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SIMPLIFYING DEVICE REGULATIONS

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MEDICAL DEVICE TRAINING COURSES

ONLINE - CUSTOMISED - IN PERSON

ISO 13485 - EU MDR - EU IVDR - CLINICAL EVALUATION - PROCESS VALIDATION - DIGITAL HEALTH - RISK MANAGEMENT


Medical Devices,
Digital Healthcare
Medical Software
Drug-Device
If you have a device with a Medical Intended Purpose, then you will most likely need to follow the Medical Device Regulations.
Are you adequately trained?
ISO 13485 - EU MDR - EU IVDR - CLINICAL EVALUATION - PROCESS VALIDATION - DIGITAL HEALTH - RISK MANAGEMENT

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QUALITY MANAGEMENT SYSTEMS FOR MEDICAL DEVICES ISO 13485: 2016

The QMS is the foundation for any Medical Device company. In most cases when developing a medical device, having a QMS is a mandatory requirement and specifically to ISO 13485. The QMS lays the needs for quality to run throughout the business as an essential practise to ensure quality is built into the device from initial development to production and final testing as well as post-market, complaints and feedback. In this course you will learn how to use ISO 13485 in practical terms.

This course is ideal for – QA Managers, Quality Assurance Specialists, Senior Management, R&D Engineers, Product Developers

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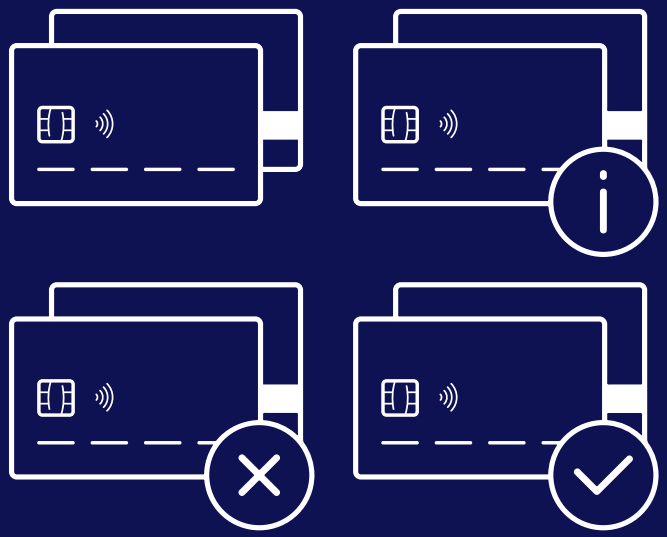
PROCESS VALIDATION (INC. SOFTWARE)



Have you had a Non-Conformance as a result of an audit related to Validation? Have you purchased new manufacturing equipment? Have you realised your equipment was never validated? Have you made changes to your process or equipment? Do you have spreadsheets making calculations? Do you have software systems that need to be validated? In this course we will give you all the tools for Process Validation.

This course is ideal for – Production Engineers, QA Engineers, Equipment Technicians, Maintenance Engineers, QA Department

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INTRODUCTION TO REGULATIONS FOR MED-TECH START-UPS

The Medical Device market is growing at an alarming rate, much of this is in the sectors of nanotechnology, AI, ML and Medical Device Software, Combination devices and more in-home medical Devices and point-of-care testing. With the complications of devices and associated potential risks the regulations have been created to ensure patient safety is paramount. This course is designed for those who need to enter this market but have questions, and need answers.

This course is ideal for – Regulatory Affairs, QA Department, Marketing, Business Entrepreneurs, Start Ups, Spinouts.

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INTRODUCTION TO THE EU MDR 2017/745

Since the inception of the EU Medical Device Regulations, selling Medical devices in Europe has become a topical discussion with much debate and discretion, manufacturers selling Medical Devices in Europe have been encouraged by the EU Parliament to continue implementing the EU MDR and transitioning from the Medical Device Directive. In this course, you shall learn what is required to implement the EU MDR using the appropriate articles and annexes from the regulation.

This course is ideal for – Regulatory Affairs, QA Department, Marketing, Business Entrepreneurs, Start Ups, Spinouts.

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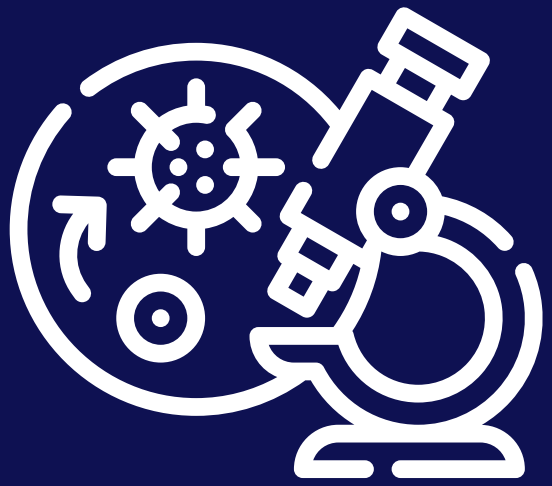
INTRODUCTION TO THE EU IVDR 2017/746



Since the inception of the EU In-Vitro Diagnostic Regulations, selling Diagnostic devices in Europe has become a topical discussion with much debate and discretion, due to the up classification of most IVDs the requirement to implement the IVDR is in many ways more challenging than any other regulation.

In this course, you shall learn to implement the EU IVDR using the appropriate articles and annexes from the regulation

This course is ideal for – Regulatory Affairs, QA department, Marketing, Business Entrepreneurs, Start Ups, Spinouts.

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MEDICAL DEVICE AUDITING - INTERNAL/EXTERNAL/SUPPLIER

Auditing is the best way to ensure your QMS is maintained and you are still in compliance. What is a Non-Conformance? and what must you do if one is raised?

In this course, you will learn how to Internal Audit, and what to expect from external audits such as notified bodies for CE marking, and ISO 13485 audits. You will also learn how to perform supplier audits, as well as deal with Non-Conformances from audits.

This course is ideal for - Quality department, Start-Ups, Procurement, Purchasing

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INTRODUCTION TO DESIGN CONTROL & RISK MANAGEMENT

In this course we will outline the need for Design Control, looking at clause 7.3 of ISO 13485, clause 820.30 of the QSR, and the needs of the FDA, EU and other jurisdictions. In the course, we will look at Design planning, Design Inputs, Design Outputs, Design Verification, and Design Validation.

We will also look at Risk Management and its fundamental role in Medical Device development, the methods used to manage and control risk using ISO 14971: 2019, and how this interacts with all Verification and Validation activities including Medical Device Software.

This course is ideal for – Design Engineers, R&D, QA department, Start-Ups.

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INTRODUCTION TO CLINICAL EVALUATION

During this course we will explore the requirements for Clinical Evaluation which looks at three possible types of data –

i) Literature searches, scoring papers and evaluating the relevancy to your technology
ii) Bench testing – comparing your device to others already on the market
iii) Clinical Investigation/ trials – performing actual trials in environments such as hospitals, home environments, etc.

We will look at the guidance documents and regulation requirements in this very vast and complex area.

This course is ideal for - Regulatory Affairs, QA Department, Clinical affairs, Scientists, Marketing

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INTRODUCTION TO SOFTWARE AS A MEDICAL DEVICE EN 62304

Medical Device Software (MDSW), apps, Software as a Medical Device (SaMD), Software in a Medical Device (SiMD), Artificial Intelligence (AI) and Machine Learning (ML) are some of the recent buzzwords. In this course we will outline the differences, and what you need to do in each case. Whether you have an implant running firmware using a PEMS (Programmable Electrical Medical System), we will look at IEC 62304 and IEC 82304 and the latest AI and ML. We will also look at Cybersecurity threats and requirements as well as interoperability of your software needs.

This course is ideal for – Software developers, Start-Ups, Design Engineers

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