MEDICO
INDUSTRIEN
MEDTECH DENMARK

2023

MedTech Academy

Har du brug for ny viden der styrker dine kompetencer?

Medicoindustrien tilbyder en bred vifte af spændende og højaktuelle uddannelsestilbud, som er målrettet dig, der sætter læring og kompetenceudvikling i fokus. Vores uddannelsesprogram for 2023 afspejler de krav til kompetenceudvikling og opdatering på den nyeste viden, som vores medlemmer efterspørger.

Vi udbyder en bred vifte af kompetenceudviklingsydelser, som omfatter kurser af både en og flere dages varighed, uddannelser og seminarer om højaktuelle emner. Du vil møde engagerede og kompetente undervisere, som er specialiserede inden for hvert deres fagfelt.

Der bliver løbende udviklet nye kurser og seminarer. Du kan følge med i udviklingen af de forskellige aktiviteter via www.medicoindustrien.dk og vores nyhedsbreve.

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.

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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Tilmeld dig vores kurser på www.medicoindustrien.dk under Academy.
Har du forslag til nye kurser eller seminarer, er du altid velkommen til at kontakte os på medico@medicoindustrien.dk eller 49 18 47 00

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Udvikling og produktion af medicinsk udstyr

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

31. januar 2023
8. september 2023

"Det hele var i et godt tempo og meget interessant at høre om." Deltager, efterår 2022

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.

Statistik for procesvalidering

27.-28. februar 2023

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

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.

Brugervejledninger til medicinsk udstyr

1.-2. marts 2023

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

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.

Project Management for Product Development of Medical Devices

12-14 April 2023
27-29 November 2023

"I gained in-depth knowledge about a number of topics as well as a great overview of the development process. It was concrete and not just theoretical so I could apply it directly to my day to day job. I feel confident that this course will strengthen me in performing my job with high quality. The teacher was very professional and you could tell that he had a lot of experience. Also, there was a great balance between exercises and presentation to make sure to keep you up to speed. All in all a really great experience." Participant, Spring 2022

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.

Course language is English

Design Control

27-28 April 2023
30-31 October 2023

"The presenter was excellent at using practical examples from the industry to underline his points, and his answers to questions posed by the participants were well founded." Participant, Spring 2022

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 employs a lean and pragmatic approach to medical device design with focus on the documentation part.

Course language is English

Clinical Evaluation for Medical Devices in Europe and International Approach

8-9 May 2023
14-15 November 2023

"The trainer is very engaged and the slides are very useful for after the course. Also, a very nice venue." Participant Spring 2022

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 marked or not are under the scope of the Medical Device Regulation's requirements.

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, and its final draft is close to being published.

Furthermore, the relationship companies have with their Notified Bodies is definitely changing, as a result of the changing climate with regards to the need for more clinical evaluation data.

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.

Course language is English

Process Validation

16-17 May 2023
8-9 November 2023

"The course gave me a very good understanding of process validation." Participant, Spring, 2022

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 has to be validated, when it needs to be done and particularly how to do it.

Course language is English

Praktisk gennemførelse af risikoanalyser ved produktudvikling

4.-5. oktober 2023

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

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 risiko-analyser. Det er et godt udgangspunkt at have et grundlæggende kendskab til ISO 14971: Håndtering af risikostyring for medicinsk udstyr.

"I gained in-depth knowledge about a number of topics as well as a great overview of the development process. It was concrete and not just theoretical, so I could apply it directly to my job. I feel confident that this course will strengthen me in performing my job with high quality. The teacher was very professional, and you could tell that he had a lot of experience. Also, there was a great balance between exercises and presentation to make sure to keep you up to speed. All in all, a really great experience"

Deltager i kurset "Project Management for Product Development of Medical Devices ", 2022

Regulatoriske forhold

Persondatareglerne i medicovirksomheder – nye afgørelser og praktiske spørgsmål

10. januar 2023 - 1/2 dag

På kurset gennemgås de vigtigste regler i GDPR, så du får et hurtigt overblik over de grundlæggende krav til databeskyttelse. Kurset tager udgangspunkt i seneste praksis og vejledninger fra Datatilsynet m.v., og hvordan reglerne håndteres konkret i hverdagen. Kursets emner er valgt ud fra, hvad der erfaringsmæssigt har vist sig at udgøre særlige udfordringer hos virksomheder. Der vil være et særligt fokus på forhold, der har relevans for medicovirksomheder.

Efter kurset vil du have et godt udgangspunkt for at vurdere problemstillinger på området for brug af sundhedsdata til forskning og statistik og i kliniske afprøvninger i samspil med GDPR, herunder de videregivelser af personoplysninger, der er nødvendige i forbindelse med kvalitetssikring og forskningsprojekter både før, under og efter projektets afslutning.

MDD to MDR Transition

23-24 January 2023
12-13 October 2023

"Good information about MDR - for my level. The group exercises worked well and I learned a lot." Participant, Spring 2022

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.

Course language is English

Person Responsible for Regulatory Compliance according to MDR and IVDR

7 February 2023
13 September 2023

"Competent teachers; nice overview." Participant

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.

Course language is English

MDR Auditing - Training of Internal Auditors in Relation to MDR

6 March 2023 - online course
23 October 2023 - online course

"The instructor is really good. He knows a lot and can give an answer to almost all questions. Mostly, I liked that the instructor gave a new perspective to look at the MDR." Participant, Fall 2022

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

Course language is English

Implementation of the IVDR for CE Marking

3-5 April 2023 - online course

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.

Course language is English

New Software as Medical Device and Quality Management

17-18 April 2023

"The instructor was very knowledgeable on a wide variety of related subjects. Good slides. Interesting subject that was well covered." Participant, Spring 2022

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.

Course language is English

Implementation of the MDR for CE Marking

18-20 April 2023 - online course

"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

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.

Course language is English

Nyt Ændringer af udbudsloven - hvad betyder det for tilbudsgivelsen i næste udbud?

21. april 2023 - 1/2 dag

Kurset har til formål at give dig et overblik over de væsentligste ændringer i udbudsloven, der trådte i kraft den 1. juli 2022 (visse dele dog først den 1. januar 2023). Hvilke ændringer skal du som tilbudsgiver være opmærksom på, når du afgiver tilbud i næste udbud?

Kurset vil efter en kort introduktion til arbejdet med revision af udbudsloven og baggrunden for ændringerne fokusere nærmere på de væsentligste regelændringer og betydningen heraf i praksis.

Introduction to Chemical Compliance for Medical Devices

24 April 2023

"Thorough introduction to chemicals and search in various databases." Participant, Fall 2021

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.

Course language is English

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

26 April 2023 - online course
2 October 2023 - online course

"A very knowledgable teacher giving examples from his previous experiences. The teacher has been working with NBs so he has been sitting on the other side of the table." Participant, Fall 2022

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.

Course language is English

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

1-2 May 2023 - 1 1/2 day

"I liked the overall content and also the section related to the MDR." Participant, Spring 2022

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, your 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.

Course language is English

ISO 13485 and Quality Management for Medical Devices / Internal Auditing

10-12 May 2023
20-22 November 2023

"I liked all of it, it really gave me the framework of our Company QMS." Participant, Fall 2022

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.

Course language is English

Medical Device Usability

25-26 May 2023
1-2 November 2023

"Very competent trainers, good presentations and involving exercises." Participant, Fall 2022

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.

Course language is English

GDPR – praktiske udfordringer i medicovirksomheder

1. juni 2023

"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, efterår 2021

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.

Technical Documentation for Medical Devices According to the MDR

1 June 2023 - online course
8 December 2023 - online course

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

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.

Course language is English

IEC 62304: Software Lifecycle

6-7 June 2023
4-5 December 2023

"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, Fall 2022

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.

Course language is English

Corrective & Preventive Actions (CAPA)

12 June 2023 - online course
18 December 2023 - online course

"Very knowledgeable instructor and excellent course materials." Participant, Spring 2020

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.

Course language is English

MDSAP Fundamentals and Readiness Training

15-16 June 2023
6-7 December 2023

" It was a very knowledgeable trainer with a lot of input and proposals on how to prepare for MDSAP audits." Participant, Fall 2021

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.

Course language is English

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

15-16 June 2023
14-15 December 2023

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

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 system. 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.

Course language is English

IVDD to IVDR Transition

19-20 June 2023 - online course

There are significant changes in the European legislation applicable to IVDs. The IVDR (In Vitro Diagnostic Regulation) (EU 2017/746) has replaced the IVD Directive (98/79/EC), and will impose new requirements on manufacturers and other Economic Operators.

This long awaited text brings a number of significant changes to the regulatory requirements for IVD manufacturers, addressing the challenges posed by the IVD Directive. 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).

Course language is English

Introduktion til udbudsloven

21. juni 2023
20. december 2023

"Rigtig god systematisk gennemgang." Deltager, forår 2021

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.

DNV Product Assurance (DNV GL Presafe) - How to Apply for MDR Certification

1 September 2023

This course gives you an understanding of the application requirements and the internal processes for application handling at DNV Product Assurance. You will understand the requirements for information needed. You will also learn how to avoid pitfalls and misunderstandings when applying for MDR certification, through advice, guidances and explanations.

Course language is English

Quality Systems Regulations (QSR)

4-5 September 2023

"I really liked that the course covered the subject thoroughly while using relevant examples." Participant

The course will give an understanding of the differences between the US and European medical device standards. This will include a review of FDA Quality System Regulations and comparison with the ISO 13485 standard. In addition, focus will be on FDA inspections, illustrated by means of case studies based on results of FDA inspections. It is designed for employees in the medical device industry who need to gain insight into FDA QSR/GMPs and employees who are about to take part in planned FDA inspections.

Course language is English

Patenter, forretnings-hemmeligheder og forskningssamarbejder

6. september 2023

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, hvad der kan beskyttes som erhvervshemmeligheder/'know-how', og hvordan krænkelsessager foregår. Kurset giver dig et overblik over disse emner, bl.a. via konkrete eksempler og cases om medicinsk udstyr.

På kurset får du også et overblik over de centrale spørgsmål i forbindelse med forskningssamarbejder, både med universiteter, hospitaler og andre offentlige institutioner og med private virksomheder.

Cybersecurity Design Considerations for Medical Device Manufacturers

18-19 September 2023

"The course had a nice high level approach to the subject with an expert instructor to highlight key details." Participation, Spring 2020

With the increasing threat of cybersecurity affecting connected medical devices, software, systems, and healthcare IT networks, manufacturers must understand how to identify and mitigate security threats to assure that products and systems are designed to be resistant to security exploits. Security functions are needed to assure that any threat surface which can expose the medical device and its network connectivity are designed in a way to be robust against common security exploits. The FDA Pre-Market Guidance for Medical Device Cybersecurity identifies a number of security functions manufacturers should consider in their design of network connected and IoT enabled medical devices.

In this training program, we will provide an overview of the recommended security functions, including authorization, authentication, encryption, and detection security functions identified in the FDA Pre-Market Guidance. We will provide practical examples of their implementation in a case study design and discuss design trade-offs.

Course language is English

Incentive Programs - Learn How to Decide, Implement and Maintain the Right Program in your Company

20 September 2023

This course gives you an introduction to incentive programs in general, especially do's and don'ts in connection with choosing which program or model is the right one for your company and a more detailed overview of some of the most common incentive programs used in start-ups and early stage growth companies.

Furthermore, you will be introduced to the legal requirements and tax issues, when establishing and maintaining an incentive program.

Course language is English

Nyt Salg til det offentlige uden udbud

3. oktober 2023 - 1/2 dag, formiddag

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 komme 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.

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

3. oktober 2023 - 1/2 dag, eftermiddag

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?

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

12-13 October 2023

"The instructor is very competent and understands Chinese regulation and mentality." Participant, Fall 2021

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.

Course language is English

FDA Regulation of Medical Devices: Recent FDA Guidance Documents

16-17 November 2023

"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, Fall 2022

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 which impact how medical devices are regulated and affect a sponsor's plans for developing medical devices and interacting with FDA.

Course language is English

New Constructing and Structuring a Cybersecurity Framework

20-22 November 2023

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, post-market vigilance and security architecture is performed.

Course language is English

Toxicological Risk Assessment for Medical Devices: Impact of ISO 10993-17:2023

23-24 November 2023

The course provides participants with a comprehensive understanding of Toxicological Risk Assessment (TRA) for medical devices, with a particular emphasis on the new ISO 10993-17:2023. TRA is a critical aspect of ensuring the safety and biocompatibility of medical devices. The course aims to give participants the knowledge and skills necessary to conduct effective TRA in compliance with international standards and regulations.

Day 1 focuses on TRA in general, covering fundamental concepts and methodologies. It guides participants through the entire TRA process, from planning according to ISO 10993-1, chemical characterization per ISO 10993-18, and overall biological safety assessment. The day also addresses the practical implementation of TRA using real cases and provides insights into dealing with situations when toxicological data is scarce.

Day 2 narrows the focus to the new TRA concepts and terms introduced in the ISO 10993-17:2023. This includes the exploration of new definitions, clauses, and flowcharts. Special attention will be given to topics such as Total Quantity (TQ), Margin of Safety (MOS), Estimated Exposure Dose (EEDmax), release kinetics and Point Of Departure (POD). The day also dives into the application of toxicological screening limits (TSL) and the journey, using actual case studies, from chemical characterization, through extractable and leachable studies, to a comprehensive TRA.

Course language is English

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

11. december 2023

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.

Kurset sætter bl.a. det enkelte ledelsesmedlem i stand til at varetage følgende krav i NIS2:

• Forstå og agere risikobaseret i forhold til relevante cybertrusler anno 2023/24

• Overvåge organisationens håndtering af cybertruslerne, herunder kunne vurdere og kvalificeret godkende organisationens risikovurderinger og foranstaltninger

• Supportere organisationens overholdelse af reglerne på operationelt niveau

• Være i stand til at påtage sig ansvaret for organisationens overholdelse af kravene

New Introduction to Cybersecurity Risk Management for TIR57 Compliance

13-14 December 2023

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 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 for a fictious product.

Course language is English

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

18-19 December 2023

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 oppose to a defending it can secure them.

Course language is English

Salg og markedsføring af medicinsk udstyr

Digital markedsføring af medicinsk udstyr

6. februar 2023
7. september 2023

"Det var en rigtig fin gennemgang, som gav en bred forståelse." Deltager, forår 2022

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.

Sundhedssystemets opbygning & Market Access

23.-24. marts 2023
9. - 10. oktober 2023

"Super gode oplægsholdere." Deltager, efterår 2021

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.

Regler om reklame, tilknytning og økonomiske fordele

23. juni 2023
13. december 2023

"Det var spændende at høre om lovgivningen direkte fra kilden - Lægemiddelstyrelsen. Generelt godt og informativt indhold, og dejligt med mulighed for at stille spørgsmål." Deltager, forår 2021

På kurset vil du høre Lægemiddelstyrelsen give en opdatering på reglerne om gennemsigtighed omkring samarbejdet mellem læger, tandlæger, sygeplejersker og 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.

New From Idea to Market Launch

25-26 September 2023

Would you like to understand what it takes to perform a successful market launch of you 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 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.

Course language is English

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

29 September 2023 - 1/2 day online course

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 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.

Course language is English

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

27 October 2023 - 1/2 day online course

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 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.

Course language is English

Reimbursement as a Driver for Commercial and Clinical Strategies

1 December 2023

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

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 medical company that intends to sell its products into the market.

Course language is English

“Gode undervisere, godt materiale, fine øvelser, god struktur og overordnet et rigtigt godt program”

Deltager i kurset ”Praktisk gennemførelse af risikoanalyser ved produktudvikling”, 2022

Øvrige

New Digital Readiness in Medtech Companies

26 January 2023

This one-day course will provide a background on Digital Readiness activities from an end user perspective and a QA perspective. You will learn overall prerequisites, dependencies, requirements and competences when implementing digital solutions such as Electronic Batch Record (EBR), Electronic Quality Management System (eQMS), Electronic Training System (eTS), Learning Management Systems (LMS), AI solutions etc. You will learn an effective process and how to set the right level of quality requirements and thereby avoid overprocessing.

Course language is English

New New Approach Methodologies (NAMs) for Medical Devices

9-10 March 2023

New Approach Methodologies (NAMs) for medical devices are non-animal-based documentation strategies that can be used in biological evaluation of medical devices.

In this 1½ day course we will cover the most recent advances in documentation alternatives to in vivo biocompatibility testing. We will review the current global regulatory acceptance of a risk-based biocompatibility approach focusing on the use of extractables and leachables data, along with in vitro testing alternatives for the irritation and sensitization endpoints. We will also discuss the status of using NAMs for future biological endpoints and which alternative testing methods are next.

At the end of the course, attendees will feel more confident on how and when to use extractables & leachables in vitro data in the biological risk assessments.

Course language is English

Introduktion til medicobranchen

28.-30. marts 2023
24.-26. oktober 2023

”Mange forskellige emner, vi kom godt ud i alle hjørner af medicobranchen. Underviserne var engagerede og dygtige. Som ny i branchen er jeg blevet endnu mere motiveret og godt rustet til at snakke med vores kunder. Succes for mig er, at få indsigt i de udfordringer, regler, begrænsninger og krav som mine kunder navigerer i. Det synes jeg helt klart, at jeg har fået på dette kursus. Tak!”
Deltager, forår 2022

Kurset er udviklet for at give nye medarbejdere et overblik overmedicobranchen 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, til produktion til salg og markedsføring. Undervisningen krydres med små workshops og opgaver.

Anatomi, fysiologi og sygdomslære

3.-4. maj 2023

”Dygtig underviser der er god til at omsætte stoffet til dagligdagen, så man bedre forstår det - en god portion humor indover gør kurset spændende, så det fænger.” Deltager, efterår 2022

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.

Målgruppen er alle, som ikke har en sundhedsfaglig baggrund.

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

15. maj 2023

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.

Personlig beskyttelse for tenikere – afbrydelse af smitteveje

4. september 2023

”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

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.

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

13. november 2023

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. Furthermore, the course will assist participants in considering important factors when choosing an eQMS and supplier.

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

12 December 2023

“It was a great overall introduction to sterilization methods.”
Participant, Fall 2022

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. Course language is English

Virksomheds-interne 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

"Jeg synes, at oplægsholderne var rigtig gode til at lede os igennem undervisningen systematisk, samtidig med de formåede at trække tråde ud i deres og vores hverdagsopgaver"

Deltager i uddannelsen "Medtech RA Officer", 2022

Uddannelser

MedTech RA Officer

Tilvalgsmodul 1: 3.-4. maj 2023
Modul 2: 22.-24. maj 2023
Modul 3: 8.-9. juni 2023
Eksamen 22. juni 2023

"Oplægsholderne var rigtig gode til at lede os igennem undervisningen systematisk, samtidig med de formåede at trække tråde ud i deres og vores hverdagsopgaver." Deltager, 2022

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 fortages 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 evalueringsrapport, 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.

Tilvalgsmodul 1: Anatomi, fysiologi og sygdomslære
Modul 2: Det europæiske godkendelsessystem for medicinsk udstyr og medicinsk udstyr til in vitro-diagnostik
Modul 3: Materialer og klinisk evaluering Eksamen

Uddannelsen er målrettet de særlige problemstillinger, som gælder på det regulatoriske område i medicoindustrien og indeholder praktiske eksempler og øvelser.

Medtech Market Access Officer

Modul 1: 28.-29. august 2023 + 11.-12. september 2023
Eksamen 6. oktober 2023
Modul 2: 9.-10. oktober 2023
Eksamen 3. november 2023
Modul 3: 6.-7. november 2023
Eksamen 1. december 2023

"Hvad var godt: Overblikket, fordybelsen, læringen, underviserne, materialet, kursisterne, eksamen og maden" Deltager, 2021

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 forløber henover 5 måneder og 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.

Online kurser i Medicoindustrien

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.

Følg MedTech Academy på LinkedIn

Medicoindustriens afdeling for kurser, uddannelser og seminarer - MedTech Academy - er kommet på LinkedIn. Få viden om nye og aktuelle kompetenceudviklingsydelser målrettet medicobranchen.

Følg Medtech Academy på LinkedIn

Scan QR-koden og følge Medtech Academy på LinkedIn

Medicoindustrien udbyder løbende højaktuelle seminarer

Følg med på www.medicoindustrien.dk under Academy

Kurser	Dato	Varighed	Pris: medlem/ ikke-medlem
Persondatareglerne i medicovirksomheder - nye afgørelser og spørgsmål	10. januar	1/2 dag	2.920/4.500
MDD to MDR Transition	23. - 24. januar	2 dage	11.300/17.380
Digital Readiness in Medtech Companies	26. januar	1 dag	5.840/8.990
Introduktion til UDI (Unique Device Identification) – identifikation og mærkning af medicinsk udstyr	31. januar	1 dag	5.840/8.990
Digital markedsføring af medicinsk udstyr	6. februar	1 dag	5.840/8.990
Person Responsible for Regulatory Compliance acc. to MDR/IVDR	7. februar	1 dag	5.840/8.990
Statistik for procesvalidering	27. - 28. februar	2 dage	11.680/17.990
Brugervejledning til medicinsk udstyr	1. - 2. marts	2 dage	11.680/17.990
MDR Auditing - Training of Internal Auditors in Relation to MDR Online course	6. marts	1 dag	5.260/8.090
New Approach Methodologies (NAMs) for Medical Devices	9. - 10. marts	1 1/2 dag	8.760/13.485
Sundhedssystemets opbygning & Market Access	23. - 24. marts	2 dage	11.680/17.990
Introduktion til medicobranchen	28. - 30. marts	3 dage	9.090/13.990
Implementation of the IVDR for CE Marking Online course	3. - 5. april	3 dage	15.780/24.270
Project Management for Product Development of Medical Devices	12. - 14. april	3 dage	17.520/26.970
Software as Medical Device and Quality Management	17. - 18. april	2 dage	11.680/17.990
Implementation of the MDR for CE Marking Online course	18. - 20. april	3 dage	15.780/24.270
Ændringer af udbudsloven - hvad betyder det for tilbudsafgivelsen i næste udbud?	21. april	1/2 dag	2.920/4.500
Introduction to Chemical Compliance for Medical Devices	24. april	1 dag	5.840/8.990
Training of Internal Auditors in relation to Country Specific Requirements within the MDSAP Program Online course	26. april	1 dag	5.260/8.090
Design Control	27. - 28. april	2 dage	11.680/17.990
Planning an Effective Post Market Surveillance Program for Medical Devices and Combination Products	1. - 2. maj	1 1/2 dag	8.760/13.485
Anatomi, fysiologi og sygdomslære	3. - 4. maj	2 dage	11.680/17.990
Clinical Evaluation for Medical Devices in Europe and International Approach	8. - 9. maj	2 dage	11.680/17.990
ISO 13485 and Quality Management for Medical Devices / Internal Auditing	10. - 12. maj	3 dage	17.520/26.970
Er du og din virksomhed klar til det udvidet producentansvar for emballage?	15. maj	1 dag	5.840/8.990
Process Validation	16. - 17. maj	2 dage	11.680/17.990
Medical Device Usability	25. - 26. maj	2 dage	11.680/17.990
GDPR – praktiske udfordringer i medicovirksomheder	1. juni	1 dag	5.840/8.990
Technical Documentation for Medical Devices according to MDR Online course	1. juni	1 dag	5.260/8.090
IEC 62304: Software Lifecycle	6. - 7. juni	2 dage	11.680/17.990
Corrective & Preventive Actions (CAPA) Online course	12. juni	1 dag	5.260/8.090

Kurser	Dato	Varighed	Pris: medlem/ ikke-medlem
MDSAP Fundamentals and Readiness Training	15. - 16. juni	2 dage	11.680/17.990
IEC 60601 – How to Apply Safety and Risk Management to Medical Electrical Equipment and Systems	15. - 16. juni	2 dage	11.680/17.990
IVDD to IVDR Transition Online course	19. - 20. juni	2 dage	10.520/16.180
Introduktion til udbudsloven	21. juni	1 dag	5.840/8.990
Regler om reklame, tilknytning og økonomiske fordele	23. juni	1 dag	5.840/8.990
DNV Product Assurance (DNV GL Presafe) - How to Apply for MDR Certification	1. september	1 dag	5.840/8.990
Personlig beskyttelse for teknikere – afbrydelse af smitteveje	4. september	1 dag	5.840/8.990
Quality Systems Regulations (QSR)	4. - 5. september	2 dage	11.680/17.990
Patenter, forretningshemmeligheder og forskningssamarbejder	6. september	1 dag	5.840/8.990
Digital markedsføring af medicinsk udstyr	7. september	1 dag	5.840/8.990
Introduktion til UDI (Unique Device Identification) – identifikation og mærkning af medicinsk udstyr	8. september	1 dag	5.840/8.990
Person Responsible for Regulatory Compliance according to MDR/ IVDR	13. september	1 dag	5.840/8.990
Cybersecurity Design Considerations for Medical Devices Manufacturers	18. - 19. september	2 dage	11.680/17.990
Incentive Programs - Learn How to Decide, Implement and Maintain the Right Program in your Company	20. september	1 dag	5.840/8.990
From Idea to Market Launch	25. - 26. september	2 dage	11.680/17.990
Digital Marketing of Medical Devices Abroad - Sweden, Germany and the USA Online course	29. september	1/2 dag	2.630/4.050
Training of Internal Auditors in relation to Country Specific Requirements within the MDSAP Program Online course	2. oktober	1 dag	5.260/8.090
Salg til det offentlige uden udbud	3. oktober	1/2 dag	2.920/4.500
Tips & tricks i forbindelse med afgivelse af tilbud i EU-udbud	3. oktober	1/2 dag	2.920/4.500
Praktisk gennemførelse af risikoanalyser ved produktudvikling	4. - 5. oktober	2 dage	11.680/17.990
Sundhedssystemets opbygning & Market Access	9. - 10. oktober	2 dage	11.680/17.990
MDD to MDR Transition	12. - 13. oktober	2 dage	11.680/17.990
New Update on China CFDA Regulation and Registration for Medical Devices with Case Studies	12. - 13. oktober	2 dage	11.680/17.990
MDR Auditing - Training of Internal Auditors in Relation to MDR Online course	23. oktober	1 dag	5.260/8.090
Introduktion til medicobranchen	24. - 26. oktober	3 dage	9.090/13.990
Digital Marketing of Medical Devices Abroad - Norway, United Kingdom and France Online course	27. oktober	1/2 dag	2.630/4.050
Design Control	30. - 31. oktober	2 dage	11.680/17.990
Medical Device Usability	1. - 2. november	2 dage	11.680/17.990
Process Validation	8. - 9. november	2 dage	11.680/17.990
Implementing Electronic Quality Management System (eQMS) in Medtech Companies	13. november	1 dag	5.840/8.990

Priserne er ekskl. moms

Kurser	Dato	Varighed	Pris: medlem/ ikke-medlem
Clinical Evaluation for Medical Devices in Europe and International Approach	14. - 15. november	2 dage	11.680/17.990
FDA Regulation of Medical Devices: Recent FDA Guidance Documents	16. - 17. november	2 dage	11.680/17.990
ISO 13485 and Quality Management for Medical Devices / Internal Auditing	20. - 22. november	3 dage	17.520/26.970
Constructing and Structuring a Cybersecurity Framework	20. - 22. november	3 dage	17.520/26.970
Toxicological Risk Assessment for Medical Devices: Impact of ISO 10993-17:2023	23. - 24. november	2 dage	11.680/17.990
Project Management for Product Development of Medical Devices	27. - 29. november	3 dage	17.520/26.970
Introduction to Chemical Compliance for Medical Devices	30. november	1 dag	5.840/8.990
Reimbursement as a Driver for Commercial and Clinical Strategies	1. december	1 dag	5.840/8.990
IEC 62304: Software Lifecycle	4. - 5. december	2 dage	11.680/17.990
MDSAP Fundamentals and Readiness Training	6. - 7. december	2 dage	11.680/17.990
Technical Documentation for Medical Devices according to MDR Online course	8. december	1 dag	5.260/8.090
Bliv klar til den nye cyberregulering, NIS2 - krav om obligatorisk uddannelse af ledelsen	11. december	1 dag	5.840/8.990
Industrial Sterilization of Medical Devices - Define and Implement Sterilization in Product Development and Manufacturing	12. december	1 dag	5.840/8.990
Regler om reklame, tilknytning og økonomiske fordele	13. december	1 dag	5.840/8.990
Introduction to Cybersecurity Risk Management for TIR57 Compliance	13. - 14 december	2 dage	11.680/17.990
IEC 60601 – How to Apply Safety and Risk Management to Medical Electrical Equipment and Systems	14. - 15. december	2 dage	11.680/17.990
Corrective & Preventive Actions (CAPA) Online course	18. december	1 dag	5.260/8.090
Threat Modelling, Security and Controls for Medical Devices: Attaching and Defending	18. - 19. december	2 dage	11.680/17.990
Introduktion til udbudsloven	20. december	1 dag	5.840/8.990

Uddannelser	Dato	Varighed	Pris: medlem/ ikke-medlem
MedTech RA Officer	3. maj - 22. juni	8 dage	22.400/34.440
Medtech Market Access Officer	28. aug.- 7. november	11 dage	38.950/59.930

Priserne er ekskl. moms

Hold dig opdateret om nye kurser og uddannelser

Tilmeld dig nyhedsbrevet "KursusNyt" på www.medicoindustrien.dk
og få nye kurser og uddannelser direkte i din indbakke

Scan QR-koden
for at tilmelde dig
nyhedsbrevet

Medicoindustrien er en brancheorganisation for mere end 230 af Danmarks førende virksomheder, der beskæftiger sig med medicinsk udstyr.

Medicoindustrien 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.

www.medicoindustrien.dk