Sensus

Delivering the new EU Medical Device
& In-Vitro Regulations

Sensus Training Academy

General Introduction

The following courses have been devised by ABC to offer a rich and rewarding training experience. The courses and numbers are strictly limited to ensure that each attendee has a maximum opportunity to interact with the course leader and other delegates in a workshop collaborative environment which can't be achieved in large public courses.

Public courses

Delegates should come prepared with their concerns, examples and questions and expect to leave with a thorough practical understanding on the subject matter discussed.

Academy Structure

We have adopted a module structure which allows the delegate to select the modules which are most applicable for their individual needs. Each module has been assessed for CPD content and includes a final assessment of the delegates course achievement in the form of either an exam or an independent skills assessment.

Module structure

Module 1	Foundation Module, Basic skills, project and time management, company records/formats, report writing and MDR overview*
Module 2	The MDR In Depth
Module 3	The IVDR In Depth
Module 4	MDR/ IVDR Clinical Evidence, specific focus on Clinical data, appraisal of data content and strategic gathering and remediation of GAPs
Module 5	MDR IVDR, supply chain and economic operators
Module 6	MDR Hazardous substances, risk management and manufacturing considerations.
Module 7	MDR/IVDR compliant Quality Systems, labelling and GSPR

Module 1: Foundation course

Target audience

Designed as a foundation element for people attending to participate in more of the elements of the Sensus Academy system, this 5 day course prepares delegate by providing insight into the core skills required to plan, communicate and implement major strategic changes in an organisation.

The course is designed as an interactive 5-day course with multiple workshop elements, including role play activities. The course will cover:

a. Documentation and effective report writing
b. Communication skills
c. Presentation skills
d. Influencing tactics
e. Change management
f. Project planning and monitoring

Learning Objectives

• A thorough understanding of the arsenal of tools required by individuals operating to implement challenging change processes within an organisation.
• This course is aimed to provide attendees with the insight and tools to plan and implement organisational strategy in environments where there is significant resistance to change and technical and time pressures are major factors.

CPD points TBC

Assessment by individual assessment, ongoing coaching and follow-up effectiveness checks are offered as options to this course.

Module 2: European Medical Device Regulations

(Richard Young)

Target audience

Designed for strategic and technical leaders responsibilities, this course quickly identifies the areas of strategic impact, possible costs, strategic solutions and the timelines associated with the new EU Medical Device Regulations.

The course is designed to conduct an in depth review of all critical elements of the new regulations and will be run as an interactive 5-day course.

Learning Objectives

- A thorough understanding of the changes and strategic consideration of the major impact areas of the revised regulations. Attendees should have conducted or should be able to conduct a strategic review of a business formulate detailed plans to meet the transition to the MDR based on this 5 day event.
- This course is aimed to provide attendees with the insight and tools to plan and implement organisational strategy for continued access to the European market by the deadlines set in the new regulations.

Event outline

The course will begin by reviewing the major clauses of the regulation. This will be followed by an in-depth review of the Annex's of the Regulation. As each point is raised, there will be ample time to review and discuss the materials and experiences within the delegate group.

- The Medical Devices Regulations are due for significant update with areas such as Post Market Surveillance and Economic Operators being major areas of change. The final form of the regulations is now set and due to be voted into European Law. The new regulations need to be considered now at all organisational levels as they will be impacting on decisions taken today.
- A detailed knowledge of requirements is required to develop pragmatic and cost effective approaches to this organisational challenge.

CPD points TBC

Assessment by Exam

Module 3: European In Vitro Diagnostic Device Regulations

(Richard Young)

Target audience

Designed for strategic and technical leaders responsibilities, this course quickly identifies the areas of strategic impact, possible costs, strategic solutions and the timelines associated with the new In Vitro Diagnostic Medical Device Regulations.

The course is designed to conduct an in depth review of all critical elements of the new regulations and will be run as an interactive 5-day course.

Learning Objectives

- A thorough understanding of the changes and strategic consideration of the major impact areas of the revised regulations. Attendees should have conducted or should be able to conduct a strategic review of a business formulate detailed plans to meet the transition to the MDR based on this 5 day event.
- This course is aimed to provide attendees with the insight and tools to plan and implement organisational strategy for continued access to the European market by the deadlines set in the new regulations.

Event outline

The course will begin by reviewing the major clauses of the regulation. This will be followed by an in-depth review of the Annex's of the Regulation. As each point is raised, there will be ample time to review and discuss the materials and experiences within the delegate group.

- The In Vitro Diagnostic Regulations are due for significant update with areas such as Post Market Surveillance and Economic Operators being major areas of change. The final form of the regulations is now set and due to be voted into European Law. The new regulations need to be considered now at all organisational levels as they will be impacting on decisions taken today.
- A detailed knowledge of requirements is required to develop pragmatic and cost effective approaches to this organisational challenge.

CPD points TBC

Assessment by Exam

Module 4: Clinical data and periodic safety reports for Medical Devices and In Vitro Diagnostics Manufacturers

Target audience

The course is designed to the clinical element of the new regulations and will be run as an interactive 5-day course designed for clinical, regulatory and quality leaders. The course is suitable to anyone who is new to Medical Devices and In Vitro Diagnostics, in addition to those who would like to further their working knowledge of current requirements.

The course will also provide detailed examination of Clinical Research and ISO14155 including study design, preparation and submission to relevant authorities.

Learning Objectives

The Medical Device Regulation (MDR), which replaces the Medical Devices Directive (93/42/EEC) and Active Implantable Medical Devices Directive (90/385/EEC) will come into effect in May 2020. Both this document and the new IVDR have similar requirements to support the continued sale of medical products with solid clinical data and justifications.

The new regulations require significant changes to the clinical evidence that Manufacturers must document, with more clinical data being required for higher class devices. This course will discuss the requirements that manufacturers of medical devices must follow in order to comply with the Regulations and explore the strategies to gather and assess this data.

The course will include the following topics:

- The Regulations and their impact on clinical evaluations.
- How to design Clinical Trials, including how the MDR will affect post market clinical studies for existing products.
- How to perform a Clinical Literature Review.
- Clinical evaluations
- Managing CERs (Clinical Evaluation Reports) throughout the life cycle of a medical device, including practical guidance on how to prepare a clinical evaluation report. This will include reference to the MED DEV 2.7.1 Rev 4
- Designing and managing a clinical evaluation
- Post-market clinical follow-up (PMCF) studies for existing products
- Overview of ISO 14155 and GCP
- Clinical evaluation throughout the product lifecycle
- The regulations and their impact on clinical evaluations.

Event outline

The aim of the course is to help attendees to develop an in depth practical understanding of the expectations of clinical evidence and its generation, including PMS when considering both Medical Devices and In Vitro Diagnostic. The course will involve a combination of theory and practical sessions/workshops. The course will also provide tools and references to help plan how to ensure clinical data is continually gathered, analysed and reported to comply with these new regulations.

CPD points TBC

Assessment by Exam

Module 5: MDR IVDR, supply chain and economic operators

Target audience

This module is specifically aimed at delegate with responsibilities for the documentation and maintenance of Economic operator relationships with an organisation. This will include supply chain managers, distribution managers, sales and marketing strategists as key participants

Learning Objectives

- Examination of the requirements for each class of economic operators
- Selection of suppliers, audit skills and assessment of capability to meet the regulatory requirements.
- Understand the importance of a strong interfaces between the customer facing groups and the design and regulatory groups.
- Examine techniques for market access and selection of critical distributors
- Traceability in the supply and distribution chain, data integrity and access.
- Documentation requirements
- Warehousing requirements (GWP)
- Process validation and assessment of hazardous materials in the supply chain
- How important are the new regulations to the sales and marketing functions
- Analysing Global distribution and strategies: direct sales, agency model, distributor models; implications of the European Agency Directive.
- Third party supplied components (Part finished)
- Virtual Manufacturing
- Testing strategies for Hazardous substances (introduction)
- Economic Operator Contract contents
- Unique Device Identification

Event outline

This 5 day course aims to integrate an understanding of this complexed area with the detailed documentation required to demonstrate compliance with the European regulations. This course will offer a workshop based learning approach to addressing this subject area.

CPD points TBC

Assessment by Exam

Module 6: MDR Hazardous substances, risk management and manufacturing considerations.

Target audience

This module is specifically aimed at delegate with operational responsibilities as the legal manufacturer as product developers and operational manufacturers. This course offers an in depth exploration of the assessment and practical steps required to review the identification and control of hazardous substances, manufacturing controls including process validations and the use of risk management to underpin these activities

Learning Objectives

- Examination of the requirements for hazardous substances
- Assessment techniques for hazardous substances
- Process control challenges
- Change Management
- Nano materials and possible sources
- Materials of human or animal origin
- Traceability in the supply and distribution chain, data integrity and access.
- Process and test validation and assessment of hazardous materials in operations
- ISO10993 and test methodologies
- Risk Management and documentation including assessment of residual risk
- Third party supplied components (Part finished)

Event outline

This 5 day course aims to integrate an understanding of this complexed area with the operational activities associated with product development and manufacturing. This course will offer a workshop based learning approach to addressing this subject area.

CPD points TBC

Assessment by Exam

Module 7: MDR/IVDR compliant Quality Systems, labelling and GSPR.

Target audience

This module examines the structures in quality management systems which are required to ensure the consistent delivery of compliance. This is aimed at all senior staff who are involved in the design and development of the quality system and its documentation.

The General safety and Performance Requirements will be used as a starting point to examine the need for a system that provide documentary evidence of compliance

Learning Objectives

GSPR a detailed review of requirements and resulting documentary controls
QMS design and purpose
Quality planning and resourcing
Auditing systems (techniques)

- Unannounced audits
- Data management and storage
- Examination of electronic QMS solutions
- Qualification of electronic systems in general including ERP systems
- ISO13485:2016
- 21CFR820
- MDSAP program
- UDI (in depth)

Event outline

This 5 day course defines the principle of a well designed QMS and how this can be assessed to identify GAPs and improve performance to allow consistent demonstration of compliance and an ongoing state of audit readiness. Delegates will be given practical strategies to deliver systems which are fit for purpose and leverage each organisations requirements and strengths.

CPD points TBC

Assessment by Exam