

COURSES

Dates from February 2008 – December 2008

Medical Devices

- » **Process Validation**
- » **Medical Device Design (and Development) Control**
- » **Introduction to the Medical Device Directive 93/42/EEC (MDD)**
- » **FDA – The Quality System Regulation (QSR, 21 CFR Part 820)**
- » **Medical Device Risk Management – ISO 14971:2007**
- » **Establishing Compliance with the Medical Device Directive 93/42/EEC (MDD)**

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1-DAY

Process Validation

Course Summary

The FDA Quality System Regulation, 21 CFR Part 820 and BS EN ISO 13485:2003 include requirements for process validation. In many cases manufacturers have not satisfactorily established compliance* with the regulation in relation to process validation and have received adverse FDA inspections including issuance of Warning Letters and Import Alerts. Moreover, process validation has the potential to deliver significant cost savings and improved process control to companies. This course is designed to ensure delegates fully understand the essential business and regulatory requirements for process validation. The programme is enhanced by the use of two case studies.

* According to FDA statistics process validation non-conformance is in the top five 483 observations

Topics covered include:

- Why validate
- Process validation
- Case study 1
- Case study 2
- Process capability
- Question and answers
- Course evaluation

Objectives

This course enables you to understand:

- The regulatory imperatives relating to process validation
- How to develop a validation master plan
- The key steps in performing an effective process validation
- The business benefits, including cost reductions, that arise from process validation

Pre-requisites

Delegates will be expected to have educational levels appropriate to the functions listed below. Some familiarity with the FDA Quality System Regulation, 21 CFR Part 820 and EN ISO 13485:2003 would be an advantage but is not a requirement.

Who should attend?

Personnel working in the following areas:

- Quality assurance
- Regulatory
- Production
- Engineering
- Managerial personnel with a responsibility or involvement in validation activities

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COURSE INFORMATION

Time

- 09:30 – 17:00

Dates

- 13 March 2008 • 13 November 2008

Venue

BSI Group Headquarters, London

Price

- £595 + VAT • Member price £535.50 + VAT

1-DAY

Medical Device Design (and Development) Control

Course Summary

The FDA Quality System Regulation, 21 CFR Part 820, and BS EN ISO 13485:2003 both contain significant requirements in relation to design control. In many cases manufacturers have not satisfactorily established compliance with the regulation and standard and have received adverse inspections, including issuance of FDA Warning Letters and Import Alerts. In practical terms, good design control results in timely, cost-effective design projects which deliver safe and effective medical devices to the market place.

Topics covered include:

- Design control; the regulatory imperatives, QSR, MDD and BS EN ISO 13485
- Compliance assessment of design control by Quality System Inspection Technique (QSIT)
- Risk analysis in relation to design control
- Elements of design control including:
 - Identification of user requirements
 - Design inputs
- Design outputs
 - Design verification
 - Design validation
 - Design change control
 - Design transfer
 - Design review
 - Design history files

Objectives

This course enables you to:

- Obtain the most up-to-date information in relation to design and development control requirements as defined in the FDA Quality System
- Regulation and BS EN ISO 13485:2003
- Understand the use of risk management in the design control process
- Understand the differences between design verification and design validation
- Understand the concept of design change control
- Understand what a design history file should contain

Pre-requisites

Delegates will be expected to have educational levels appropriate to the functions listed below. Some familiarity with the FDA Quality System Regulation, 21 CFR Part 820 and EN ISO 13485:2003 would be an advantage but is not a requirement.

Who should attend?

Personnel in the following areas:

- Quality assurance
- Regulatory
- Production
- Engineering
- Management personnel and product managers who have responsibility for, or involvement in, design control

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COURSE INFORMATION

Time

- 09:30 – 17:00

Dates

- 21 February 2008 • 23 October 2008

Venue

BSI Group Headquarters, London

Price

- £595 + VAT • Member price £535.50 + VAT

1-DAY

Introduction to the Medical Device Directive 93/42/EEC (MDD)

Course Summary

This introduction to the MDD covers the background to the Directive and its key features. The intention is to make its content and application intelligible to those in the management structure who need to understand their own roles in the organization's Quality Assurance and Regulatory Affairs activities. It is not intended to be a substitute for the in-depth training provided in the 3-day course Compliance with the Medical Device Directive 93/42/EEC (MDD).

Topics covered include:

- Background to European Regulation of Medical Devices (MDD)
- Development of European Directives
- Common steps to compliance
- Product classification
- Technical documentation
- Role of Competent Authority, Notified Body and Manufacture
- Role of harmonized standards including EN ISO 13485:2003
- Conformity assessment routes
- Technical documentation (technical files)
- 'Private Labelling'

Objectives

In the context of compliance with the MDD (93/42/EEC) to understand:

- The role of European Directives
- Legal necessity for compliance
- The structure of the Directive
- The mechanisms of compliance
- The importance of the concept of risk
- How to find the key elements within the text of the Directive
- The roles of the various functions within the organization including those at all levels of management
- The role of external bodies such as Notified Bodies and Competent Authorities

Pre-requisites

Delegates will be expected to have educational levels appropriate to the functions listed below. Some familiarity with the MDD and EN ISO 13485:2003 would be an advantage but is not a requirement.

Who should attend?

Anyone within the company's management structure whose role is impacted by the requirement for the organization to comply with the MDD or EN ISO 13485:2003

- Senior management
- Quality assurance and regulatory affairs managers
- Project managers
- Product designers/developers
- Operations managers (manufacturing, sterilization, assembly and despatch, etc)
- Sales and marketing managers
- Customer service personnel

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COURSE INFORMATION

Time

- 09:30 – 17:00

Dates

- 15 April 2008 • 2 October 2008

Venue

BSI Group Headquarters, London

Price

- £595 + VAT • Member price £535.50 + VAT



2-DAY

FDA – The Quality System Regulation (QSR, 21 CFR Part 820)

Course Summary

According to FOI data in 2001, 56% of foreign medical device manufacturers inspected by FDA, were issued with a Form 483. The current FDA Quality System Regulation, 21 CFR Part 820, including the Design Control requirements, came into full effect in June 1998. In many cases manufacturers have not satisfactorily established compliance with the regulation and have received adverse FDA inspections, including issuance of Warning Letters and Import Alerts.

Topics covered include:

- FDA history, organization and foreign inspection history
- Overview of the QSR 21 CFR 820
- How to prepare for and manage an FDA inspection
- What happens after the inspection
- Software validation including requirements of 21 CFR 11, electronic data and signatures
- Process validation
- Complaint handling and medical device reporting 21 CFR 803 and 804
- Introduction to the Quality System Inspection Technique (QSIT)
- QSIT requirements in relation to management responsibility
- QSIT requirements in relation to non-conformity and Corrective and Preventive Action (CAPA)
- QSIT requirements in relation to design control
- QSIT requirements in relation to production and process controls
- Good manufacturing or good management practice?
- Test (optional)

Objectives

This course will enable you to:

- Obtain the most up-to-date information available on the Quality System Regulation and how compliance with the regulation is determined through the use of the QSIT
- Obtain a good working knowledge of all aspects of the Quality System Regulation, and how this relates to the EU's Medical Devices Directive
- They will be able to prepare for and host an FDA inspection with confidence and learn new quality improvement strategies and techniques

Pre-requisites

Delegates will be expected to have educational levels appropriate to the functions listed below. Some familiarity with the FDA Quality System Regulation, 21 CFR Part 820 and EN ISO 13485:2003 would be an advantage but is not a requirement.

Who should attend?

- Quality assurance personnel
- Company personnel who are responsible and perform any regulated function including design, manufacturing, training, purchasing, etc and who may be required to answer questions from FDA Investigators
- Regulatory affairs professionals
- Operators of a CAPA system
- Those involved in the review and oversight of the CAPA system

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COURSE INFORMATION

Time

• Day 1: 09:30 – 17:15 • Day 2: 09:30 – 17:00

Dates

• 18-19 June 2008 • 26-27 November 2008

Venue

BSI Group Headquarters, London

Price

• £795 + VAT • Member price £715.50 + VAT

2-DAY

Medical Device Risk Management – ISO 14971:2007

Course Summary

ISO 14971:2007 is the specified standard for risk management used to demonstrate compliance with the Risk Management requirements of the Medical Devices Directive (MDD) and the In Vitro Diagnostic Device Directive (IVDD). Additionally, review of the MDD by the European Commission concluded that manufacturers did not address risk management sufficiently, hence the increased emphasis on risk requirements in the update to the MDD. The revision to ISO 14971 has also been implemented to address these requirements. This course provides a thorough introduction and interpretation of ISO 14971:2007 risk management, throughout the product lifecycle, including a summary of the latest changes to the standard.

Topics covered include:

- Regulatory requirements for medical device risk management
- Content and interpretation of ISO 14971:2007
- Alignment of ISO 14971:2007 to ISO 13485:2003
- What is a risk management plan?
- How to conduct a risk analysis
- What is risk control?
- Requirements for a Risk to Benefit evaluation
- The risk management process within the product lifecycle
- ISO 14971:2007 – main changes from EN ISO 14971:2000
- Test (optional)

Objectives

- To understand that risk analysis is a regulatory requirement for all classes of medical device
- To understand risk management versus risk analysis
- To understand the interaction with ISO 13485:2003
- To be able to construct a basic risk management plan
- Use of the ISO 14971:2007 annexes in conducting a risk analysis
- To identify key quality management system procedures which need to link to risk management
- To understand that FMEA (Failure Mode and Effects Analysis) alone is not medical device risk analysis
- The requirements and structure of a Risk Management File
- Awareness of changes from ISO 14971:2000 to ISO 14971:2007

Pre-requisites

Basic understanding of the Medical and In Vitro Diagnostic Devices Directives; awareness of ISO 13485:2003; basic understanding of Design and Development Control. Previous knowledge of ISO 14971:2007 not required

Who should attend?

- Senior managers
- Product designers
- Regulatory affairs professionals
- Clinical affairs professionals
- Quality assurance professionals
- Manufacturing operations personnel

From the following sectors:

Medical and In Vitro diagnostic device manufacturers, suppliers to the medical device industry and health service medical physics

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COURSE INFORMATION

Time

• Day 1: 09:30 – 17:00 • Day 2: 09:30 – 17:00

Dates

• 10-11 June 2008 • 11-12 November 2008

Venue

BSI Group Headquarter, London

Price

• £795 + VAT • Member price £715.50 + VAT

3-DAY

Establishing Compliance with the Medical Device Directive 93/42/EEC (MDD)

Course Summary

This covers the content of the Directive in some detail and the intention is to assist delegates in becoming familiar with its provisions. All key aspects are addressed, enabling participants to navigate between the Articles and Annexes with confidence. It is designed to be of assistance to personnel within quality assurance and regulatory affairs departments, and to staff within Notified Bodies and Competent Authorities who are expected to audit against the Directive or to administer its provisions.

Topics covered include:

- Background to European Regulation of Medical Devices (MDD)
- Development of European Directives
- Common steps to compliance
- Product classification
- Technical documentation
- Role of Competent Authority, Notified Body and Manufacture
- Role of harmonized standards including EN ISO 13485:2003
- Conformity assessment routes
- Technical documentation (technical files)
- 'Private Labelling'

Objectives

In the context of compliance with the MDD (93/42/EEC) to understand:

- The role of European Directives
- Legal necessity for compliance
- The structure of the Directive
- The mechanisms of compliance
- The importance of the concept of risk
- How to find the key elements within the text of the Directive
- The roles of the various functions within the organization including those at all levels of management
- The role of external bodies such as Notified Bodies and Competent Authorities

Pre-requisites

Delegates will be expected to have educational levels appropriate to the functions listed below. Some familiarity with the MDD and EN ISO 13485:2003 would be an advantage but is not a requirement.

Who should attend?

Anyone within the company's management structure whose role is impacted by the requirement for the organization to comply with the MDD or EN ISO 13485:2003 but in particular:

- Quality assurance personnel
- Regulatory affairs personnel
- Notified Body auditors
- Competent Authority personnel involved in the enforcement of the Directive

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COURSE INFORMATION

Time

• Days 1 & 2: 09:30 – 17:00 • Day 3: 09:30 – 14:45

Dates

• 16-18 April 2008 • 2-4 December 2008

Venue

BSI Group Headquarters, London

Price

• £995 + VAT • Member price £895.50 + VAT

Medical Devices

Dates from February 2008 – December 2008


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