

medical device regulation

essential requirements and material selection



**Short Course at Smithers Rapra Technology Limited,
Shawbury, Shropshire, UK**

14-15 June 2011

15-16 November 2011

Organised by:



www.rapra.net
www.rapratraining.com

medical device regulation - essential requirements and material selection

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Course Overview

This Course is provided to give product designers and developers an understanding of the underlying principles of medical device regulations and their requirements for medical device design and to then apply these requirements when identifying plastics materials that are suitable for use with medical devices. A detailed overview of the EU Medical Device Directive 93/42/EEC is given and the technicalities of its compliance explained. The use of polymers as medical devices is considered in terms of design and material selection. The course modules also focus on material testing requirements and look to the developments in ISO 10993 Biological Evaluation of Medical Devices where new standards are provided which allow alternatives to traditional animal testing.

Who will benefit?

- This course is intended for people involved in technical, design, research or engineering roles who conduct, or have responsibility for, the design and material selection for medical devices and/or have responsibility or input into Medical Device CE marking.
- This course is equally applicable to Regulatory and Quality personnel who have a responsibility for product regulatory submissions and require an understanding of the technical aspects of material selection and proof of function and safety.

Course Fee: £550.00 plus VAT

Course Objectives

To enable delegates to apply the requirements of medical device regulation to plastics materials.

Venue

Smithers Rapra, Shawbury, Shropshire, UK. SY4 4NR

Organisers – Smithers Rapra Technology

Course Presenters

Tom Donnelly – Medicom Consulting

Tom Donnelly graduated in Microbiology from Queens University Belfast, and then worked for the healthcare industry in Ireland for thirteen years, before founding Medicom Consulting (www.medicom.ie) in 1995. He has been extensively involved in both US and EU Device and Drug GMP compliance, and his experience encompasses the design and manufacture of both non-sterile and sterile medical devices (disposable, reusable, implantable and medical equipment), by terminal and aseptic sterilisation processes.

He regularly assists manufacturers prepare for FDA and Notified Body inspections by provision of auditing, consultancy and training services, and has provided such services in Ireland, the UK, Europe, USA, Mexico and the Far East.

Paul Shipton - BSc., PhD.

Dr. Paul Shipton is founder of Plastics Consultancy Services. Previously he was head of Plastics Technology and Polymer Processing at Rapra Technology. For over 11 years he was the Technical Manager of Ticona's UK engineering plastics manufacturing facility where he was accountable for the development and quality of medical grade products made in the UK. He has over 20 years of processing, materials selection and problem solving in plastic raw materials and products.

Registration Conditions

Registrations can only be accepted if made in writing, by fax, post or on our secure website www.rapratraining.com. Payment must be received in advance of attendance on the course and can be made in £ Sterling, US\$ or E Euro.

Provisional Bookings

Please contact the Training Organiser to make a provisional booking. To secure your place written confirmation must be received within 10 days of the provisional booking being made.

Joining Instructions

i.e. letter of confirmation, directions to Rapra, and hotel information will be sent on receipt of your registration. Accommodation is not included in the course fee, however Smithers Rapra has negotiated rates with several hotels in the vicinity. Details will be sent on confirmation of booking.

Cancellations and Transfers

Please note, we endeavour to accommodate our delegates requests, however, most of our courses have limited numbers to maximise the interactivity between delegates and tutors. Cancellations or transfers at late notice may jeopardise the commercial viability of the course.

For this reason we are obliged to charge the following administration fees or surcharges: Cancellations made up to 14 days or more before the requested course date will be refunded, less a 20% administration fee. Requests to transfer made up to 14 days or more before the requested course date will be accommodated, subject to availability of places on the new course date and transfer conditions, see below.

Cancellations and requests to transfer made within 14 days of the course date will be subject to the FULL course fee and no refund will be given.

Delegate Substitutions

can be made at any time without incurring penalty.

Amendments to Programmes

Smithers Rapra reserves the right to cancel or modify any event in its programme. In the event of a cancellation where an alternative cannot be provided, payment received in respect of that course will be refunded in full. The liability of Smithers Rapra is limited to the reimbursement of the course/seminar fee.

course content

■ **History and overview of the EU Medical Devices Directive (MDD)**

An introduction to the European New Approach Directives and a brief history of the Healthcare and specifically the Medical Devices Directive introduction.

■ **Structure of the MDD, Key Annexes and Articles**

A description of the 3 main sectors within the Directive, explaining differences and relation between Recitals, Articles and Annexes, and how Conformity Assessment can be achieved for a device depending upon its intended use. The Conformity Assessment process will introduce the requirements for Technical Aspects of the device.

■ **Annex 1 – Essential Requirements**

A review of all the Essential Requirements – Annex I – which may be applicable to the medical device, and how the Essential Requirements can be used as a designers checklist.

■ **Material Specific Essential Requirements**

A focus of a selection of the Essential Requirements which are specifically aimed at medical device material selection, proof of function and proof of safety when used in contact with a patient.

■ **Classification and Conformity Assessment**

Describes the rules for classifying medical devices, which can significantly affect the amount of design work required in respect of the product. The Conformity Assessment Route results from the device classification and impacts on the amount of data, including design data, which has to be provided to and reviewed by the Notified Body for certification and ultimately CE Marking.

■ **Plastics in Medical Device Design**

An overview of the main plastics materials types and their properties and how these are affected by:

- The structural design of the device the required duration of the device
- The chemical resistance issues associated with its intended use.
- Sterilization methods
- Solvent bonding of like and dissimilar plastics and the toxicological issues associated with this.

■ **Assembly of Medical Devices**

A review of modern assembly techniques that are suitable in the design of medical devices. Emphasis is given to minimizing part count and reducing assembly costs.

■ **Sterilization and Material Selection**

Matching a plastic medical device to a suitable sterilization technique is important to ensure the long term durability of the device. The influence of different sterilization techniques on plastics is explored and the implications explained for material selection.

■ **Structure and Key Clauses of ISO 14971 – Medical Devices Risk Management**

A detailed review of the updated standard – ISO 14971 – Medical Device Risk Management – and how Risk Management is a key aspect of both the Technical Review by the Regulatory Authorities and Quality System.

■ **Key Steps in Conducting Risk Analysis**

A detailed insight into the structure of the risk management standard, how to conduct a risk analysis and how risk management should be conducted throughout the lifetime of the device.

■ **Assessing Toxicological Risk – Introduction to Biological Evaluation of Medical Devices**

An overview of the recognized standards for biological evaluation of medical devices – ISO 10993 – demonstrating how the standards should be used, and also highlighting differences between EU and US requirements.

■ **Harmonised Standards**

An understanding of the Technical Standards that have been developed to assist Medical Device Designers to demonstrate compliance to the medical device directives, and provide an understanding of the hierarchy of the standards which should be considered.

■ **ISO 10993 part 18 and its Part in the Process of Materials Selection**

How to use chemical analysis to establish biological safety data.

■ **Technical Document Compilation**

A summary of how to compile all the Technical Documentation / Design Dossier into a format that will be expected by the Regulatory Authorities for review and approval.

Registration Form

Fax to
+44 (0)1939 251118

Medical Device Regulation

- 14-15 June 2011
 15-16 November 2011

(please use one form per delegate, photocopies are acceptable)

Surname.....Title.....
Forename.....
Job Title/Position.....
Company.....

Contact Address

Address.....
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.....
.....
Telephone.....
Fax.....
Email.....

Invoice Address (if different)

Company.....
Address.....
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Telephone.....
Fax.....
Email.....

Payment Information

Payment must be received prior to attending the course and can be made in £ Sterling, € Euro or \$US.

Please indicate in which currency you wish to pay. If no box has been ticked the default currency will be £ Sterling.

- £ Sterling
 € Euro (This will be applicable at the prevailing rate)
 \$US (This will be applicable at the prevailing rate)
 Please invoice my company - Purchase Order Number (if required)
 Cheque/Bank Transfer

- Credit Card Payment: MasterCard Visa American Express (please indicate)

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Expiry Date:

Signature

Name on Credit Card (in CAPITALS)

Security Number (as printed in signature box on reverse of card)

Return to:

Gill Tunnicliffe, Training Dept, Smithers Rapra
Technology Limited, Shawbury, Shrewsbury,
Shropshire, SY4 4NR, United Kingdom.

Tel: +44(0)1939 250383 Fax: +44(0)1939 251118

Email: gtunnicliffe@rapra.net

Enrol online at:

www.rapratraining.com

Registration Terms: By completing and returning this form delegates are agreeing to be bound by conditions of registration.