



2022

MedTech Academy

Har du brug for ny viden der styrker dine kompetencer?

Medicoindustrien tilbyder en bred vifte af spændende og højaktuelle uddannelses tilbud, som er målrettet dig, der sætter læring og kompetenceudvikling i fokus. Vores uddannelsesprogram for 2022 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

1. marts 2022

5. september 2022

”Jeg havde en følelse af både at få udvidet, uddybet og bekræftet min viden på UDI området. Det var også rigtig fedt at tage udgangspunkt i de virksomheder der var til stede.” Deltager, efterår 2021

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.

Brugervejledninger til medicinsk udstyr

28. februar - 1. marts 2022

”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 vil kunne sætte 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.

Design Control

30-31 March 2022

10-11 October 2022

“My general understanding of the design control concepts and process was hugely improved.” Participant, Spring 2021

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.

For advanced course please see page 22.

Process Validation

9-10 May 2022

1-2 November 2022

“It’s a new field for me so it gave me a good insight in process validation that I can use in my future carrier. The teacher was very enthusiastic, helpful and mediated a good discussion with especially all the participants who are experienced in process validation.” Participant, Fall 2021

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.

For advanced course please see page 23.

Course language is English.

Clinical Evaluation for Medical Devices in Europe and International Approach

11-12 May 2022

10-11 November 2022

“Danielle Giroud was very present, engaged and used her slides as backup but did not just read them. She had many examples and was open for questions which she used as examples.” Participant, Spring 2021

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.

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.

Project Management for Product Development of Medical Devices

23-25 May 2022

7-9 November 2022

“The instructor had a good way of communicating and involved the participants during the course. It went through the areas that I felt needed to be covered.” Participant, Spring 2021

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.

Praktisk gennemførelse af risikoanalyser ved produktudvikling

1.-2. juni 2022

”God kombination af teori og praktiske øvelser. Kursets indhold blev målrettet efter det behov, som vi havde som deltagere, og det var fedt.” Deltager, efterår 2021

Dette kursus henvender sig til personer, der skal medvirke ved gennemførelse 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, 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.

Sustainability in Medtech Companies – Accelerating Your Impact

15-16 September 2022

Completing this two-day course will enable you to shape, sharpen and execute sustainability strategies for your company, for real concrete actions.

You will learn about the United Nations Global Goals and how to translate global sustainability expectations into your medical device offerings. The course will give you concrete tools and help you with a simple process enabling you to both make the case for your leadership team and execute on the proposed actions afterwards.

You will get a deeper understanding about circularity in your product lifecycle, and touch on some of the inbuilt dilemmas that medical device companies have with circular product streams.

Course language is English.

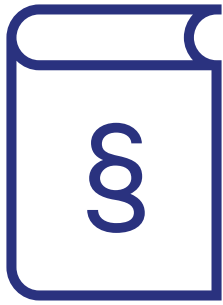
Statistik for procesvalidering

15.-16. december 2022

”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.



Regulatoriske forhold

Planning an Effective Post Market Surveillance Program for Medical Devices

23 March 2022

“Great combination of basic knowledge regarding PMS and the newest knowledge related to MDR. Since PMS is new for me, I valued this highly.” Participant, Fall 2020

In today’s regulatory context, post market surveillance (PMS) is a necessary part of the medical device life-cycle, requiring analysis of information from both reactive and proactive sources and its integration with the device risk management program, in order to maintain regulatory compliance. Increased enforcement of device regulation is an inevitable consequence of recent publicity concerning higher risk devices, but manufacturers should be aware that PMS requirements apply to all classes of device under European legislation.

Course language is English.

Economic Operators

12 January 2022

The participants will achieve an understanding of the obligations of Economic Operators (EO) with respect to Competent Authorities, Notified Body and the other operators in the supply chain of medical devices. An overview of all activities and documents to be established regarding compliance with the new rules will be presented.

Course language is English.

MDD to MDR Transition

2-3 February 2022 - online course
7-8 September 2022 - online course

“Great course. I liked the systematic approach from medical device to post market surveillance report. It was very nice with exercises and discussions in groups.” Participant, Spring 2021

BSI 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 2022
9 September 2022

“Competent teachers; nice overview.” Participant, Fall 2019

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.

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

10-11 February 2022 - online course
16-17 June 2022
8-9 December 2022

“The course gave a great overall experience with the standard and how to face it. The trainer made it very easy to understand the principles and how to solve the issues addressed in the standard.” Participant, Spring 2020

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.

Nyt Persondatareglerne i medicovirksomheder – nye afgørelser og praktiske spørgsmål

4. marts 2022 - 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.

MDR Auditing - Training of Internal Auditors in Relation to MDR

7 March 2022 - online course
31 October 2022

"I liked the structured approach. The instructor was very knowledgeable about MDR." Participant, Spring 2021

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.

ISO 13485 and Quality Management for Medical Devices / Internal Auditing

9-11 March 2022
14-16 November 2022

"Competent and experienced trainers. Well structured presentations. Good dialogue between trainers and participants." Participant, Spring 2021

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.

New Technical Documentation for Medical Devices According to the MDR

14 March 2022 - online course
7 December 2022 - online course

"Very well organized; good presenter." Participant, Spring 2021

This one-day course 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.

Medical Device Usability

21-22 March 2022

24-25 October 2022

“I liked the different angles that the two instructors represented. I also liked that it was from one end to the other; it covered all major aspects. Also, it included personal experiences.” Participant, Fall 2021

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.

New Software as Medical Device and Quality Management

4-5 April 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.

The course is designed to provide you with a pragmatic and practical approach to establish and maintain quality oversight for software as medical device. Key standards will be introduced, but the standards will not be covered in detail.

Course language is English.

Implementation of the IVDR for CE Marking

11-13 April 2022 - online course

12-14 October 2022 - 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.

Implementation of the MDR for CE Marking

11-13 April 2022 - online course

12-14 October 2022 - 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, Fall 2019

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.

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

20 April 2022 - online course
12 October 2022

“The trainer was attentive to questions and very knowledgeable.”
Participant, Fall 2020

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.

IEC 62304: Software Lifecycle

16-17 May 2022
17-18 November 2022

“Very competent trainers. Good introduction to software development according to IEC 62304. Good course level, not too detailed, but not too generalized either.” Participant, Fall 2021

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.

Cybersecurity Risk Management & Introduction to AAMI TIR57

30-31 May 2022

“Highly qualified presenters.” Participant, Spring 2021

The course will provide you with the essential activities which should be performed as part of a robust Security Risk Analysis process. The course will focus primarily on the AAMI TIR57 – Principles for Medical Device Security – Risk Management standard and demonstrate how the methods can be used to supplement your organizations ISO 14971 Risk Management Process with a focus on cybersecurity. The course will also present supporting information from the NIST Cybersecurity Framework and the NIST SP 800-30 publication to further enhance learning.

Course language is English.

FDA Regulation of Medical Devices: Recent FDA Guidance Documents

30-31 May 2022

“The trainer was very good. The session worked excellently. Nice to get an understanding of the mindset in FDA - knowledge which is not really possible to gain by reading articles.” Participant, Fall 2020

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.

GDPR – praktiske udfordringer i medicovirksomheder

3. juni 2022

“Det var rart at få en 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.

Corrective & Preventive Actions (CAPA)

3 June 2022

13 December 2022

“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

13-14 June 2022

1-2 December 2022

“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.

IVDD to IVDR Transition

16-17 June 2022 - online course

8-9 December 2022 - 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

20. juni 2022

13. december 2022

”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.

Quality Systems Regulations (QSR)

1-2 September 2022

“I really liked that the course covered the subject thoroughly while using relevant examples.” Participant, Fall 2019

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.

Beskyt din virksomheds ideer: Patenter, forretningshemmeligheder og forskningssamarbejder i medicobranschen

9. september 2022

For en medicovirksomhed er det helt afgørende, at viden og produkter sikres mod kopiering og andre krænkelse, 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

19-20 September 2022

“The course had a nice high level approach to the subject with an expert instructor to highlight key details.” Participant, 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.

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

23 September 2022

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.

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

28 September 2022

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.

New Introduction to Chemical Compliance for Medical Devices

5 October 2022

"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.

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

21-22 November 2022

“The trainer was great at presenting the updates to the Chinese Regulation, as well as mentioning the nuances of the requirements and how these are interpreted.” 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.

ANSI/UL 2900 Cybersecurity Testing for Medical Device Manufacturers

6-7 December 2022 - online course

In this training program, we will describe and demonstrate the minimum set of cybersecurity testing activities recommended in the guidance documents. We will provide a description of the testing methods and their use in cybersecurity validation. We will identify the available tools to perform the tests and provide either live or video demonstration of the testing methods and outputs.

The testing methods will be mapped to best practice methods as well as to standards, including the IEC 62443 and ANSI/CAN/UL 2900 standards.

Course language is English.



Salg og markedsføring af medicinsk udstyr

Digital markedsføring af medicinsk udstyr

4. februar 2022

6. september 2022

”God formidling og godt med brug af eksempler fra den virkelige verden. Inddragelse af kursisterne gjorde kurset endnu mere interessant.” Deltager, efterår 2021

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.

Nyt Sundhedssystemets opbygning & Market Access

24.-25. marts 2022

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.

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

29 March 2022 - 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.

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

22 April 2022 - 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.

Regler om reklame, tilknytning og økonomiske fordele

22. juni 2022

12. december 2022

"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 de nye regler for tilknytning mellem medicoindustrien og visse sundhedsfaglige personalegrupper, samt hvordan disse tilknytningsforhold skal indberettes.

Reimbursement as a Driver for Commercial and Clinical Strategies

19 December 2022

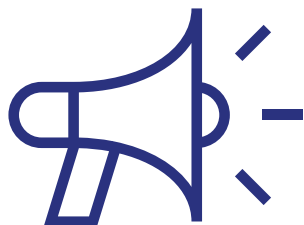
"Good introduction to the subject, good interaction with the other participants." Participant, Spring 2021

This is a full day in which attendees 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.

**“Vi kom hele vejen rundt omkring
produkternes udvikling, krav og
markedsføring, kroppens anatomi og
fysiologi samt hvordan produkterne
afhjælper problemer i kroppen. Har
givet et rigtig godt indblik i, alt andet
omkring et medicinsk udstyr, end den
del jeg selv sidder med”**

Deltager i kurset "Introduktion til medicobranschen", 2021



Øvrige

Introduktion til medicobranchen

27.-29. april 2022

26.-28. oktober 2022

”God og relevant undervisning. Gode kompetente undervisere, som tydeligt brænder for deres fag. God tid og mulighed for at netværke med andre kursister.” Deltager, efterår 2021

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, til produktion til salg og markedsføring. Undervisningen krydres med små workshops og opgaver.

Anatomi, fysiologi og sygdomslære

5.-6. maj 2022

”Meget inspirerende underviser. God til at formidle stoffet, som for mig er svært.” Deltager, forår 2021

Kurset vil give 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.

New Industrial Sterilization of Medical Devices - An Introduction to the Practical Approach of Sterilization

7 June 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.

The course will look into the most common design challenges related to sterilization and will make the participants 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 including other associated sterilization relevant standards.

Course language is English

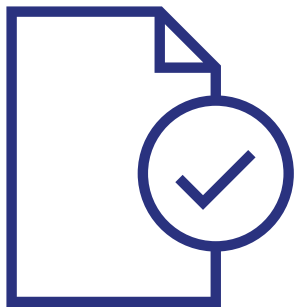
Personlig beskyttelse for teknikere – afbrydelse af smitteveje

2. september 2022

”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 smitekilder, 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.



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

Next level Design Control – in-depth and customized internal course

Are you struggling with design control in your company, or do you wish you could develop products with a shorter time to market or improve your working methods while maintaining compliance?

Medicoindustrien offers a company internal Design Control course focusing on using the company's procedures as effectively as possible. Compared to the open course, this course is more in-depth with your own procedures, and it is customized to your needs.

This internal course includes best practices and comparisons with how you work, which facilitates finding areas to improve and suggestions on improvements regarding processes and procedures. The course assumes that access is given to procedures to allow for customization of the course.

Content

- Project process and design control
- Establishing design inputs
- Design transfer
- Design verification and validation
- Integration of risk management and usability engineering

Target group

Project Managers, Design Engineers with an interest in the product development process, process owners and QA personnel.

Participants who have participated in the Design Control course.

Advanced Process Validation – company internal course

This is an advanced class for process validation, customized on your company needs. If you have already acquired the basic principles of process validation and you want a one-to-one, hands-on deeper review of your procedures, protocols and reports, Medicoindustrien offers this two-day internal course at your location.

The first part of the course will be spent visiting the manufacturing areas where production processes take place. The purpose of this initial tour is to see the processes so the course can focus on discussion and evaluation of your specific processes rather than being generic. Afterwards, the process validation course will be interactively focused on your processes and products.

Content

The course will focus on:

- Plant tour on your location
- Document review: Procedures, protocols and reports
- Discussion and workshop on areas of improvement and Q&A session

Target group

Company functions such as Manufacturing, Maintenance, Process Engineering, QA and R&D could benefit from this on-site, mock-inspection style, review of company procedures and practices.

Participants should have participated in the Process Validation course.

“Engagerede undervisere, som på relativ kort tid skulle give introduktion og indblik i kompliceret stof. De medbragte mange gode overvejelser og gav lyst til at dykke dybere ned i materialet. Godt udgangspunkt for videre arbejde med emnet”

Deltager i uddannelsen ”Medtech RA Officer”, 2021



Uddannelser

Medtech Market Access Officer 2023

(tidl. Medicokonsulent)

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, efterår 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 6 måneder og består af 3 moduler:

Modul 1 - Anatomi, fysiologi og sygdomslære

Du får 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.

MedTech RA Officer 2022

Tilvalgsmodul 1: 5.-6. maj 2022

Modul 2: 18.-20. maj 2022

Modul 3: 9.-10. juni 2022

Eksamen 24. juni 2022

”Vi kom igennem rigtig mange emner trods den korte tid. Underviserne er meget dygtige til at forklare tingene på en pædagogisk måde og er åbne overfor alle spørgsmål.” Deltager, 2021

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 medicobranschen.

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 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.

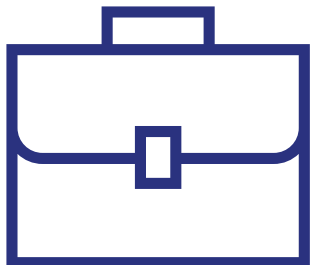
Tilvalgsmodul 1: Anatomi, fysiologi og sygdomslære

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 medicindustrien og indeholder praktiske eksempler og øvelser.



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.

Medicoindustrien udbyder løbende højaktuelle seminarer

Følg med på www.medicoindustrien.dk under Academy

Kurser	Dato	Varighed	Pris: medlem/ ikke-medlem
Economic Operators	12. januar	1 dag	5.650/8.690
MDD to MDR Transition Online course	2. - 3. februar	2 dage	10.180/15.640
Digital markedsføring af medicinsk udstyr	4. februar	1 dag	5.650/8.690
Person Responsible for Regulatory Compliance acc. to MDR/IVDR	7. februar	1 dag	5.650/8.690
IEC 60601 – How to Apply Safety and Risk Management to Medical Electrical Equipment and Systems Online course	10. - 11. februar	2 dage	10.180/15.640
Brugervejledning til medicinsk udstyr	28. februar - 1.marts	2 dage	11.300/17.380
Introduktion til UDI (Unique Device Identification) – identifikation og mærkning af medicinsk udstyr	1. marts	1 dag	5.650/8.690
Persondatareglerne i medicovirksomheder - nye afgørelser og spørgsmål	4. marts	1/2 dag	2.830/4.350
MDR Auditing - Training of Internal Auditors in Relation to MDR Online course	7. marts	1 dag	5.090/7.820
ISO 13485 and Quality Management for Medical Devices / Internal Auditing	9. - 11. marts	3 dage	16.950/26.070
Technical Documentation for Medical Devices according to MDR Online course	14. marts	1 dag	5.090/7.820
Medical Device Usability	21. - 22. marts	2 dage	11.300/17.380
Planning an Effective Post Market Surveillance Program for Medical Devices	23. marts	1 dag	5.650/8.690
Sundhedssystemets opbygning & Market Access	24. - 25. marts	2 dage	11.300/17.380
Digital Marketing of Medical Devices Abroad - Sweden, Germany and the USA Online course	29. marts	1/2 dag	2.550/3.910
Design Control	30. - 31. marts	2 dage	11.300/17.380
Software as Medical Device and Quality Management	4. - 5. april	2 dage	11.300/17.380
Implementation of the IVDR for CE Marking Online course	11. - 13. april	3 dage	15.270/23.460
Implementation of the MDR for CE Marking Online course	11. - 13. april	3 dage	15.270/23.460
Training of Internal Auditors in relation to Country Specific Requirements within the MDSAP Program Online course	20. april	1 dag	5.090/7.820
Digital Marketing of Medical Devices Abroad - Norway, United Kingdom and France Online course	22. april	1/2 dag	2.550/3.910
Introduktion til medicobranschen	27. - 29. april	3 dage	8.780/13.510
Anatomi, fysiologi og sygdomslære	5. - 6. maj	2 dage	11.300/17.380
Process Validation	9. - 10. maj	2 dage	11.300/17.380
Clinical Evaluation for Medical Devices in Europe and International Approach	11. - 12. maj	2 dage	11.300/17.380
IEC 62304: Software Lifecycle	16. - 17. maj	2 dage	11.300/17.380
Project Management for Product Development of Medical Devices	23. - 25. maj	3 dage	16.950/26.070
Cybersecurity Risk Management & Introduction to AAMI TIR57	30. - 31. maj	2 dage	11.300/17.380
FDA Regulation of Medical Devices: Recent FDA Guidance Documents	30. - 31. maj	2 dage	11.300/17.380
Praktisk gennemførelse af risikoanalyser ved produktudvikling	1. - 2. juni	2 dage	11.300/17.380
GDPR – praktiske udfordringer i medicovirksomheder	3. juni	1 dag	5.650/8.690

Kurser	Dato	Varighed	Pris: medlem/ ikke-medlem
Corrective & Preventive Actions (CAPA)	3. juni	1 dag	5.650/8.690
Industrial Sterilization of Medical Devices - An Introduction to the Practical Approach of Sterilization	7. juni	1 dag	5.650/8.690
MDSAP Fundamentals and Readiness Training	13. - 14. juni	2 dage	11.300/17.380
IEC 60601 – How to Apply Safety and Risk Management to Medical Electrical Equipment and System	16. - 17. juni	2 dage	11.300/17.380
IVDD to IVDR Transition Online course	16. - 17. juni	2 dage	10.180/15.640
Introduktion til udbudsloven	20. juni	1 dag	5.650/8.690
Regler om reklame, tilknytning og økonomiske fordele	22. juni	1 dag	5.650/8.690
Quality Systems Regulations (QSR)	1. - 2. september	2 dage	11.300/17.380
Personlig beskyttelse for teknikere – afbrydelse af smitteveje	2. september	1 dag	5.650/8.690
Introduktion til UDI (Unique Device Identification) – identifikation og mærkning af medicinsk udstyr	5. september	1 dag	5.650/8.690
Digital markedsføring af medicinsk udstyr	6. september	1 dag	5.650/8.690
MDD to MDR Transition Online course	7. - 8. september	2 dage	10.180/15.640
Beskyt din virksomheds ideer: Patenter, forretningshemmeligheder og forsknings Samarbejder i medicobranschen	9. september	1 dag	5.650/8.690
Person Responsible for Regulatory Compliance acc. to MDR/IVDR	9. september	1 dag	5.650/8.690
Sustainability in Medtech Companies – Accelerating Your Impact	15. - 16. september	2 dage	11.300/17.380
Cybersecurity Design Considerations for Medical Devices Manufacturers	19. - 20. september	2 dage	11.300/17.380
DNV Product Assurance (DNV GL Presafe) - How to Apply for MDR Certification	23. september	1 dag	5.650/8.690
Incentive Programs - Learn How to Decide, Implement and Maintain the Right Program in your Company	28. september	1 dag	5.650/8.690
Introduction to Chemical Compliance for Medical Devices	5. oktober	1 dag	5.650/8.690
Design Control	10. - 11. oktober	2 dage	11.300/17.380
Training of Internal Auditors in relation to Country Specific Requirements within the MDSAP Program	12. oktober	1 dag	5.650/8.690
Implementation of the IVDR for CE Marking Online course	12. - 14. oktober	3 dage	15.270/23.460
Implementation of the MDR for CE Marking Online course	12. - 14. oktober	3 dage	15.270/23.460
Medical Device Usability	24. - 25. oktober	2 dage	11.300/17.380
Introduktion til medicobranschen	26. - 28. oktober	3 dage	8.780/13.510
MDR Auditing - Training of Internal Auditors in Relation to MDR	31. oktober	1 dag	5.650/8.690
Process Validation	1. - 2. november	2 dage	11.300/17.380
Project Management for Product Development of Medical Devices	7. - 9. november	3 dage	16.950/26.070
Clinical Evaluation for Medical Devices in Europe and International Approach	10. - 11. november	2 dage	11.300/17.380
ISO 13485 and Quality Management for Medical Devices / Internal Auditing	14. - 16. november	3 dage	16.950/26.070
IEC 62304: Software Lifecycle	17. - 18. november	2 dage	11.300/17.380

Kurser	Dato	Varighed	Pris: medlem/ ikke-medlem
New Update on China NMPA Regulation and Registration for Medical Devices with Case Studies	21. - 22. november	2 dage	11.300/17.380
MDSAP Fundamentals and Readiness Training	1. - 2. december	2 dage	11.300/17.380
ANSI/UL 2900 Cybersecurity Testing for Medical Devices Manufacturers Online course	6. - 7. december	2 dage	10.180/15.640
Technical Documentation for Medical Devices according to MDR Online course	7. december	1 dag	5.090/7.820
IEC 60601-Series – How to Apply Safety and Risk Management to Medical Electrical Equipment and System	8. - 9. december	2 dage	11.300/17.380
IVDD to IVDR Transition Online course	8. - 9. december	2 dage	10.180/15.640
Regler om reklame, tilknytning og økonomiske fordele	12. december	1 dag	5.650/8.690
Corrective & Preventive Actions (CAPA)	13. december	1 dag	5.650/8.690
Introduktion til udbudsloven	13. december	1 dag	5.650/8.690
Statistik for procesvalidering	15. - 16. december	2 dage	11.300/17.380
Reimbursement as a Driver for Commercial and Clinical Strategies	19. december	1 dag	5.650/8.690

Uddannelser	Dato	Varighed	Pris: medlem/ ikke-medlem
Medtech Market Access Officer 2023	28. aug. - 1. dec 2023	11 dage	37.640/57.900
MedTech RA Officer 2022	5. maj - 24. juni 2022	8 dage	32.930/50.660

Priserne er ekskl. moms

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Tilmeld dig Nyhedsbrev/arrangementer på www.medicoindustrien.dk
og få nye kurser og uddannelser direkte i din indbakke.

**Medicoindustrien er en brancheorganisation
for mere end 220 af Danmarks førende
virksomheder, der beskæftiger sig med
medicinsk udstyr.**

Medicoindustrien har til formål at fremme medlemsvirksomhedernes erhvervmæssige 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.

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