MEDICO INDUSTRIEN
MEDTECH DENMARK

2021

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 2021 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

Kurser - Udvikling og produktion af medicinsk udstyr

Kurser - Regulatoriske forhold

Kurser - Salg og markedsføring af medicinsk udstyr

Kurser - Øvrige

Kurser - Virksomhedsinterne

Uddannelser

Kurser - Online

Udvikling og produktion af medicinsk udstyr

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

22. januar 2021 - Online kursus
13. september 2021

"Godt kursusmateriale. Undervisernes villighed til at adressere specifikke emner som jeg bad om at få diskuteret. Meget relevant for mine ansvarsområder så der var ikke meget spildtid for mig." Deltager, efterår 2020

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

4.-5. februar 2021 - Online kursus

"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.

Project Management for Product Development of Medical Devices

15-17 March 2021
22-24 November 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.

Design Control

29-30 March 2021
6-7 October 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.

Clinical Evaluation for Medical Devices in Europe and International Approach

25-26 May 2021
10-11 November 2021

"Expert insight into the discipline of clinical evaluation, incl. clinical trials, with a practical take on the tasks of writing CEP, CER and CIP." Participant, Fall 2020

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 2-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

27-28 May 2021
18-19 November 2021

"The instructor seemed very competent and gave good examples and convincing answers to all our questions. The instructor was very present, and you felt safe and educated. Working with different cases was good. The possibility of one-to-one discussions was good." Participant, Fall 2020

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.

Praktisk gennemførelse af risikoanalyser ved produktudvikling

1.-2. juni 2021

"De praktiske øvelser var rigtig gode. Gav en god forståelse af, hvordan man skal tænke risiko." Deltager, efterår 2019

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, gennemførsel, 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.

New Sustainability in Medtech Companies – Accelerating Your Impact

16-17 September 2021

Completing this 2-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 inbuild dilemmas that medical device companies have with circular product streams.

Course language is English.

Statistik for procesvalidering

6.-7. december 2021

"En meget energisk og kompetent underviser, der kan lære fra sig og gøre teorien spændende og relevant." Deltager, forår 2017

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.

“Virkeligt godt kursus der dækker medicobranchen bredt og giver god basisviden. Alt i alt et super godt kursus, dygtige undervisere. Tak for nu og på gensyn”

Deltager i kurset ”Introduktion til medicobranchen”, efterår 2020

Regulatoriske forhold

IEC 62304: Software Lifecycle

13-15 January 2021 - Online course
10-11 May 2021
15-16 November 2021

“The trainer was very skilled within the topic and very good at English.” Participant, Spring 2020

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.

Digital markedsføring af medicinsk udstyr

2.-3. februar 2021 - Online kursus
21. september 2021

”Virkelig gode undervisere, god debat, højt niveau.” Deltager, efterår 2020

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.

MDD to MDR Transition

2-3 February 2021 - Online course
9-10 September 2021

”Good way to present a legislation change, high professional skills and energy level of the teacher, I have learned a lot about MDR and I can see how it will affect regulatory tasks in our department.” Participant, Spring 2019

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 willl 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

10 February 2021
8 September 2021

"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.

ISO 13485 and Quality Management for Medical Devices / Internal Auditing

24-26 February 2031
10-12 May 2021
1-3 November 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 works 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.

MDR Auditing - Training of Internal Auditors in Relation to MDR

10 March 2021 - Online course
12 November 2021

"The presenter was good and the exercises were good. It kind of help you to see if you had understood the training." Participant, Fall 2020

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.

New Economic Operators

11 March 2021

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.

Nyt Dialog med ordregiver i udbud - hvor går grænsen?

12. marts 2021 - Online kursus
1. oktober 2021

Formålet med kurset er at sætte fokus på, hvilken dialog en leverandør eller potentiel leverandør kan have med ordregiver før, under og efter et udbud.

Kurset henvender sig til personer, der arbejder med at lave tilbud i udbudsprocesser samt contract managers og key account managers, som har brug for at få kendskab til de fleksible udbudsformer og rammerne for dialog før, under og efter udbuddet, der findes i forbindelse med udbudsloven.

Training of internal auditors in relation to country specific requirements within the MDSAP program

6 April 2021 - Online course
5 November 2021

"The teacher was attentive to questions and 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.

Medical Device Usability

19-20 April 2021
14-15 September 2021

"I liked the thorough walkthrough of the process both in terms of the standards and in real life." Participant, Fall 2020

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 Implementation of the IVDR for CE Marking

21-23 April 2021 - 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.

Cybersecurity Risk Management & Introduction to AAMI TIR57

17-18 May 2021

"Very good instructors - both interesting to listen to." Participant, Spring 2020

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.

MDSAP Fundamentals and Readiness Training

3-4 June 2021
16-17 December 2021

"Very informative and interesting. The overall picture on how to approach the MDSAP became very clear." Participant, Fall 2018

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.

Nyt GDPR – praktiske udfordringer i medicovirksomheder

7. juni 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.

EN 60601-series – how to apply safety and risk management to medical electrical equipment and systems

15-16 June 2021
20-21 December 2021

"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/clauses addressed in the standard." Participant, Spring 2020

The objective of this course is to create a general understanding of the EN 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.

New ANSI/UL 2900 Cybersecurity Testing for Medical Device Manufacturers

17-18 June 2021

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.

Corrective & Preventive Actions (CAPA)

21 June 2021
14 December 2021

"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.

New IVDD to IVDR Transition

22-23 June 2021
8-9 December 2021

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

25. juni 2021
22. december 2021

"Afstemningen af indhold og kompetence fra underviseren var rigtig god." Deltager, forår 2019

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)

2-3 September 2021

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

The course will present and assist 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 medicobranchen

13. september 2021

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.

CE mærkning af medicinsk udstyr

20. september 2021

"Undervisere med meget erfaring og fra forskellige afdelinger." Deltager, efterår 2017

Formålet med kurset er at give deltagerne en god forståelse og overblik over de krav og elementer, der indgår i CE-mærkningen for medicinsk udstyr. På kurset kommer vi rundt om de væsentlige krav til produkterne og den dokumentation, som skal være på plads. Der vil også være fokus på markedsovervågning og indberetningssystemet.

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

22 September 2021

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

23 September 2021

The course gives you an understanding of the application requirements and the internal processes for application handling at DNV Product assurance. You will understand the details 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.

Planning an Effective Post Market Surveillance Program for Medical Devices

24 September 2021

"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.

Cybersecurity Design Considerations for Medical Device Manufacturers

29-30 September 2021

"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.

Implementation of the MDR for CE Marking

25-27 October 2021

"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 focus 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.

FDA Regulation of Medical Devices: Recent FDA Guidance Documents

4-5 November 2021

"I liked the stringent logic in how to think regulatory strategy. Something I have missed in other presentations about FDA strategy." Participant, Fall 2018

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

29-30 November 2021

"I really liked the well organized structure through the whole course. The trainer was very competent and very good at communicating the content to the participants." Participant, Fall 2018

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

Course language is English.

"The course had a nice high level approach to the subject with an expert instructor to highlight key details"

Participant from the course "Cybersecurity Design Considerations for Medical Device Manufacturers", Spring 2020

Salg og markedsføring af medicinsk udstyr

Nyt Sundhedssystemets opbygning & Market Access

22.-23. marts 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

14. juni 2021
13. december 2021

"Vi kom godt rundt om emnerne. Underviserne var godt inde i stoffet. Der var god tid til spørgsmål og diskussion. Emnerne var super relevante." Deltager, forår 2019

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

15 December 2021

"Very good introduction to reimbursement, knowledgeable trainer and a nice small group of participants." Participant, Fall 2019

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.

"Giver et rigtig godt og solidt overblik over EU's regulatoriske system. Hvis man ikke har et indblik i det, så får man det i hvert fald"

Deltager i uddannelsen "Medtech RA Officer", 2019

Øvrige

Introduktion til medicobranchen

27.-29. april 2021
12.-14. oktober 2021

"Virkeligt godt kursus der dækker medicobranchen bredt og giver god basisviden. Alt i alt et super godt kursus, dygtige undervisere. Tak for nu og på gensyn." Deltager, efterår 2020

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 2021

"Super kursus. Godt at der var plads til spørgsmål." Deltager, efterår 2020

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.

Præsentationsteknik – forøg din gennemslagskraft!

7.-8. juni 2021

"Jeg blev udfordret både fagligt og menneskeligt." Deltager, efterår 2016

Det overordnede fokus er på dine egne præsentationer og især din måde at fremlægge budskabet på. Vi ser på kommunikative virkemidler og på, hvordan krop, stemme og den tekniske del kan forenes til at blive mest mulig effektiv overfor både beslutningstagere og managementgrupper. Du lærer at involvere publikum, at overbevise og få accept og få mennesker til at drømme sig til en bedre situation. Resultatet skal blive mere sælgende præsentationer og dig som en præsentatør, der bliver husket og skaber en forskel hos tilhørerne.

Personlig beskyttelse for tenikere – afbrydelse af smitteveje

1. september 2021

"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, efterår 2016

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.

"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/clauses addressed in the standard"

Participant from the course "EN 60601-series – how to apply safety and risk management to medical electrical equipment and systems", Spring 2020

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

New 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 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 comparison 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.

New 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 days 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 at the Process Validation course.

"Giver et rigtig godt og solidt overblik over EU's regulatoriske system. Hvis man ikke har et indblik i det, så får man det i hvert fald"

Deltager i uddannelsen "Medtech RA Officer", 2019

Uddannelser

Medtech Market Access Officer 2021

(tidl. Medicokonsulent)

Modul 1: Den 18.-19. januar og
den 8.-9. februar 2021
Eksamen den 12. marts 2021

Modul 2: Den 22.-23. marts 2021
Eksamen den 16. april 2021

Modul 3: Den 3.-4. maj 2021
Eksamen den 11. juni 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 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.

MedTech RA Officer 2021

Tilvalgsmodul 1: Den 5.-6. maj 2021
Modul 2: Den 19.-21. maj 2021
Modul 3: Den 9.-10. juni 2021
Eksamen: Den 24. juni 2021

"Jeg synes uddannelsen giver et rigtig godt og solidt overblik over EU's regulatoriske system. Hvis man ikke har et indblik i det, så får man det i hvert fald. Et godt springbræt til at gå i dybden med stoffet i en ny stilling. Eller til at give en medarbejder en ide om, hvilke udfordringer organisationen står overfor på det regulatoriske område." Deltager, 2019

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 2 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.

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 medico-virksomheder 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

Følg med på www.medicoindustrien.dk under Academy

Kurser	Dato	Varighed	Pris: medlem/ ikke-medlem
Reimbursement as a driver for commercial and clinical strategies	11. januar	1 dag	5.380/7.690
IEC 62304: Software Lifecycle Online kursus	13. - 15. januar	3 dage	9.680/13.840
Introduktion til UDI (Unique Device Identification) – identifikation og mærkning af medicinsk udstyr Online kursus	22. januar	1 dag	4.840/6.920
Digital markedsføring af medicinsk udstyr Online kursus	2. - 3. februar	2 dage	4.840/6.920
MDD to MDR Transition Online course	2. - 3. februar	2 dage	9.680/13.840
Brugervejledning til medicinsk udstyr Online kursus	4. - 5. februar	2 dage	9.680/13.840
Person Responsible for Regulatory Compliance acc. to MDR/IVDR	10. februar	1 dag	5.380/7.690
ISO 13485 and Quality Management for Medical Devices / Internal Auditing	24. - 26. februar	3 dage	15.940/22.770
MDR Auditing - Training of Internal Auditors in Relation to MDR Online course	10. marts	1 dag	4.840/6.920
Economic Operators	11. marts	1 dag	5.380/7.690
Dialog med ordregiver i udbud - hvor går grænsen? Online kursus	12. marts	1 dag	2.420/3.460
Project Management for Product Development of Medical Devices	15. - 17. marts	3 dage	15.940/22.770
Sundhedssystemets opbygning & Market Access	22. - 23. marts	2 dage	10.760/15.380
Design Control	29. - 30. marts	2 dage	10.760/15.380
Training of internal auditors in relation to country specific requirements within the MDSAP program	6. april	1 dag	4.840/6.920
Medical Device Usability Online course	19. - 20. april	2 dage	10.760/15.380
Implementation of the IVDR for CE Marking Online course	21. - 23. april	3 dage	14.350/20.490
Introduktion til medicobranchen	27. - 29. april	3 dage	7.950/11.350
Anatomi, fysiologi og sygdomslære	5. - 6. maj	2 dage	10.760/15.380
ISO 13485 and Quality Management for Medical Devices / Internal Auditing	10. - 12. maj	3 dage	15.940/22.770
IEC 62304: Software Lifecycle	10. - 11. maj	2 dage	10.760/15.380
Cybersecurity Risk Management & Introduction to AAMI TIR57	17. - 18. maj	2 dage	10.760/15.380
Clinical Evaluation for Medical Devices in Europe and International Approach	25. - 26. maj	2 dage	10.760/15.380
Process Validation	27. - 28. maj	2 dage	10.760/15.380
Praktisk gennemførelse af risikoanalyser ved produktudvikling	1. - 2. juni	2 dage	10.760/15.380
MDSAP Fundamentals and Readiness Training	3. - 4. juni	2 dage	10.760/15.380
GDPR – praktiske udfordringer i medicovirksomheder	7. juni	1 dag	5.380/7.690
Præsentationsteknik – forøg din gennemslagskraft!	7. - 8. juni	2 dage	10.760/15.380
Regler om reklame, tilknytning og økonomiske fordele	14. juni	1 dag	5.380/7.690
EN 60601-series – how to apply safety and risk management to medical electrical equipment and systems	15. - 16. juni	2 dage	10.760/15.380
ANSI/UL 2900 Cybersecurity Testing for Medical Devices Manufacturers	17. - 18. juni	2 dage	10.760/15.380

Kurser	Dato	Varighed	Pris: medlem/ ikke-medlem
Corrective & Preventive Actions (CAPA)	21. juni	1 dag	5.380/7.690
IVDD to IVDR Transition	22. - 23. juni	2 dage	10.760/15.380
Introduktion til udbudsloven	25. juni	1 dag	5.380/7.690
Personlig beskyttelse for teknikere – afbrydelse af smitteveje	1. september	1 dag	3.780/5.400
Quality Systems Regulations (QSR)	2. - 3. september	2 dage	10.760/15.380
Person Responsible for Regulatory Compliance acc. to MDR/IVDR	8. september	1 dag	5.380/7.690
MDD to MDR Transition	9. - 10. september	2 dage	10.760/15.380
Beskyt din virksomheds ideer: Patenter, forretningshemmeligheder og forskningssamarbejder i medicobranchen	13. september	1 dag	5.380/7.690
Sustainability in Medtech Companies – Accelerating Your Impact	16. - 17. september	2 dage	10.760/15.380
CE mærkning af medicinsk udstyr	20. september	1 dag	5.380/7.690
Introduktion til UDI (Unique Device Identification) – identifikation og mærkning af medicinsk udstyr	13. september	1 dag	5.380/7.690
Medical Device Usability	14. - 15. september	2 dage	10.760/15.380
Digital markedsføring af medicinsk udstyr	21. september	1 dag	5.380/7.690
Incentive Programs - Learn How to Decide, Implement and Maintain the Right Program in your Company	22. september	1 dag	5.380/7.690
DNV Product Assurance (DNV GL Presafe) - How to Apply for MDR Certification	23. september	1 dag	5.380/7.690
Planning an Effective Post Market Surveillance Program for Medical Devices	24. september	1 dag	5.380/7.690
Cybersecurity Design Considerations for Medical Devices Manufacturers	29. - 30. september	2 dage	10.760/15.380
Dialog med ordregiver i udbud - hvor går grænsen?	1. oktober	1 dag	5.380/7.690
Design Control	6. - 7. oktober	2 dage	10.760/15.380
Introduktion til medicobranchen	12. - 14. oktober	3 dage	7.950/11.350
Implementation of the MDR for CE Marking	25. - 27. oktober	3 dage	15.940/22.770
ISO 13485 and Quality Management for Medical Devices / Internal Auditing	1.- 3. november	3 dage	15.940/22.770
FDA Regulation of Medical Devices: Recent FDA Guidance Documents	4. - 5. november	2 dage	10.760/15.380
Training of internal auditors in relation to country specific requirements within the MDSAP program	5. november	1 dag	5.380/7.690
Clinical Evaluation for Medical Devices in Europe and International Approach	10. - 11. november	2 dage	10.760/15.380
MDR Auditing - Training of Internal Auditors in Relation to MDR	12. november	1 dag	5.380/7.690
IEC 62304: Software Lifecycle	15. - 16. november	2 dage	10.760/15.380
Process Validation	18. - 19. november	2 dage	10.760/15.380
Project Management for Product Development of Medical Devices	22. - 24. november	3 dage	15.940/22.770
New Update on China CFDA Regulation and Registration for Medical Devices with Case Studies	29. - 30. november	2 dage	10.760/15.380

Priserne er ekskl. moms

Kurser	Dato	Varighed	Pris: medlem/ ikke-medlem
Statistik for procesvalidering	6. - 7. december	2 dage	10.760/15.380
IVDD to IVDR Transition	8. - 9. december	2 dage	10.760/15.380
Regler om reklame, tilknytning og økonomiske fordele	13. december	1 dag	5.380/7.690
Corrective & Preventive Actions (CAPA)	14. december	1 dag	5.380/7.690
Reimbursement as a driver for commercial and clinical strategies	15. december	1 dag	5.380/7.690
MDSAP Fundamentals and Readiness Training	16. - 17. december	2 dage	10.760/15.380
EN 60601-series – how to apply safety and risk management to medical electrical equipment and systems	20. - 21. december	2 dage	10.760/15.380
Introduktion til udbudsloven	22. december	1 dag	5.380/7.690

Uddannelser	Dato	Varighed	Pris: medlem/ ikke-medlem
Medtech Market Access Officer 2021	18. januar - 11. juni	11 dage	28.000/56.000
MedTech RA Officer 2021	5. maj - 24. juni	8 dage	31.360/44.810

Priserne er ekskl. moms

Hold dig opdateret om nye kurser og uddannelser

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 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.

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