

Introduction to Extractables & Leachables Testing



Short Course at Smithers Rapra,
Shawbury, Shropshire, UK

20th May 2010

7th October 2010

Organised by:



 **SMITHERS**
iSmithers

www.ismithers.net
www.rapratraining.com

*i*Smithers is the information business
within Smithers Rapra Technology Limited

 **SMITHERS**
Rapra

www.rapra.net

Introduction to Extractables & Leachables Testing

20th May 2010

7th October 2010

Course Overview

This course will give participants an understanding of how polymeric materials are used in pharmaceutical products and how additives and other materials related to those polymers i.e. the extractables and leachables, may be of concern or risk to the patient.

The course will also cover the regulatory aspects and requirements relating to E & L, and will highlight some of the guidelines developed to assist medical companies in defining strategy and limits for testing.

Analytical methodology, instrumentation and sample preparation will be discussed and the basic steps required for performing an E & L study will be described, including stability plans and method validation. Case studies will be used to demonstrate the processes involved.

Who will benefit from attending?

People involved in or with medical device manufacture who require an understanding of why and when extractables and leachables testing is required and how this can be achieved, for example:

- Project Managers
- Production Management
- Component Device Engineers
- Quality Assurance/Regulatory Affairs Managers
- Purchasing

Course Objectives

Participants will receive the information to be able to:

- understand exactly what information can be gained from the various tests
- decide whether E & L tests are necessary for their products, in consideration of legislation and best practice guidelines
- make the best use of the information obtained from test results

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.

Course Fee

£325.00 plus VAT

Course Presenters

Tim Hulme, Principal Pharmaceutical Consultant, Smithers Rapra, Michael Creese, Senior Consultant, Smithers Rapra, Donna Howells, Senior Consultant, Helen Lewis, Senior Consultant

Venue

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

Organisers – iSmithers

iSmithers is the information business within Smithers Rapra Technology Limited.

Smithers Rapra Technology Limited

Smithers Rapra Technology Limited, better known as Smithers Rapra, is a wholly owned subsidiary of The Smithers Group and is recognised as a world leading plastics and rubber consultancy. Smithers Rapra provides a comprehensive independent service covering technology and information services for the polymer industry and industries using plastics and rubber in any component, product or production process.

Extractables and Leachables Testing at Smithers Rapra

Smithers Rapra has considerable experience working for a wide client base; often in support of client's own in-house laboratory facilities. The test results and data has been used to support successful regulatory submissions to both the FDA and EMEA. Our consultants have a proven track record in testing and analysing a wide range of medical devices.

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 to another course 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.

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

iSmithers 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 iSmithers is limited to the reimbursement of the course/seminar fee.

course content

Background to Polymers

- Discussion of polymeric and elastomeric materials available for use, and where and why the various polymers are used.
- Polymer additives, potential impurities and the reasons for their presence.
- Review of polymer processing

Regulations and Guidelines

- Why we are interested in extractable and leachables
- Why we have to test for extractable and leachables
- Regulatory standpoints and requirements
- Working groups and guidance documents

Introduction to Extractable and Leachables

- Definition of extractables and leachables
- How extractable compounds become leachables
- Factors affecting the migration of compounds

Analytical Techniques & Approaches

- Component review & selection of critical parts
- Aim of extractable study
- Extraction methods, including solvent choice and sample preparation techniques.
- Analytical techniques overview:
 - *Gas chromatography mass spectrometry (GC-MS)*
 - *Liquid chromatography mass spectrometry (LC-MS/UV)*
 - *Non volatile residue (NVR)*
 - *Fourier transform infra spectroscopy (FT-IR)*
 - *Inductively coupled plasma atomic emission spectroscopy (ICP-AES).*
 - *Extractable study case studies*
 - *Laboratory tour*

Leachable Method Development & Validation

- Leachable method development:
 - *Selection of extractable / leachable compounds*
 - *Development of leachable analytical methods*
- Leachable method validation:
 - *Aim*
 - *Guidance / standard review*
 - *Validation parameters discussion*
 - *How to execute validation*
 - *Validation case studies*
- Leachable studies:
 - *Stability storage overview*
 - *Leachable time point analysis*

Registration Form

Fax to
+44 (0)1939 251118

Introduction to Extractables & Leachables Testing

- 20th May 2010
 7th October 2010

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

Surname.....Title

Forename

Job Title/Position

Company

Contact Address

Address.....

.....

.....

.....

Telephone.....

Fax.....

Email.....

Invoice Address (if different)

Company.....

Address.....

.....

.....

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)

Expiry Date:

Signature

Name on Credit Card (in CAPITALS)

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

Return to:

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

Tel: +44 (0)1939 250383 Fax: +44 (0)1939 251118
e-mail: gtunncliffe@ismithers.net

www.rapratraining.com

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