere og godkende organisationens anbefalinger til håndteringen af disse risici.

Du lærer at varetage følgende krav i NIS2: Forstå og agere risikobaseret i forhold til relevante cybertrusler anno 2024, overvåge organisationens håndtering af cybertruslerne, supportere organisationens overholdelse af reglerne på operationelt niveau samt være i stand til at påtage sig ansvaret for organisationens overholdelse af kravene.

Dato
25. april 2024

Varighed
1 dag

Medlemspris/ ikke-medlemspris
6.020 kr./9.260 kr.

Sprog
Dansk

Training of Internal Auditors in Relation to Country Specific Requirements within the MDSAP Program

MDSAP is an auditing approach integrating the applicable requirements of the participating jurisdictions into an audit under ISO 13485. ISO 13485 requires compliance to applicable regulatory requirements of the target markets and the MDSAP defines the framework of the applicable requirements that must be covered by the manufacturers' quality systems for the MDSAP jurisdictions. The course discusses the MDSAP audit approach that is focused on the logical links and flow of information. Further, we will discuss the logic of the audit to follow according to the MDSAP Companion chapters throughout the different subsystems. The specific national requirements of the participating jurisdictions (Ord.169, 21CFR820, RDC 16/2013, SOR 98-282, TGA MDR 2002) will be addressed and compared using examples sampled over the subsystems.

"High knowledge level of course leader." Participant, 2023

Date
26 April 2024
2 October 2024

Duration
1 day

Member price/ non member price
5.410 kr./8.330 kr.

Language
English

Online

ISO 13485 and Quality Management for Medical Devices / Internal Auditing

The course consists of two parts: Quality management for Medical Devices and ISO 13485 (2 days) & Internal auditing for medical device companies and ISO 19011.

This course is specifically tailored to make the requirements of the ISO 13485 as tangible and concrete as possible, so participants can confidently work in an organization where ISO 13485 requirements apply. The second, and optional, part of the course will take you through the steps of performing an internal audit based on the principles of ISO 19011.

Instruction is targeted towards professionals who work with a quality management system in a medical device organization where ISO 13485 requirements apply, and those who typically are engaged in supporting QA related tasks such as CAPA, complaints, risk management, documentation and internal auditing

"In depth walkthrough of the material and a good dialogue." Participant, 2023

Date
22-24 May 2024
27-29 November 2024

Duration
3 days

Member price/ non member price
18.060 kr./27.780 kr.

Language
English

Medical Device Usability

The participants will achieve an understanding of how to document the usability of medical devices in order to achieve compliance through a thorough introduction to the usability engineering process, a thorough walk-through of the requirements in IEC 62366-1 and -2 and the FDA Human Factor Engineering guide, and practical application of usability techniques during design and post marketing.

Usability of medical devices and the documentation of the usability engineering process have become increasingly important for the medical device industry. During the course, the participants will learn about the usability engineering process including specification of a medical device application with focus on user interface, identification of hazardous situations related to usability, handling of risk related to the user interface and the summative evaluation of the user interface design. Preparation of the usability engineering file will be described and different methods for integrating the file in development documentation will be suggested.

"The trainers knowledge was very good, and also the way things were presented. I also found the balance between Usability and Risk Management interesting and useful." Participant, 2023

Date
27-28 May 2024
11-12 November 2024

Duration
2 days

Member price/non member price
12.040 kr./18.520 kr.

Language
English

IEC 62304: Software Lifecycle

This training aims to bring a complete overview of the implementation of the IEC 62304 for the development of a software as a medical device. The regulatory context will be discussed, the integration of software aspects within a medical device are reviewed and all aspects associated to IEC 62304 will be presented in order to be able to implement a compliant software development process.

"Very competent lecturers. Good introduction to software development according to IEC 62304. Relevant level of course, not too detailed, but not too generalized either." Participant, 2022

Date
3-4 June 2024
3-4 December 2024

Duration
2 days

Member price/ non member price
12.040 kr./18.520 kr.

Language
English

MDSAP Fundamentals and Readiness Training

This course is broken down into a combination of knowledge and skills. You will increase your knowledge of the guidelines for conducting MDSAP Regulatory audits and the skills needed within your organization to know you are prepared and ready to host the audit.

"Motivated and very skilled teacher. I liked that we used examples from every day life in the medical device industry." Participant, 2023

Date
6-7 June 2024
12-13 December 2024

Duration
2 days

Member price/non member price
12.040 kr./18.520 kr.

Language
English

Introduktion til udbudsloven

Introduktion til udbudsloven er et grundkursus for dig, der har brug for at få helt styr på udbudsreglerne og ønsker et overblik over, hvordan man skal bruge dem i praksis. På kurset får du en overordnet forståelse for, hvornår udbudsreglerne finder anvendelse, og hvordan en udbudsprocedure gennemføres i henhold til udbudsloven.

"Vigtige læringer som kan anvendes i dagligdagen. Åbent forum for diskussioner." Deltager, 2023

Dato
12. juni 2024
10. december 2024

Varighed
1 dag

Medlemspris/ ikke-medlemspris
6.020 kr./9.260 kr.

Sprog
Dansk

Corrective & Preventive Actions (CAPA)

The CAPA subsystem is the backbone of a management system to maintain compliance, effectiveness and efficiency. Failing to meet requirements of effective CAPA handling, especially investigations of root causes, and verification of effectiveness are among the most frequent serious audit and inspection findings. This course is intended to familiarize participants with the requirements for a CAPA subsystem and the methods for effective CAPA implementation.

"It was very informative and everybody could participate." Participant, 2023

Date
14 June 2024
6 December 2024

Duration
1 day

Member price/non member price
5.410 kr./8.330 kr.

Language
English

Online

GDPR - praktiske udfordringer for medicovirksomheder

Dato
19. juni 2024

Varighed
1 dag

Medlemspris/ ikke-medlemspris
6.020 kr./9.260 kr.

Sprog
Dansk

På kurset gennemgås de emner, som erfaringsmæssigt giver anledning til særlige udfordringer hos mange virksomheder og med fokus på forhold af relevans for medicovirksomheder. Der lægges vægt på den praktiske vinkel og konkrete anvendelse af reglerne frem for en teoretisk gennemgang.

"Rigtig god gennemgang af de komplekse udfordringer der opstår, når man skal være i overensstemmelse med GDPR. Det var en meget vidende underviser, der kom med eksempler til at understøtte teorien." Deltager, 2021

New Threat Modelling, Security Architecture & Controls for Medical Devices: Attacking and Defending

Date
20-21 June 2024

Duration
2 days

Member price/ non member price
12.040 kr./18.520 kr.

Language
English

In this course participants will gain experience with articulating threats in a threat model, how to apply tools like MITRE ATT&CK and D3FEND to construct a two-sided narrative to security controls in your architecture. We will investigate the concept of digital artifacts, and how attacking a system exposes changes opposed to defending it can secure them.

After the course, the participants will be able to utilize a toolset to perform technical threat modelling, know the recommended security functions for regulatory requirements, have the knowledge to perform a structured way documentation of a cyber security analysis in your design and architecture, and gain knowledge of a technical toolset to help enumerate and discover security controls in your system.

New US Quality System Regulation and other US Regulations for Medical Devices – Concepts and Application

The course is designed for staff in the medical device industry who need to gain insight into FDA QSR/GMPs and people about to take part in planned FDA inspections. It is a benefit to have some familiarity with the US FDA QSR and ISO 13485 before the course.

The course is based on the ISO 13485:2016 edition and selected country-specific requirements for the USA from the Medical Device Single Audit Program (MDSAP). In addition, focus will be on FDA inspections, illustrated by means of case studies based on results of FDA inspections (Warning Letters).

Date
29-30 August 2024

Duration
2 days

Member price/ non member price
12.040 kr./18.520 kr.

Language
English

Planning an Effective Post Market Surveillance Program for Medical Devices and Combination Products

The purpose of this course is to provide you high level details on regulatory requirements on post market surveillance (PMS) and vigilance on medical devices and combination products and how to ensure regulatory compliance when marketing medical devices and combination products in EU and US. After the course, you will have essential knowledge and skills within PMS and vigilance regulatory requirements on how to conduct a PMS plan, report and PSUR and MIR reporting.

"Good level of discussions, group work and presentations."
Participant, 2023

Date
26-27 September 2024

Duration
1 1/2 day

Member price/ non member price
9.030 kr./13.890 kr.

Language
English

Introduction to Chemical Compliance for Medical Devices

The objective is to give participants an understanding of their obligations regarding justification of chemical safety of their devices and how to tackle these obligations.

The course will give the overall framework in relation to aspects regarding chemical safety of medical devices. Focus will be on regulatory requirements and chemical testing. In addition, the course will focus on the toxicological evaluation of chemical substances and basic toxicological principles and terms will be explained. Further, the course will cover how to evaluate which type of exposure and which type of effects are of concern, how to gather relevant data and perform a safety assessment and how to estimate risk/safety of the device.

"I liked the combination of highlights and detailed information." Participant, 2023

Date
7 October 2024

Duration
1 day

Member price/ non member price
6.020 kr./9.260 kr.

Language
English

New Update on China NMPA Regulation and Registration for Medical Devices with Case Studies

The Chinese market becomes more and more important for medical device manufacturers due to its large volume. The NMPA registration process is very time and cost consuming. Also, China NMPA is updating the regulations very rapidly recently. This course aims to provide the participants with a deep understanding of the up-to-date NMPA regulatory policies and practical solutions to the problems of frequent occurrence during Chinese market entry.

"The course leader is very competent and understands Chinese regulation and mentality." Participant, 2021

Date
24-25 October 2024

Duration
2 days

Member price/ non member price
12.040 kr./18.520 kr.

Language
English

FDA Regulation of Medical Devices: Recent FDA Guidance Documents

In order to avoid extremely costly delays, it is essential to understand the laws, regulations, processes and guidance for medical devices in order to be successful in getting medical devices into the US marketplace. There are several recent guidance documents which are key to effectively navigating FDA.

Participants will leave with a clear understanding of the basic laws, regulations, processes and guidance for oversight of medical devices in the US which is essential to successful device development, testing and applications. In particular participants will have received a detailed discussion of several of the most recent and important guidance documents that impact how medical devices are regulated and affect a sponsor's plans for developing medical devices and interacting with FDA.

"The instructor was very experienced in the field and exemplified the content of his presentation based on his own experience, which made the course very interesting & enjoyable. Very good overall structure of the course, starting with a general overview of the FDA. Excellent delivery throughout the two days; participants were engaged." Participant, 2022

Date
14-15 November 2024

Duration
2 days

Member price/ non member price
12.040 kr./18.520 kr.

Language
English

Salg og markedsføring af medicinsk udstyr

Digital markedsføring af medicinsk udstyr

Formålet med kurset er, at du bliver i stand til at mestre reglerne inden for digital markedsføring af medicinsk udstyr. Du lærer at identificere problemstillinger i forbindelse med markedsføring af medicinsk udstyr, og du får håndgribelige værktøjer til at navigere i mulige løsninger.

Du får mulighed for at styrke din viden om, hvorledes digitale medier kan bruges lovligt i forbindelse med markedsføring og videregivelse af information om medicinsk udstyr. Derudover giver kurset dig et indblik i kommunikation mellem din virksomhed og sundhedspersoner.

"Virkelig godt med indholdet, alle eksemplerne, formidlingen, de andre elevers deltagelse og organiseringen." Deltager, 2023

Dato
5. februar 2024
9. september 2024

Varighed
1 dag

Medlemspris/ ikke-medlemspris
6.020 kr./9.260 kr.

Sprog
Dansk

Digital Marketing of Medical Devices Abroad - Sweden, Germany and the USA

Gain insights from leading legal experts within the medical device industry on how to optimize your local footprint when marketing medical devices in Sweden, Germany and the USA. Due to the EU legal framework, many online advertising activities will be covered by the principle of 'home country control' (i.e., laws not stricter than those in the country where the company is established). That said, there are many online/cross-border marketing activities not covered by the home country control-principle and there are also exceptions to this under national law.

The purpose of this course is to provide you with a high-level overview of relevant rules to consider when structuring a marketing strategy to reach Sweden, Germany and the USA, including how these rules are enforced by the local regulators.

Date
5 March 2024

Duration
1/2 day

Member price/ non member price
2.700 kr./4.170 kr.

Language
English

Online

Digital Marketing of Medical Devices Abroad - Norway, United Kingdom and France

Gain insights from leading legal experts within the medical device industry on how to optimize your local footprint when marketing medical devices in Norway, United Kingdom and France. Due to the EU legal framework, many online advertising activities will be covered by the principle of 'home country control' (i.e., laws not stricter than those in the country where the company is established). That said, there are many online/cross-border marketing activities not covered by the home country control-principle and there are also exceptions to this under national law.

The purpose of this course is to provide you with a high-level overview of relevant rules to consider when structuring a marketing strategy to reach Norway, United Kingdom and France, including how these rules are enforced by the local regulators.

Date
22 March 2024

Duration
1/2 day

Member price/ non member price
2.700 kr./4.170 kr.

Language
English

Online

Regler om reklame, tilknytning og økonomiske fordele

På kurset hører du Lægemiddelstyrelsen give en opdatering på reglerne om gennemsigtighed omkring samarbejdet mellem læger, tandlæger, sygeplejersker, apotekere og øvrige sundhedsfaglige grupper og medicoindustrien. Du bliver klædt på til at kunne håndtere de nye regler, og hvordan du skal agere som aktør på området fremover. Kurset tager udgangspunkt i de danske reklameregler for medicinsk udstyr og sætter fokus på reglerne for økonomiske fordele til de sundhedsfaglige personalegrupper. Kurset sætter også fokus på reglerne for tilknytning mellem medicoindustrien og visse sundhedsfaglige personalegrupper, samt hvordan disse tilknytningsforhold skal indberettes.

"Meget relevant, spændende og i et sprog alle kan forstå. Super undervisere." Deltager, 2022

Dato
18. juni 2024
9. december 2024

Varighed
1 dag

Medlemspris/ ikke-medlemspris
6.020 kr./9.260 kr.

Sprog
Dansk

New From idea to Market Launch

Would you like to understand what it takes to perform a successful market launch of your medtech solution? At this course you will learn to understand the possibilities and challenges getting a new medical device from the idea to market launch - and you will understand how to do it in practice including tools like “Validation of product idea”, “Evaluation of business potential”, “Identification of potential customers”, “Regulatory overview and authority expectations”, “How to prepare and organize the technical file” and finally “How to ensure market positioning”.

You will be provided with a structured roadmap to process the complex commercial and regulatory elements needed to gain success in the market, which can be applied to both start-ups and international companies already on the market with other products.

Date
11-12 September 2024

Duration
2 days

Member price/ non member price
12.040 kr./18.520 kr.

Language
English

Sundhedssystemets opbygning og Market Access

På kurset lærer du, hvordan man får medicinsk udstyr ud på det danske marked og ind i det danske sundhedsvæsen. Du lærer, hvordan sundhedsområdet er organiseret og finansieret samt om de økonomiaftaler, der danner rammen for indkøb af medicinsk udstyr. På kurset får du en grundig forståelse for de mange forskellige aktører på området, og hvilke aktører du med fordel har mulighed for at påvirke.

Du får kendskab til sundhedsøkonomiske modeller, beregninger og design af studier. Kurset sætter fokus på implementering og brug af relevant evidens i Market Access arbejdet, og på hvordan produkterne prisfastsættes.

”Super gode oplægsholdere.” Deltager, 2021

Dato
8.-9. oktober 2024

Varighed
2 dage

Medlemspris/ ikke-medlemspris
12.040 kr./18.520 kr.

Sprog
Dansk

Reimbursement as a Driver for Commercial and Clinical Strategies

The course will focus on what the concept behind reimbursement is, who the key market decision-makers are and what their needs are, and how reimbursement drives commercial and strategic strategies. Attendees will understand the process to maximize the efficiency (return on investment) of commercial and clinical strategies towards reimbursement. This means developing a process that will generate measurable positive results for a medtech company that intends to sell its products into the market.

"Good introduction to the subject, good interaction with the other participants." Participant, 2021

Date
2 December 2024

Duration
1 day

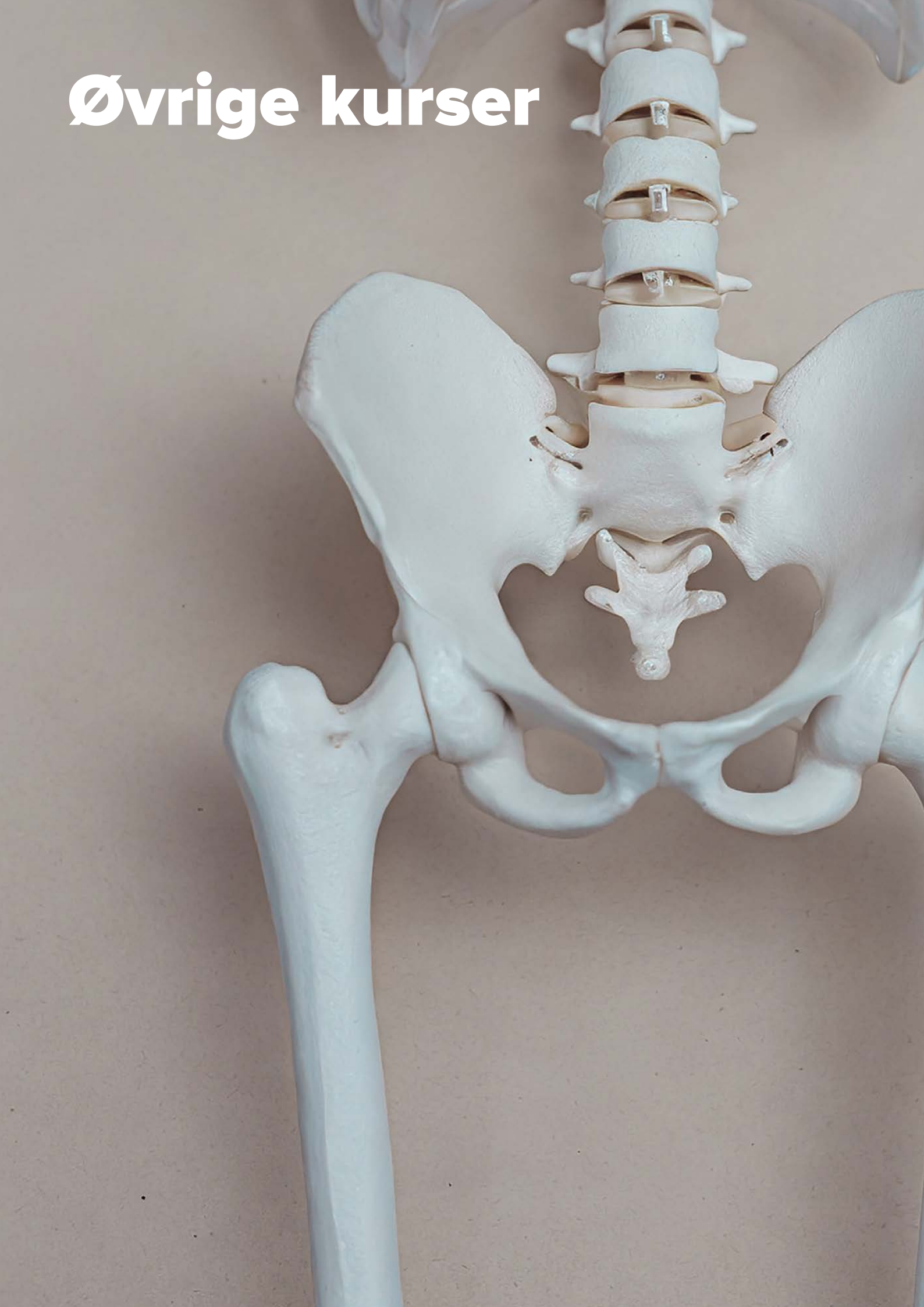
Member price/ non member price
6.020 kr./9.260 kr.

Language
English

Følg MedTech Academy på LinkedIn

Scan QR-koden og få viden om nye og aktuelle kompetenceudviklingsydelser målrettet medicobranchen

Øvrige kurser



Introduktion til medicobranchen

Kurset er udviklet for at give nye medarbejdere et overblik over medicobranchen og henvender sig bredt til alle, der har brug for indsigt i branchen og en forståelse for de metoder, relationer og lovkrav, der er essentielle for at agere i medicobranchen.

Undervisningen varetages af fagfolk fra branchen, der hver især giver indlæg om deres faglige områder – fra idé til produktudvikling, produktion, til salg og markedsføring. Undervisningen krydres med små workshops og opgaver.

"Kurset giver et rigtig godt overblik, som kan anvendes af alle enten som en intro eller som overbliksskabende. Vil anvende kurset bredere i vores organisation." Deltager, 2023

Dato
10.-12. april 2024
30. oktober-
1. november 2024

Varighed
3 dage

Medlemspris/ ikke-medlemspris
9.370 kr./14.410 kr.

Sprog
Dansk

Er du og din virksomhed klar til det udvidede producentansvar for emballage?

Danmark er som de øvrige EU-lande forpligtet til senest 31. december 2024 at indføre et udvidet producentansvar for alle typer emballager. Det gælder også for emballager til medicinsk udstyr. Det betyder at medicovirksomheder, der importer eller bruger emballage til deres produkter, fra og med 1. januar 2025 bærer det finansielle og organisatoriske ansvar for håndtering af emballageaffald, herunder indsamling, sortering og behandling. Det kan virksomheden vælge selv at stå for, eller de kan vælge at tilslutte sig en såkaldt kollektiv ordning, som på vegne af producenterne kan varetage de administrative og praktiske opgaver, som følger af producentansvaret.

På kurset gennemgås seneste nyt om det udvidet producentansvar for emballage (EPR), herunder de konsekvenser, det vil få for de berørte parter – fremstillere, påfyldere og grossister, samt hovedpunkterne i EU-Kommissionens forslag til ny forordning for emballage- og emballageaffald.

"Det var godt med konkrete eksempler på emballage. Godt flow i kursets opbygning ift. tid og oplæg. Svarvillige oplægsholdere." Deltager, 2023

Dato
6. maj 2024

Varighed
1 dag

Medlemspris/ ikke-medlemspris
6.020 kr./9.260 kr.

Sprog
Dansk

Anatomi, fysiologi og sygdomslære

Kurset giver et overblik over og en forståelse for menneskets opbygning og funktion hos raske og syge mennesker. Du lærer, hvordan den raske krop er opbygget og fungerer, og hvordan kroppen fungerer, når den ikke er rask.

Du hører om nogle af de hyppigt forekommende akutte og kroniske somatiske sygdomme i det danske sundhedsvæsen. Du lærer, hvordan sygdomsprocesser manifesterer sig klinisk og paraklinisk, og hvilke årsager kendes samt relevante muligheder for diagnostik, behandling og forebyggelse.

"Engageret underviser med stor viden og evner til at formidle viden, godt program og materiale." Deltager, 2023

Dato
16.-17. maj 2024

Varighed
2 dage

Medlemspris/ ikke-medlemspris
12.040 kr./18.520 kr.

Sprog
Dansk

Personlig beskyttelse for teknikere - afbrydelse af smitteveje

Kurset består af 2 dele: Generel hygiejne & strålehygiejne. Deltagerne opnår viden om smittekilder, smitterisici samt metoder til, hvordan de kan undgå at blive smittet og afbryde smitteveje. Desuden får deltagerne viden om faremærker, personlig beskyttelse og adfærd på sygehuset samt strålebeskyttelse.

Kurset henvender sig til serviceteknikere, røntgenteknikere og andet teknisk personale, der har ansvar for installation, vedligeholdelse og reparation af medicinsk udstyr.

"Kurset dækker to vigtige områder i mit daglige arbejde, som ikke nødvendigvis har så stor fokus til dagligt. God info og tid til spørgsmål." Deltager

Dato
28. august 2024

Varighed
1 dag

Medlemspris/ ikke-medlemspris
6.020 kr./9.260 kr.

Sprog
Dansk

New Implementing Electronic Quality Management System (eQMS) in Medtech Companies

With the increasing number and complexity of regulatory requirements, managing all quality processes relying on manual paperwork can pose significant challenges. Moreover, from a sustainability and efficiency standpoint, adopting electronic processes is preferable to a paper-based approach. As a result, numerous companies are transitioning to Electronic Quality Management System (eQMS) to leverage associated benefits, such as streamlined workflows, efficient document management, reduced time and costs, and cloud-based document storage and archive.

Participants will be introduced to the concept of eQMS and the significant advantages it offers. They will learn how to define the requirements for implementing an eQMS within their organization. The course will provide participants with the knowledge needed to begin this journey. By the end of the course, participants will have a comprehensive understanding of eQMS and its advantages, as well as the prerequisites, dependencies, the importance of defining requirements, and competences involved in eQMS implementation.

Date
23 September 2024

Duration
1 day

Member price/ non member price
6.020 kr./9.260 kr.

Language
English

Industrial Sterilization of Medical Devices - Define and Implement Sterilization in Product Development and Manufacturing

The course gives a basic introduction to industrial sterilization of medical devices. The course will focus on the different industrial sterilization methods used for medical devices but also briefly describe other sterilization methods used within the medical device industry. The key purpose of the course is to make the participants able to make a qualified initial choice of the most suitable sterilization method for their device in question.

You will learn about the most common design challenges related to sterilization and you will be able to understand the implications of the choice of materials. On an overall level, the course will give input to sterilization validation approach, and will give the participants a practical insight to sterilization project management. Finally, the course will give an overview of the key international standards within sterilization area including other associated sterilization relevant standards.

“Content and level were spot on.” Participant, 2022

Date
5 December 2024

Duration
1 day

Member price/ non member price
6.020 kr./9.260 kr.

Language
English

Uddannelser

MedTech RA Officer 2024

Formålet med uddannelsen er at give dig et bredt overblik over de regulatoriske aspekter, som knytter sig til medicinsk udstyr og medicinsk udstyr til in vitro-diagnostik, på et grundlæggende niveau. Du får en række regulatoriske kompetencer, som er helt essentielle for at kunne arbejde i og forstå medicobranchen.

På uddannelsen får du viden om og forståelse for den menneskelige organismes opbygning og funktion hos raske og syge mennesker.

Der sættes fokus på, hvordan du understøtter udvikling af personsikkert medicinsk udstyr ved at arbejde efter et kvalitetsledelsessystem. Du lærer, hvordan kvalitetsledelsessystemer til medicinsk udstyr er opbygget, hvilke handlinger der skal foretages for at opnå denne sikkerhed, og hvorfor markedsovervågning efterfølgende er lovpligtig.

Du får kendskab til forskellige typer af materialer og til kravene til klinisk evaluering. Du lærer om kravene til en klinisk evaluerings-rapport, herunder hvordan en litteratursøgning skal dokumenteres. Derudover får du en introduktion til kliniske afprøvninger og hvilke regler, der gælder på dette område samt en introduktion til brugervenlighedsstudier, og hvordan de adskiller sig fra kliniske studier.

Indhold
Uddannelsen består af 3 moduler, hvor det 1. modul er et frivilligt tilvalgsmodul. Uddannelsen forløber hen over to måneder og afsluttes med en skriftlig eksamen. Tilvalgsmodulet er målrettet de deltagere, som ikke har en sundhedsfaglig baggrund, og som har brug for grundlæggende viden inden for anatomi, fysiologi og sygdomslære.

Modul 1 **Anatomi, fysiologi og sygdomslære (tilvalg)**

Modul 2 **Det europæiske godkendelsessystem for medicinsk udstyr og medicinsk udstyr til in vitro-diagnostik**

Modul 3 **Materialer og klinisk evaluering**

Eksamen

”Hvad var godt: Overblikket, fordybelsen, læringen, underviserne, materialet, kursisterne, eksamen og maden.” Deltager, 2022

Modul 1 (tilvalg)
16.-17. maj 2024

Modul 2
29.-31. maj 2024

Modul 3
10.-11. juni 2024

Eksamen
19. juni

Varighed
7 dage

Medlemspris/ ikke-medlemspris
35.100 kr./54.000 kr.

Sprog
Dansk

MedTech Market Access Officer 2024

Uddannelsen gør dig i stand til at imødekomme de stadigt stigende krav fra hospitaler og indkøbere om faglighed, dokumentation og professionalisme i salgsrelationerne mellem leverandører og indkøbere af medicinsk udstyr.

Uddannelsen giver:

- Almen viden om og forståelse for anatomi, fysiologi og sygdomslære
- Overblik over opbygningen af det danske sundhedssystem
- Market Access - du lærer, hvordan man får medicinsk udstyr ud på det danske marked og ind i det danske sundhedsvæsen
- Kendskab til lovgivning og regler for medicinsk udstyr

Uddannelsen består af 3 moduler:

Modul 1 - Anatomi, fysiologi og sygdomslære
Du får en almen viden om og forståelse for den menneskelige organismes opbygning og funktion hos raske og syge mennesker. Du hører om nogle af de hyppigt forekommende akutte og kroniske somatiske sygdomme i det danske sundhedsvæsen. Du lærer, hvordan sygdomsprocesser manifesterer sig klinisk og paraklinisk, og hvilke årsager kendes samt relevante muligheder for diagnostik, behandling og forebyggelse.

Modul 2 - Sundhedssystemets opbygning & Market Access
Du hører, hvordan man får medicinsk udstyr ud på det danske marked og ind i det danske sundhedsvæsen. Du lærer, hvordan sundhedsområdet er organiseret og finansieret samt om de økonomiaftaler, der danner rammen for indkøb af medicinsk udstyr. Du får kendskab til sundhedsøkonomiske modeller, beregninger og design af studier. Uddannelsen sætter fokus på implementering og brug af relevant evidens i Market Access arbejdet og på, hvordan produkterne prisfastsættes.

Modul 3 - Lovgivning i forbindelse med godkendelse og salg af medicinsk udstyr
Du får kendskab til og forståelse for godkendelsesregler samt regler for markedsføring og salg af medicinsk udstyr. Du lærer om aftale- og købeloven, markedsføringsloven samt udbudsreglerne for medicinsk udstyr.

Eksamen

”Jeg synes at oplægsholderne var rigtig gode til at lede os igennem undervisningen systematisk, samtidig med at de formåede at trække tråde ud i deres og vores hverdagsopgaver. Flere emner blev gjort enormt interessante og vedrørende, på trods af emnernes kompleksitet.” Deltager, 2022

Modul 1
3.-4. september
16.-17. september

Eksamen
4. oktober

Modul 2
8.-9. oktober

Eksamen
25. oktober

Modul 3
7.-8. november

Eksamen
22. november

Varighed
8 dage

Medlemspris/ ikke-medlemspris
40.100 kr./61.700 kr.

Sprog
Dansk

”The instructor was very experienced in the field and exemplified the content of his presentation based on his own experience, which made the course very interesting & enjoyable. Very good overall structure of the course, starting with a general overview of the FDA. Excellent delivery throughout the two days; participants were engaged.”

Participant from FDA Regulation of Medical Devices:
Recent FDA Guidance Documents, 2022

Virksomhedsinterne kurser

Skræddersyede kurser

Medicoindustrien udvikler og gennemfører i stigende grad også virksomhedsinterne kurser.

Kurserne skræddersyes specifikt efter virksomhedens behov og giver mulighed for frie diskussioner om konkrete problemstillinger. Den stigende efterspørgsel på virksomhedsspecifikke kurser begrundes ofte med behov for optimering af de ressourcer, der er til rådighed for efteruddannelse og ønsket om at frigøre interne ressourcer. Hvad enten I vælger at afholde et virksomhedsinternt kursus med samme indhold som vores åbne kurser, eller I vælger et tilpasset kursus, så hjælper vi med at tilrettelægge og gennemføre kurset, så I får et målrettet og sammenhængende kompetenceudviklingsforløb.

Jeres udbytte:

- Medarbejdere får samme kompetenceløft samtidigt
- Tilpasset indhold i forhold til uddannelsesniveau, ønsker og behov
- Målrettet undervisning i forhold til egne strategier og værdier
- Trygge rammer for at arbejde med konkrete og fortrolige opgaver
- Styrket intern kommunikation, samarbejde og kultur
- Fælles sprog og retningslinier

Online kurser med WMDO

Partnerskab med WMDO

Medicoindustrien har indgået et strategisk partnerskab med WMDO, som er den førende globale udbyder af online medtech kurser, om at udbyde online kurser indenfor medico området.

Partnerskabet tilbyder danske medicovirksomheder adgang til WMDO's omfattende katalog af online kurser igennem Medicoindustrien. Du vil finde et omfattende katalog med mere end 200 online kurser indenfor pre-clinical, clinical evaluation, regulatory affairs, quality assurance, health economics and reimbursement, combination products and start-ups & business ethics.

Medicoindustrien er eksklusiv partner til WMDO i Danmark og er glade for at kunne tilbyde vores medlemmer og ikke-medlemmer adgang til relevante online kurser, som et supplement til vores i forvejen store og brede palette af kurser og uddannelser.

Du vil opnå en fordelagtig rabat på 10%, som kun er mulig igennem dette partnerskab.

En brancheorganisation for mere end 230 af Danmarks førende medicovirksomheder

Medicoindustrien er en brancheorganisation for virksomheder der beskæftiger sig med medicinsk udstyr og har til formål at fremme medlemsvirksomhedernes erhvervsmæssige og politiske interesser.

I Danmark er Medicoindustrien høringsinstans for myndighederne i spørgsmål og sager, som angår branchen for medicinsk udstyr. Medicoindustrien deltager aktivt i råd og udvalg, som har indflydelse på erhvervsvilkårene for branchen.

På internationalt plan yder Medicoindustrien en aktiv indsats i de fælles europæiske og amerikanske søsterorganisationer.

Medicoindustrien
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