MAETRICS

Compliance Agility + Global Acumen

TRAINING 2017

www.maetrics.co.uk

ABOUT US

MAETRICS+

Compliance Agility + Global Acumen

Maetrics is dedicated to guiding life sciences companies through the challenges related to quality, regulatory, and compliance. Our comprehensive services allow clients to reach new efficiencies as well as business goals.

Maetrics' specialised training courses and seminars are an extension to our broad portfolio of service offerings. Founded in the US in 1984, with the UK office operating since 2002, Maetrics has been providing full-service consulting services globally to life-science companies for over 30 years. Maetrics has provided services to eight of the top 10 pharmaceutical companies, six out of the top 10 biopharmaceutical companies and four out of the top five medical device companies worldwide. We work with large and small companies in a highly practical, collaborative and hands-on approach, breaking the mould of "typical" consultancies. We don't just advise on issues and problems we solve them too.

75% OF LIFE SCIENCE COMPANIES SAY THAT REGULAR TRAINING FOR REGULATORY AND QUALITY STAFF IS EXTREMELY IMPORTANT.

***Source: Medicines and Healthcare Products Regulatory Compliance, MindMetre Research and Maetrics**

- REGULATORY COMPLIANCE
- QUALITY MANAGEMENT SYSTEMS
- VALIDATION
- RISK MANAGEMENT
- MERGERS AND ACQUISITIONS
- PERFORMANCE IMPROVEMENT
- INFORMATION TECHNOLOGY
- TRAINING

CONTENTS

Public training courses

Maetrics' public training courses offer small group workshop and classroom based education in a variety of courses. Suited to beginners, those who require bringing up to date with new developments in the medical device industry and those who need a refresher, all courses include time for learning, discussions, questions and practical tips. All delegates receive a full set of accompanying notes and following completion of the course a certificate of training. All public training courses are independently CPD certified and certificates for CPD hours can also be provided.

Public training courses are held at a specialist training venue in central Birmingham, UK, close to main line train stations and Birmingham International airport.

Our courses in Switzerland are held at a venue set in the heart of Basel's old town with excellent transport links.

In-house training courses

For companies that have a number of staff who need training in specific areas, an in-house training course can be a very effective way to achieve a company's commitment to investing in their staff and providing them with the tools they need to complete their work in an effective way. All in-house training courses can be facilitated at the clients' own premises or at off-site venues. In-house training courses can be replicas of public training courses, customised to be more relevant to your company or bespoke to cover all the elements and topics that you want them to. Our website shows the most popular in-house courses that we have delivered and we are happy to discuss your specific requirements.

PUBLIC TRAINING

IN-HOUSE COURSES

CPD CERTIFIED
The CPD Certification Service

EN ISO 13485
INTERNAL AUDITOR

2 day course

£995
(early bird)

£1100
(full price)

Book 6 weeks in advance to qualify for discount

2017 COURSE DATES:

29/30 March
13/14 September

LOCATION:

Birmingham

CPD CERTIFIED The CPD Certification Service

CPD HOURS: 15

One unique aspect of working in medical device manufacture is that it has its own specific quality management system, EN ISO 13485. This goes beyond the standard EN ISO 9001 in a number of ways, and requires specialist skills. One of the key requirements for running and maintaining an EN ISO 13485 compliant quality management system is having a programme of internal audits.

This course is suitable for new and trainee internal auditors, as well as those who are trained to 9001 but need to take their knowledge further. It will give you the tools and confidence to handle the different approach required for internal auditing in a regulated environment.

By the end of this practical and interactive course, delegates are able to plan, conduct, report and follow up an internal audit, and evaluate any corrective and preventive actions arising from the audit. In addition to teaching the EN ISO 13485 standard itself, the course explains how it integrates with other regulations and quality management systems, including the Medical Devices Directive and the FDA's 21 CFR 820 system.

Who should attend:

This introductory course is of value to employees at all levels within the organisation of Medical Device manufacturers, and suppliers to the Medical Devices industry including:

- New or intended internal auditors
- Internal Auditors without 13485 audit training – OR - Internal Auditors with only 9001 training
- Existing Auditors for refresher purposes
- Lead Auditors without formal 13485 training
- Quality Managers
- Regulatory Affairs Managers

Topics covered include:

- Overview of EN ISO 13485 standard including definitions and terms
- Cross linking to other regulations
- The types of audits
- Preparing an Audit Schedule
- Identification of key auditor skills and Auditing Techniques
- Planning a process based audit including resources and timings
- Checklists – development and uses
- Evaluating the significance of audit findings
- Audit Reports

PUBLIC

CREATING A TECHNICAL FILE/ DESIGN DOSSIER

1 day course

Topics covered include:

- Introduction and definitions to technical files in global requirements
- Brief Overview of the Global Harmonization Task Force (GHTF) and IMDRF
- GHTF guidance including GHTF/SG1/N011:2008 Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)
- Purpose and Use of the STED format
- Technical File requirements for CE marking to the current Medical Device Directives
- EU conformity assessments
- Changes affecting Technical files in the new Medical Device Regulation
- How to incorporate the new EU requirements with existing STED format
- Structure, layout and contents of Technical File including MDR requirements:
- Declaration of Conformity

When you place a medical device on the market in Europe, you must compile a technical file as part of CE marking requirements. Other markets globally also require a similar set of technical documentation to support market clearance. This course guides you step-by-step through how to put together a file of technical documentation with the focus on European requirements in light of the new Medical Device Regulation, including what evidence and level of detail you need to supply in order to demonstrate your product conforms to relevant safety and performance principles.

We also show you how to use the STED (Summary Technical Documentation) format for technical files and design dossiers and how this can provide a baseline for global technical documentation convergence. By using this internationally recognised approach, you can ease the task of global regulators and thereby smooth the review process. Many companies find it reduces time to market and costs, so this course could be hugely valuable for your organisation – especially if you want a regulatory submission that is recognised across global key territories.

Who should attend:

This course is of value to employees at all levels within the organisation of Medical Device manufacturers, and suppliers to the Medical Devices industry including:

- Members of the Senior Management Team
- Regulatory Affairs Managers
- Regulatory Affairs Officers
- Quality Assurance Professionals
- Quality Assurance Officers
- Development Engineers
- Operations Managers
- Technical Sales and Marketing Professionals

BOOK NOW at www.maetrics.co.uk/training

£575
(early bird)

£650
(full price)

Book 6 weeks in advance to qualify for discount

2017 COURSE DATES:

8 June
6 December

LOCATION:

Birmingham

CPD CERTIFIED The CPD Certification Service

CPD HOURS: 7½

PUBLIC

MEDICAL DEVICE SOFTWARE & MOBILE APPS

1 day course

£575
(early bird)

£650
(full price)

Book 6 weeks in advance to qualify for discount

2017 COURSE DATES:

27 April
19 October

LOCATION:

Birmingham

CPD CERTIFIED The CPD Certification Service CPD HOURS: 7½

Smartphone and tablet technology is transforming the medical device industry, creating new opportunities to develop innovative software and apps. Among the innovative apps to be developed are apps contributing to the treatment of diabetes, apps facilitating the transfer of lab results, and apps helping to detect cognitive disorders.

This highly topical course will bring you fully up to date with all you need to know in this area: for example, how to decide whether an app, or other form of software, is a medical device under EU regulations and therefore subject to the Medical Devices Directive; how to comply with the IEC 62304 standard which specifies the development cycle for such software; when computer systems validation is required; and what are the necessary elements of GAMP (Good Automated Manufacturing Practice) you need to follow. It's all essential knowledge if you want to make the most of the new technology opportunities.

Who should attend:

This introductory course is of value to employees at all levels within the organisation of Medical Device manufacturers, and suppliers to the Medical Devices industry including:

- Members of the Senior Management Team
- Software Engineers
- App Developers
- Regulatory Affairs Professionals
- Quality Assurance Professionals
- Development Engineers
- Technical Sales & Marketing Professionals

Topics covered include:

- Brief history and overview of the Medical Devices Directive 93/42/EEC
- How to decide if software is a Medical Device
- How to classify software under the Directive
- The information that a Manufacturer/Developer has to generate and provide
- How to build a technical file for a device which is software
- Intended use and device description
- Essential Requirements of the Directive
- Software identification
- Instructions for the user
- Risk Management
- Post Market Surveillance of device performance
- Vigilance
- Software Development Lifecycle
- Operating System updates and how to handle them

PUBLIC

USABILITY & HUMAN FACTORS AND ELECTRICAL MEDICAL EQUIPMENT

1 day course

Topics covered include:

- Summary of main points of 14971
- Overview of BS EN 62366 Usability Engineering
- Risk Evaluation for user interfaces
- Use errors – unintended use and misuse and definitions used in Human Factors assessments
- Overview and interpretation of BS EN 60601-1 Medical Electrical Devices and links to Risk management
- Risk Reports and Risk/benefit analysis
- Post Production and surveillance activities
- Links to other standards

To attend the course, it is recommended that delegates first attend our Risk Management – EN ISO 14971, 2-day course, or have a good understanding of the EN ISO 14971 standard.

If you're familiar with EN ISO 14971, you'll already have a good grounding in risk management. EN ISO 14971 is a widely used standard for the design and manufacture of medical devices, but if your organisation incorporates user interfaces in your devices and needs to consider human factors and potential device misuse or manufactures electrical medical devices, you need to extend your risk management activities beyond that. This practical one-day workshop shows you how.

The course teaches two other key risk management standards: BS EN 62366 & BS EN 60601-1, each of which link to EN ISO 14971. These help ensure electrical safety and reduce the risks associated with potential misuse or misinterpretation of user interfaces.

By the end of this course you'll be able to improve the risk management activities in your organisation, and demonstrate your understanding of BS EN 62366 & BS EN 60601-1 to customers and other stakeholders.

Who should attend:

This course is of value to employees at all levels within the organisation of Medical Device manufacturers, and suppliers to the Medical Devices industry including:

- Regulatory Affairs Professionals
- Quality Assurance Professionals involved in design and/or manufacturing
- User Interface and Software Designers
- Electrical Designers
- Product Management Professionals
- Personnel involved in risk assessment and risk management activities

£575
(early bird)

£650
(full price)

Book 6 weeks in advance to qualify for discount

2017 COURSE DATES:

11 May
9 November

LOCATION:

Birmingham

CPD CERTIFIED The CPD Certification Service

CPD HOURS: 7½

BOOK NOW at www.maetrics.co.uk/training

PUBLIC

POST MARKET SURVEILLANCE AND ADVERSE EVENT REPORTING

1 day course

£575
(early bird)

£650
(full price)

Book 6 weeks in advance to qualify for discount

2017 COURSE DATES:

29 June
28 September

LOCATION:

Birmingham

CPD CERTIFIED The CPD Certification Service — CPD HOURS: 7½

Suitable for anyone who has a part to play in Vigilance and Post Market Surveillance (PMS), this course focuses on practical advice and workshops that will improve your organisation's performance in this area. Topics studied include the terminologies of PMS (proactive) and Vigilance (reactive); European and FDA regulatory requirements; recalls and field safety notices; and when, how and where to report adverse incidents.

We also look at Post-Market Clinical Follow-up (PMCF), which is increasingly the focus for manufacturers entering the market with new devices. The course explains the PMCF requirements, how to evaluate the need for PMCF, and the best approach for designing PMCF plans.

By the end of the course, you should understand all the regulatory requirements for PMS and Vigilance, and have a better idea of how to integrate PMS and PMCF activities into your EN ISO 14971 risk management cycle. As a result, you should be better placed to meet your regulatory obligations effectively.

Who should attend:

This introductory course is of value to employees at all levels within the organisation of Medical Device manufacturers, and suppliers to the Medical Devices industry including:

- Members of the Senior Management Team
- Manufacturers/Testers
- Regulatory Affairs Managers
- Regulatory Affairs Officers
- Internal Auditors
- Clinical Affairs Specialists
- Quality Assurance Managers
- Marketing and Sales Professionals

Topics covered include:

- EU Regulatory requirements for PMS, including recalls, field safety notices and vigilance
- Post-Market Clinical Follow-up requirements and Notified Body expectations
- FDA regulations 21 CFR part 803 Medical Device Reporting, part 806 Reports of Corrections and Removals and part 822 Post Market Surveillance
- Responsibilities for Post-Market Surveillance
- Guidance documents for PMS and Vigilance
- Key elements of PMS (proactive) and Vigilance (reactive)
- The correlation between PMS and principles of EN ISO 14971 "Application of risk management to medical devices"
- Exchange of information: PMS databases e.g. MAUDE and EUDAMED
- Study Group II of the IMDRF (formerly GHTF)
- Legal, warning letters, shutdown & Medical Device Alerts implications

PUBLIC

CLINICAL EVALUATION REPORTS

1 day course

Topics covered include:

- An overview of the regulatory requirements for clinical evaluations and their importance
- Identifying areas that require support from clinical data
- Research methodology
- Sources of data
- Analysis of data – screening and selecting
- When a clinical investigation is required
- Structuring and collating the report

With the forthcoming implementation of the Medical Device Regulation and a number of high profile adverse events over the last few years, there is greater scrutiny than ever before of the clinical evaluations prepared by device manufacturers. Without a clear and systematic clinical evaluation report in the technical file, a medical device cannot be sold into Europe, regardless of its classification.

So just how clear and systematic do you need to be? Many companies underestimate the extent of the requirements – perhaps because they're hazy about the difference between a clinical evaluation and a clinical trial or investigation. Another common slip-up is when firms don't appreciate that the clinical evaluation is a 'live' document, which must be regularly updated and reviewed in relation to the results of post-market surveillance activities, and as more clinical data becomes available.

This practical course demystifies the clinical evaluation process, and provides a structured approach for producing fully compliant clinical evaluations.

Who should attend:

This course is of value to employees at all levels within the organisation of Medical Device manufacturers, and suppliers to the Medical Devices industry including:

- Regulatory Affairs Professionals
- Engineering Professionals
- Research/Development Professionals
- Personnel involved in any aspect of the clinical evaluation process
- Quality Assurance Professionals

£575
(early bird)

£650
(full price)

Book 6 weeks in advance to qualify for discount

2017 COURSE DATES:

24 May
23 November

LOCATION:

Birmingham

2017 COURSE DATES:

12 October

LOCATION:

Basel

770 CHF (early bird) **960 CHF** (full price)

CPD CERTIFIED The CPD Certification Service

CPD HOURS: 7½

PUBLIC

RISK MANAGEMENT: EN ISO 14971

2 day course

£995
(early bird)

£1100
(full price)

Book 6 weeks in advance to qualify for discount

2017 COURSE DATES:
14/15 March
4/5 October

LOCATION:
Birmingham

2017 COURSE DATES:
10/11 May

LOCATION:
Basel

1400 CHF (early bird) **1750 CHF** (full price)

CPD CERTIFIED The CPD Certification Service

CPD HOURS: 15

PUBLIC

Risk management is ever-more important for medical device companies, and it's a complex process. EN ISO 14971 enables companies to integrate risk management into their existing quality systems and provides a disciplined approach for decision-making and implementation of strategy in this area. The latest version of the standard has given device manufacturers significant challenges in terms of meeting revised harmonisation annexes, and may require them to modify their approach.

This practical course provides delegates with the tools and techniques to understand and apply EN ISO 14971 – not just those new to the area, but those who want an update on the latest annexes to the standard (annexes ZA, ZB and ZC). It shows you how to integrate risk management and EN ISO 14971 into your own organisation, and enhance your existing quality systems.

You will also learn how to modify your approach - including how to upgrade existing files to comply with the latest version, EN ISO 14971:2012, harmonised to the Medical Device Directives.

Who should attend:

This thorough and practical course is of value to employees at all levels within the organisation of Medical Device manufacturers, and suppliers to the Medical Devices industry including:

- Regulatory Affairs Professionals
- Quality Assurance Professionals involved in design and/or manufacturing
- Design Engineering Professionals
- Clinical Professionals
- Product Management Professionals
- Personnel involved in risk assessment and risk management activities

Topics covered include:

- Overview of the EN ISO 14971:2012 standard, including definitions and terms and the annexes confirming harmonisation to the Medical Device Directives
- An explanation of the latest annexes ZA, ZB and ZC and how to conduct risk management activities to remain compliant.
- IMDRF/GHTF Guidance "Implementation of Risk Management Principles and Activities within a Quality Management System."
- Lifecycle of Risk
- Risk Management File & Plan
- Risk Evaluation—Identification of harms, hazards and hazardous situations, tools and techniques including FMEA, Fault Tree Analysis
- Risk Control and Reduction
- Residual Risk Evaluation
- Risk Report including the risk benefit analysis
- Production / Post Production Requirements as part of ongoing Post Market Surveillance activities
- Links to other medical device standards including EN ISO 10993-1 Biological evaluation of medical devices and BS EN 62366 Medical devices usability engineering

PROCESS VALIDATION: IQ, OQ, PQ

1 day course

Topics covered include:

- What is process validation?
- Validation vs Verification
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Capability Studies
- Statistical methods & data interpretation
- Maintaining a state of validation

In the pressure to get products to market, process validation is very often rushed through or inadequately completed. It's partly a question of time, but also that this area is not as well understood as it should be. Staff often do not fully grasp how to show that a process has been successfully validated, for instance, or the differences between IQ, OQ and PQ. And many professionals tell us they are daunted by the statistical processes and interpretation involved.

Under EN ISO 13485 and 21 CFR Part 820, all critical processes must be validated when the process cannot be successfully verified, so it's important to keep on top of this subject. However, many professionals aren't 100% clear on what needs to be documented to show that a process has been successfully validated.

This course helps you get on top of the subject – explaining all the requirements and steps involved in validating a process; getting you up to scratch with the regulatory requirements; and providing you with all the tools to understand and interpret the statistical data.

Who should attend:

This introductory course is of value to employees at all levels within the organisation of Medical Device manufacturers, and suppliers to the Medical Devices industry including:

- Development Engineering Professionals
- Quality Engineering Professionals
- Production Engineering Professionals
- Personnel involved in design transfer activities
- Quality Assurance Professionals
- Regulatory Affairs Professionals

£575
(early bird)

£650
(full price)

Book 6 weeks in advance to qualify for discount

2017 COURSE DATES:

20 April
1 November

LOCATION:

Birmingham

2017 COURSE DATES:

29 June

LOCATION:

Basel

770 CHF (early bird) **960 CHF** (full price)

CPD CERTIFIED The CPD Certification Service CPD HOURS: 7½

PUBLIC

BOOK NOW at www.maetrics.co.uk/training

EU AND US DESIGN CONTROL REQUIREMENTS

1 day course

£575
(early bird)

£650
(full price)

Book 6 weeks in advance to qualify for discount

2017 COURSE DATES:

17 May
30 November

LOCATION:

Birmingham

CPD CERTIFIED The CPD Certification Service

CPD HOURS: 7½

To stay active in the market there is a drive to continually introduce new medical device products, but how do we ensure new product designs are introduced in a complaint way to ISO 13485 and US FDA requirements and still meet customer requirements?

This course will detail what is required to implement a quality system that incorporates the regulatory requirements for design controls for various classes of medical devices for both the European and United States markets.

Project teams need to have an understanding of the key requirements for design control for key departments including QA, Regulatory, Development and importantly, Sales & Marketing. This course outlines the design process including terms: design planning, design input, design output, design review, verification, validation, transfer, changes and the creation of the essential design history file. The course will also detail the FDA QSIT inspection techniques for design control and provide a review of common audit findings.

Who should attend:

This course is of value to employees at all levels within the organisation of Medical Device manufacturers including:

- Design Engineers
- Development Engineers
- Product Testing Engineers
- Project Managers
- Regulatory Affairs Professionals
- Quality Assurance Professionals
- Technical Sales & Marketing Professionals
- Members of the Senior Management Team
- Operations Managers

Topics covered include:

- European and US Design control requirements
  - Design & Development planning
  - Design inputs
  - Design outputs
  - Design reviews
  - Design verification and validation
  - Design transfer
  - Design changes
  - Design history file
- QSIT inspection techniques for Design control and common FDA audit findings
- Case study: Design control scenarios

PUBLIC

CE MARKING 93/42/EEC AND THE NEW MDR

2 day course

Topics covered include:

- Brief history of the directives
- Notified Bodies & Competent Authorities Harmonised standards
- Medical Device Directive 93/42/EC
- Active Implantable Medical Devices 90/385/EEC
- In-vitro Diagnostic Devices 98/79/EC)
- What will change with the New Medical Device Regulations
- Product Classification
- Conformity Assessment Routes
- Contents of a Technical File (New MDR requirements & STED Format)
- Risk Management
- Labelling
- Vigilance
- Post Market Surveillance

Every medical device you place on the market in the EU must have a CE mark – it's a mandatory legal requirement. You probably know that already, but are you sure you are fully up to date with all the regulatory requirements and standards involved, especially in the current changing regulatory environment? Would you benefit from a refresher on CE marking coupled with a deep dive into the new Medical Device Regulation to understand the impact this could have on both new and already marketed Medical Devices?

This course provides a working understanding of the major features of the Medical Devices Directive and comparisons to the new Medical Device Regulation, including terminology, product classification, conformity assessment routes, and Technical Files, including the Essential Requirements and will look at the significant changes on the horizon.

As well as guiding you through the Medical Device Directive, it brings you up to scratch with all the other relevant legislation you need to understand, including the new Medical Device Regulations and the implementation timelines.

Who should attend:

This course is of value to employees at all levels within the organisation of Medical Device manufacturers, and suppliers to the Medical Devices industry including:

- Members of the Senior Management Team
- Regulatory Affairs Managers
- Regulatory Affairs Officers
- Quality Assurance Professionals
- Quality Assurance Officers
- Development Engineers
- Operations Managers
- Technical Sales & Marketing Professionals

BOOK NOW at www.maetrics.co.uk/training

£995
(early bird)

£1100
(full price)

Book 6 weeks in advance to qualify for discount

2017 COURSE DATES:
5/6 July
12/13 December

LOCATION:
Birmingham

2017 COURSE DATES:
20/21 September

LOCATION:
Basel

1400 CHF (early bird) **1750 CHF** (full price)

CPD CERTIFIED The CPD Certification Service CPD HOURS: 15

PUBLIC

IN-HOUSE COURSES

Replica courses

All our public courses and any of our in-house courses listed can be run at your own premises or at an offsite venue as a replica off the shelf standard course.

This option is particularly popular when you have 3 or more staff to train.

" Very well delivered from a competent and knowledgeable trainer and questions all answered clearly and completely."

FDA QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT)

This course is a must for any medical device manufacturer that wants to sell into the US. It will give you the skills, knowledge and confidence to prepare for a visit and inspection by the FDA and achieve a successful outcome. QSIT sets out a predetermined regime for how FDA investigations are conducted, and this course will show you just what to expect from a QSIT investigations. If you do have ambitions to sell into the US this course is essential preparation – not just for your own company but for associated critical suppliers, who may also face an inspection.

INTRODUCTION TO MEDICAL DEVICES - QUALITY & REGULATORY FRAMEWORK

If you're an individual or organisation new to the medical device industry, this course is your first port of call in terms of training. It deciphers all the regulatory jargon, and shows you how to correctly regulate a medical device, plan your compliance strategy, and progress stress-free through the regulatory labyrinth. Subjects covered include the Medical Device Directives, CE marking, device classification, risk management and quality management systems, technical file requirements, and post-production obligations. By the end of the course, delegates are well set up to understand the requirements and responsibilities, and plan your organisation's regulatory strategy.

UNDERSTANDING EN ISO 13485:2016 MEDICAL DEVICES

Whether you're new to the Quality System requirements of EN ISO 13485:2016 or familiar with superseded versions of this standard this course will fill in the gaps for you. Guiding you clause by clause through the requirements of EN ISO 13485:2016, you will gain a good understanding of this key industry standard. For those new to the requirements of a Quality System you will gain the knowledge and understanding to develop and implement a quality management system with your organisation. Those that currently operate to an older version of this standard will gain the relevant knowledge and confidence to update their quality system in line with the significant changes introduced by the 2016 update.

CE MARKING & 98/79/EC – THE IN VITRO DIAGNOSTIC MEDICAL DEVICE DIRECTIVE

All in vitro devices placed on the market anywhere in the EU must have CE marking, and must follow the This course is an essential guide to the CE marking and the Directive, not just for those new to the area, but for anyone who may need a refresher or update to understand some of the changes expected as part of the new IVD regulation. It covers all the major features of the Directive, including jargon, harmonised standards, conformity assessment routes, product classification, and how to prepare a Technical File. By the end of the course you'll have a working understanding of all the regulatory requirements.

PREPARING FOR A REGULATORY AUDIT

If you have never experienced an audit by a regulatory body, this course is essential learning for you and your organisation. Suitable for all types of audit including quality management system audits, technical file reviews and FDA inspection visits, the course has a practical focus. You'll receive practical advice on how to prepare; what to say and do; what not to say and do; how to maximise the opportunities for a positive outcome; and how to minimise the likelihood of further audits, warning letters, or even import embargos. As we said - essential information for any firm expecting a regulatory audit.

BUILDING & SUBMITTING A 510(K) SUBMISSION

This highly informative and interactive course is designed for those companies either planning to sell or contemplating selling their medical devices into the USA. Aimed at all levels of regulatory staff and also senior management, this course gives an in depth review of the Pre Market Notification registration process, otherwise known as a 510(k).

Our course walks you through the entire 510(k) process from ensuring that 510(k) is the right route for you, to understanding what should be submitted in the 510(k) file, how it should be submitted, what the FDA expect to see covered, your design history file, how to handle queries raised by the FDA and the timescales involved including those that you have to meet.

With many real life examples, our course is delivered by experienced regulatory experts who have successfully registered medical devices with the FDA and regularly assist clients with their 510(k) and PMA applications.

BOOK NOW at www.maetrics.co.uk/training

Tailored

Take any of our standard public and in-house courses and following a detailed discussion with our training experts these courses can be customised to focus on certain areas of the standard courses using more specific examples relevant to your organisation.

" Well-structured course that will enable me to properly complete the process validation activity."

Bespoke

Our experts can design and deliver a bespoke course written purely for your business needs.

Your team can talk frankly and openly about specific problems or issues directly related to your business and cover all the elements and topics you want to.

" There was a lot of interaction throughout the course which made a good learning experience for all attendees."

STERILISATION: GAMMA AND ELECTRON BEAM, EN ISO 11137-1:2015, EN ISO 11137-2:2015

This course is designed for anyone with an interest in irradiation-based sterilisation techniques. It covers both the practical aspects of the process and the detailed regulatory requirements for compliance with the Medical Device Directives and EN ISO 11137 series. Among the topics covered are the different microbiological sterilisation validation methodologies; how to establish minimum and maximum doses for medical devices; how to validate both the product and the process; and what you have to do if things go wrong. In addition to microbiological sterilisation validation, we discuss process validation and dose mapping. We also look at the ongoing manufacturers' obligations for ensuring microbiological control in their facility.

DESIGNING FOR STERILISATION

Choosing the best method of sterilisation for medical devices can have a significant impact on your commercial results. Selecting the appropriate method for each product can keep down project costs and time to market. Poor choices can achieve the opposite. This course will educate you about the different sterilisation methods; their impact on devices and packaging; and how best to optimise your product design and sterilisation processes. The course is intended for all staff involved in the design, development and production of sterile medical devices, and it's a day that could substantially improve the commercial outcomes of your design and production processes.

MICROBIOLOGY FOR COMPLIANCE TEAMS

An understanding of microbiology is essential for all sterile medical device manufacturers. This course opens up the subject to non-microbiologists, removing the mystique and explaining the key concepts and terminology you need to know. As well as clarifying the types and nuances of microbiology testing, it explores the sources and types of microorganisms typically found on medical devices and within cleanrooms, and shows their implications for your organisation and devices. Among the types of microbiology testing we look at are bioburden testing and sterility testing, explaining the different types of testing; how to determine an appropriate Sterility Assurance Level (SAL); the importance of compliance with the EN ISO 11737-1:2006 and EN ISO 11737-2:2009 standards; and how to demonstrate that in your own organisation.

CLEANROOM GOOD MANUFACTURING PRACTICE (GMP)

All staff who work in a controlled environment must understand cleanroom Good Manufacturing Practice, as should any other staff whose work impacts on your cleanroom – even occasionally. The consequences of slips or knowledge gaps can be dire. This useful course gives staff all the dos and don'ts of cleanroom good manufacturing practice. It shows how to monitor cleanroom conditions; what to do if airborne particle levels increase; and how to clean and maintain cleanrooms to the required standards. It also shows staff how their own habits can lead to contamination. The better people understand cleanroom GMP, the greater your powers to control contamination, so this is a course with long-term benefits.

STERILISATION: ETHYLENE OXIDE, EN ISO 11135:2014

If you need to understand the ethylene oxide sterilisation process – the method of choice for heat-sensitive and gamma-sensitive products, this course covers all the practical and regulatory knowledge you need to plan and execute sterilisation validation projects. The course takes you through the entire ethylene oxide cycle, and explores the different methods of sterilisation validation described within ISO 11135. The course gives practical examples of key issues such as deviation disposition and investigation, and packaging considerations; and, to help you understand what limits to apply to medical devices, it discusses the implications of ethylene oxide residuals and residual decay dynamics as part of EN ISO 10993-7. We also consider microbiological control of product bioburden, and post-sterilisation endotoxin, to help you comply with the regulatory framework.

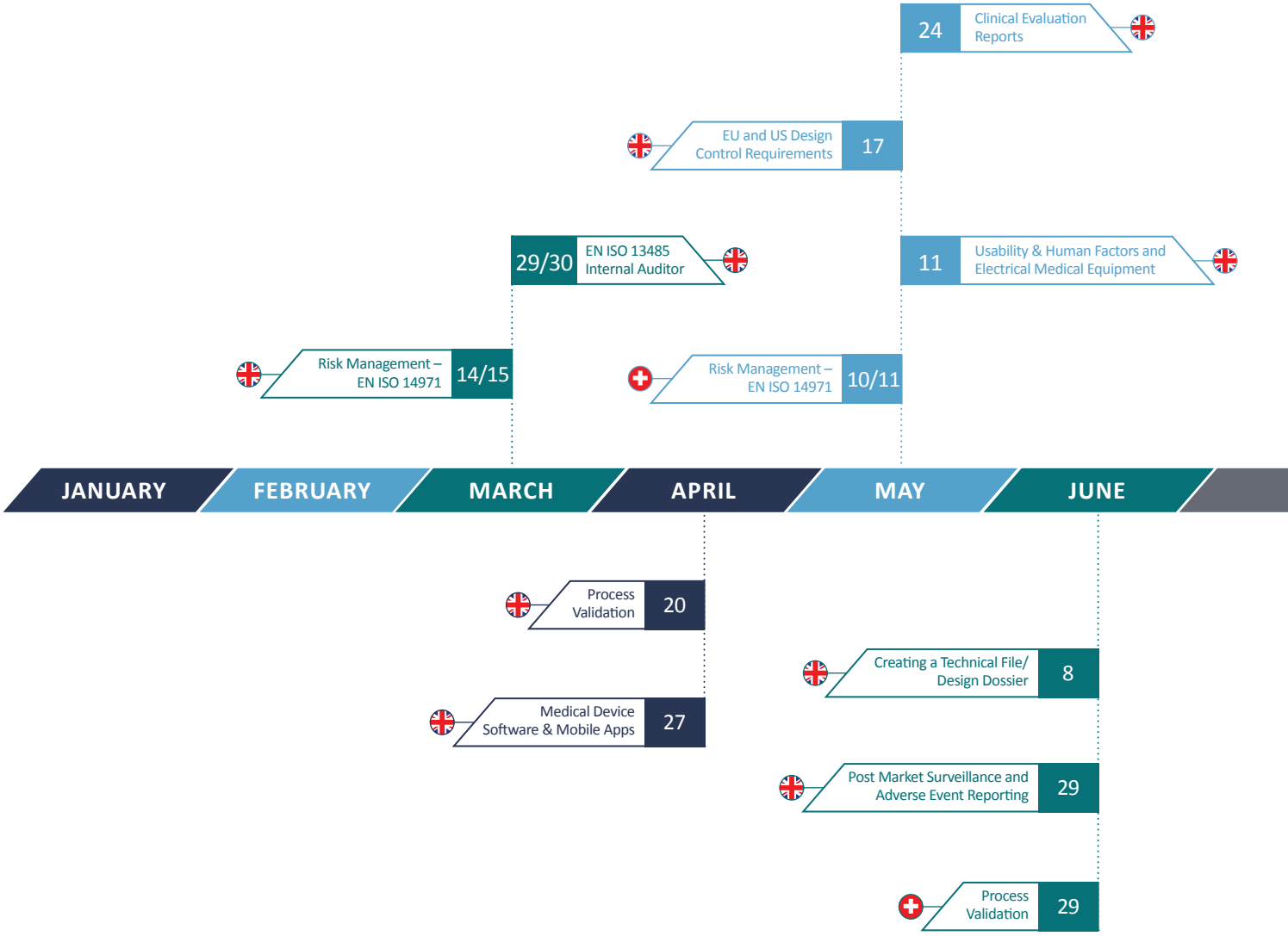
Next steps.....

Our experts are happy to discuss your in-house training needs and tailor a traing solution to meet your business needs.

Call us today on +44 115 9216200 or email uktraining@maetrics.com

" Great course, content and presenter. Was given a solid foundation and understanding. Will definitely recommend."

PLANNER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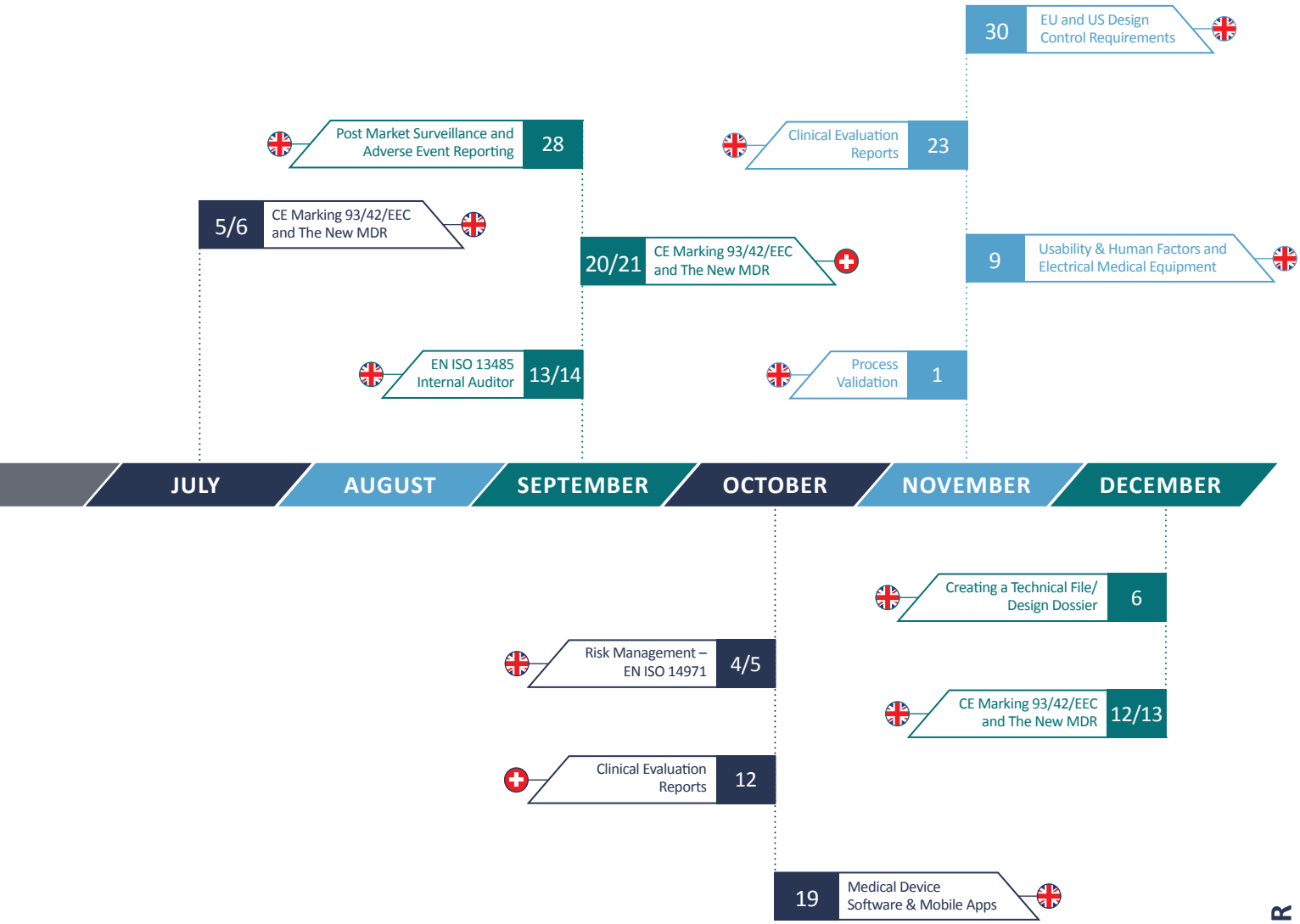
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