Course Overview
This course will take place over 2 days, 9.15–16.00 on the first day and 09.00–15.30 on the second day. 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 will explore the scope and impact of the European Medical Device Directive (MDD) Regulations in relation to their use.

Objectives
The objective is to provide companies entering the medical device and/or accessories supply chain manufacturing or supplying plastic or rubber products, or already supplying into the device and/or accessories supply chain manufacturing or supplying plastic or rubber products, or already supplying into it but with little experience of using these materials, with an insight into the requirements of this rapidly expanding market that they need to consider and meet.

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.

Course Presenters:
Tom Forsyth, Consultant, Smithers Rapra
Tom joined Smithers Rapra in 2008, prior to which he was Technical Director of BM Polyco, a manufacturer of medical products. Before BM Polyco, he was a Technical Manager with London International Group (Durex condoms and Marigold gloves). Tom has direct experience of setting up the regulatory and testing facilities for certification of products to the Medical Devices Directive 93/42/EEC; and has conducted audits of sub-contractors to the requirements of ISO 13485 – Quality Management Systems. As a Principal Consultant, Tom continues to provide advice on medical device compliance.

Martin Forrest, Consultant, Smithers Rapra
Martin commenced his career in 1977 with James Walter & Co. Ltd, a manufacturer of rubber based products. He has a first degree and an MSc in Polymer Science and Technology and a PhD in Polymer Chemistry. He joined Rapra Technology Ltd., later Smithers Rapra in 1988 and has worked on a range of medical device related projects involving plastics and rubber, and other polymeric materials. These have addressed a wide range of topics, such as extractable and leachable studies, material selection, and failure diagnosis. During this time, he has also had senior technical roles in research projects concerned with the medical sector, such as the EU funded project Custom IMD, which was concerned with the development of novel, customised medical devices.

Paul Shipton, Director of Consultancy, Smithers Rapra
Prior to joining Smithers Rapra, Paul ran Plastics Consultancy Services. He has special interest in material selection, product development and failure diagnosis of medical devices.
Paul Shipton holds doctorate in polymer technology. Previous positions include Technical Manager for Ticona UK Ltd, Visiting Lecturer to the School of Engineering and Built Environment, University of Wolverhampton and Consultant to the Technology Innovation Centre, Birmingham City University.
His latest publication in material science is on the topic of the innovative use of polymers.

Course Fee: £520.00 plus VAT
Venue: Smithers Rapra, Shawbury, Shropshire, UK, SY4 4NR

Registration Conditions
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
- 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.
- Smithers Rapra cannot be held responsible for delegate cancellations and ‘no-shows’ arising from situations beyond its control, e.g. failures 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.
- Delegte 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 subject to the FULL course fee and 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.
Setting the Scene: the regulatory impact on requirements for performance of plastics and rubber materials in medical devices – While the EU Medical Devices Directive (MDD) does not specifically mention polymer materials, it does impact on the chemical, physical and microbiological requirements for performance of polymer materials, including sterilisation and bio-burden. This section will provide 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) – Medical Devices and accessories are subject to classification rules according to the degree and time of contact with the patient. An explanation of the classification system will be given. The relationship between Medical Device classification and European Standards such as ISO10993 and harmonised European Standards will be discussed.

Quality Management Systems for Medical Devices – An overview of the Quality System Standards ISO13485 and ISO9001 will be presented, with a focus on the sections of ISO13485 that address essential requirements of the Medical Devices Directive.

Introduction to the Medical Device Risk Assessment Standard ISO 14971 – ISO14971 is an important harmonised standard that details the requirements for the application of a risk management system for medical devices. The last revised version: ISO14971:2012 applies to manufacturers placing medical devices on the market in Europe. An overview will be given of this medical device risk management standard, which will explain the actions that should be taken to meet the requirements of this standard.

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. A method of material selection criteria will be explored focusing on the special considerations needed to ensure a device performs safely. An important consideration is disinfection or sterilisation.

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 – An overview will be given which will provide a general introduction to the subject and the types of tests that can be employed to assess the interaction between medical devices and patients. The contents and scope of the international biocompatibility standard, ISO 10993 will be included and a comparison provided of how the EU and USA/FDA biocompatibility testing requirements and application of this standard differ from one another.

Packaging Systems for Medical Devices – Medical Devices are required to provide the desired function after they have passed through the distribution system from manufacturer to patient. Packaging systems are an integral part of the function of a medical device. Requirements for packaging systems will be discussed with reference to performance specified by European Standards, including integrity and testing.

Learning Outcomes:

Attendees will

- Gain an awareness of the scope of the EU Medical Device Directive and its impact
- Understand what is classified as a Medical Device
- Appreciate the essential differences between quality systems ISO 9001 and ISO 13485
- Gain detailed awareness of the additional technical criteria which apply in the selection of medical grade polymer materials.
- Understand the options for sterilisation and their impact on different plastics and rubber materials types
- Discover the different options for testing for biocompatibility, when to use them and what they will reveal
- Appreciate the general requirements for manufacturing medical devices, depending upon classification and type.
Registration Form

Introduction to Plastics and Rubber Materials in Medical Devices

- 19-20 May 2015
- 3-4 November 2015

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

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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 (if required)

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- Cheque/Bank Transfer

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

Name on Credit Card (in CAPITALS)

Security Number

(Visa/Mastercard - last 3 numbers in the signature box on reverse of card. Amex - 4 number code on the front of the card)

Expiry Date: Signature:

Return to:
Smithers Rapra, Shawbury, Shrewsbury, Shropshire, SY4 4NR, United Kingdom.
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Fax: +44 (0) 1939 251118
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