PROMOTE YOUR PROFESSIONAL GROWTH
by training with the Plastic and Rubber Experts

AN INTRODUCTION TO:
PLASTICS AND RUBBER MATERIALS IN MEDICAL DEVICES
MATERIAL REQUIREMENTS, MANUFACTURING ENVIRONMENT AND EUROPEAN REGULATORY (MDD) CONSIDERATIONS

SHORT COURSE AT:
SMITHERS RAPRA, SHAWBURY, UK
14-15 MARCH 2018
5-6 DECEMBER 2018
An introduction to: Plastics and Rubber Materials in Medical Devices

COURSE OVERVIEW

Depending upon the application and classification of a medical device and/or accessories, the use of a plastic or rubber material in its manufacture may require consideration of biocompatibility, traceability, sterilisation techniques and their impact, manufacturing environment, regulation and testing, in addition to the engineering requirements and capabilities of the material to be used.

This course will concentrate on providing an introduction to the material requirements and manufacturing conditions which may apply and explore the scope and impact of the European Medical Device Directive (MDD) Regulations in relation to their use.

COURSE CONTENT

- The regulatory impact on requirements for performance of plastics and rubber materials in medical devices - An overview and guidance on the parameters and impact of the regulations with regard to plastics and rubber materials.
- Overview of the EU Medical Devices Directive (MDD) - An explanation of the classification system.
- Quality Management Systems for Medical Devices - An overview of the Quality System Standards ISO 13485 and ISO 9001 will be presented.
- Introduction to the Medical Device Risk Assessment Standard ISO 14971 - An overview of the standard explaining the actions necessary to meet its requirements.
- Material Selection for Medical Devices, including sterilisation methods and their impact - A review of the different types of plastics and rubber materials which can be used for medical devices and accessories.
- Manufacturing Environment for Medical Devices: options and requirements - An overview of the manufacturing arrangements needed for medical devices and where these differ from other products.
- An Overview of biocompatibility and types of testing - A general introduction and an explanation of the types of tests employed to assess the interaction between medical devices and patients.
- The contents and scope of ISO 10993 and a comparison of how the EU and USA FDA biocompatibility testing requirements and application of this standard differ from one another.
- Packaging Systems for Medical Devices - Requirements for packaging systems with reference to performance specified by European Standards including integrity and testing.

COURSE PRESENTERS

This course is presented by Tom Forsyth, Principal Consultant, Dr Martin Forrest, Principal Consultant, and Dr Paul Shipton, Consultancy Director.

WHO WILL BENEFIT?

- Moulders and fabricators considering supplying medical device companies:
  - Technical Managers, Quality Managers and others needing insight into the material and manufacturing and quality systems requirements and scope of MDD regulations which may apply when making medical devices or medical grade materials. Existing suppliers or medical device manufacturers with little or no experience of engineering with plastics or rubber materials:
    - Designer/Engineers and Technical/Production managers and others needing to understand the additional material specific considerations, the scope of the MDD regulations in relation to their use and how these may differ from traditional engineering materials.

LEARNING OUTCOMES

- An awareness of the scope of the EU Medical Device Directive and its impact.
- An understanding as to what is classified as a Medical Device.
- An appreciation of the essential differences between quality systems ISO 9110 and ISO 13485.
- A detailed awareness of the additional technical criteria which apply in the selection of medical grade polymer materials.
- An understanding of the options for sterilisation and their impact on different plastics and rubber materials types.
- Understanding the different options for testing for biocompatibility, when to use them and what they will reveal.
- An appreciation of the general requirements for manufacturing medical devices, depending upon classification and type.

COURSE FEE

£680 plus VAT, includes course manual, lunches and refreshments, accommodation not included.
Registration Form

Please reserve a place on the **Introduction to Plastics and Rubber Materials in Medical Devices** Course:

- [ ] 14-15 March 2018
- [ ] 5-6 December 2018

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

Surname ..............................................................

Forename ..............................................................

Job Title/Position ..............................................................

Company ..............................................................

**CONTACT ADDRESS**

Address ..............................................................

Telephone ..............................................................

Fax ..............................................................

Email ..............................................................

**INVOICE ADDRESS** (if different)

Company ..............................................................

Address ..............................................................

Telephone ..............................................................

Fax ..............................................................

Email ..............................................................

**PAYMENT INFORMATION**

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*  
Please enter your company Reg. no.:  
Please enter your company VAT no.:  

*Please note company name on PO must state: 'Smithers Rapra and Smithers Pira Ltd'

- [ ] Cheque/Bank Transfer
- [ ] Credit Card Payment:  
  - [ ] MasterCard
  - [ ] Visa
  - [ ] American Express (please indicate)

Card number: ..............................................................

Expiry date: ..............................................................

Security Number: ..............................................................

Name on Credit Card (in CAPITALS) ..............................................................

Signature: ..............................................................

**CANCELLATION TERMS** By completing and returning this form delegates are agreeing to be bound by the cancellation terms and conditions of registration.

RETURN TO:

Smithers Rapra, Shawbury, Shrewsbury, Shropshire, SY4 4NR, United Kingdom. Enquiries Tel: +44 (0)1939 252312 Fax: +44 (0) 1939 251118  
Scan and email to: kharalambou@smithers.com  
Enrol online at: www.rapratraining.com
For more information and courses please visit:
www.smithersrapra.com/training

Conditions of Registration

Payment must be received prior to attending the event and can be paid in £ Sterling, € Euro or US $. NB: Credit card payments can only be taken in £ Sterling, unless payment is made online via our secure payment system.

The Course/Seminar Fee includes training course/seminar lecture notes, lunches and refreshments. Accommodation is not included in the fee.

Joining instructions i.e. a letter of confirmation, directions and hotel information will be sent upon receipt of your registration. Please contact the training administrator if you have not received these within 7 days of registration.

Cancellations

1. Cancellation terms for Courses/Seminars held at Shawbury:
   - Cancellations made up to 14 days or more before the requested course/seminar date will be refunded, less a 20% administration fee.
   - Cancellations made within 14 days of the course/seminar date will be subject to the FULL course fee and no refund will be given.

2. Smithers Rapra cannot be held responsible for delegate cancellations and ‘no-shows’ arising from situations beyond its control, e.g. failure to travel or attend owing to cancelled flights, missed connections, weather conditions, strikes etc., emergency or illness. Smithers Rapra may, at its discretion, provide a substitute event, or alternative date, if available.

Delegate Substitutions can be made at any time without incurring extra charge.

Transfers to later Course/Seminar Dates - this option only applies when more than one date is offered for the same course/seminar.

- Requests to transfer to a later course/seminar date made up to 14 days or more before the requested course date will be accommodated, subject to availability of places on the new course/seminar date.
- Requests to transfer to a later course/seminar date made within 14 days of the course date will be regarded as a cancellation and will be subject to the FULL course fee. No refund will be given.
- The option to transfer can be used only once, after which non-attendance will be treated as a cancellation and all outstanding invoices will be due.

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.

Delivered by experts who understand the challenges faced by those working in the industry, courses are held throughout the year at Smithers Rapra’s European HQ in Shropshire. We also offer in-company bespoke training covering polymeric materials and technology to provide support for product developers and manufacturers across all industry sectors.