

EXTRACTABLES & LEACHABLES for PHARMACEUTICAL PRODUCTS **2011**

4th International Conference

27-28 September 2011

The Ashling Hotel, Dublin

*Maintaining the integrity of drug products through
best practice extractables and leachables testing*

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22 July 2011
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27-28 September 2011

Extractables and leachables are becoming an ever increasing area of regulatory scrutiny, which could be related to a number of product recalls associated with leachables. Regulators are concerned with the interaction of various drug delivery devices, such as metered dose and dry powder inhalers (MDI and DPI) and now PODPs (Parenteral and Ophthalmic Drug Products) are of increasing interest, as well as pharmaceutical process equipment.

Smithers' fourth international conference builds on the success of the previous conferences which have been beneficial to both new entrants to the field but also to those wanting to know where the field is going.

This year's conference features many leading experts from industry, the regulators (FDA and Health Canada) and industry working groups such as the PQRI, BPSA and ELSIE. There will be a particular emphasis this year on PODPs (Parenteral and Ophthalmic Drug Products) as the PQRI have recently produced the latest recommendations for extractable and leachable testing with these drug delivery devices.

Don't miss this opportunity to network with your industry peers and be brought up-to-date on the latest issues affecting extractables and leachables testing for pharmaceutical products. We look forward to seeing you in Dublin!

Early Registration Offers

Register before **22 July 2011** to take advantage of the special Early Bird Discount registration fee.

Companies sending one or two delegates

€799 + Irish VAT @ 21% per delegate before 22 July 2011

€1099 + Irish VAT @ 21% per delegate after 22 July 2011

Companies sending three or more delegates

€699 + Irish VAT @ 21% per delegate before 22 July 2011

€999 + Irish VAT @ 21% per delegate after 22 July 2011

Registration includes a copy of the proceedings, lunches and refreshments during the day. The cost of accommodation is not included in the delegate registration fee.

Sponsorship & Exhibition

A limited number of cost-effective sponsorship opportunities are available to promote your products and/or services to a highly targeted audience. Starting from as little as €750 for a wallet service this is an ideal opportunity to maximise your company's profile at one of the industry's leading events. For further information please contact Helen Charlesworth, email hcharlesworth@ismithers.net.

About the Organisers

Smithers has been organising world class technical conferences for the polymer and related industries for over 30 years. Drawing authorities from industry and academia, conferences offer the ideal forum to hear original, pioneering technical papers and meet and exchange ideas with like-minded peers from across the world. With topics spanning the latest developments in rubber and plastics technology, legislative changes and market trends, Smithers conferences continue to attract over 1,200 senior technical executives and decision makers per year.

Conference Venue

The Ashling Hotel, Parkgate Street
Dublin 8
Ireland

Tel: +353 (0)1 677 2324 Fax: +353 (0)1 679 3783

Email: info@ashlinghotel.ie www.ashlinghotel.ie

Visiting Dublin city centre couldn't be easier from the Ashling Hotel. It's just 20 minutes away by foot or take the Luas tram which takes you to the city centre in just 5 minutes. For journeys further afield, the Ashling Hotel is just a 2 minute walk from Heuston Intercity Railway Station, and a short drive to the M50 motorway – connecting you with all major routes serving the rest of Ireland. The hotel has its own multistorey car park.



The Ashling Hotel Dublin is only a 5 minute walk from the National Museum of Ireland in Collins Barracks and close to Guinness Storehouse. The Phoenix Park, Dublin Zoo and Smithfield are also within walking distance.

Accommodation

We are holding a number of rooms at the Ashling Hotel at a specially negotiated rate. Accommodation booking forms will be sent with your joining instructions on receipt of your completed conference registration form.

For further assistance please contact Sharon Garrington, email sgarrington@ismithers.net.

Extractables & Leachables Testing at Smithers Rapra

Smithers Rapra has considerable experience working for a wide client base, often in support of the clients' own in-house laboratory facilities. Test results and data generated by Smithers Rapra have been used to support successful regulatory submissions to both the FDA and EMEA.

Smithers Rapra has a proven track record in testing and analysing the following therapeutic areas and devices:

- Inhalation Products
- Nasal Products
- Medical Devices
- Endoscopes
- Ophthalmic
- Stents
- Stoppers
- DPI
- pMDI
- Implantables
- APIs
- Oral
- Nebulisers
- Injectables
- Catheters
- Topical Creams

For more information please contact info@rapra.net

Conference Agenda

Tuesday 27 September

- 08.15 COFFEE AND REGISTRATION
- 09.15 Welcome Introduction – iSmithers
- 09.30 Origins of extractables and leachables from polymer products
Tim Hulme & Dr Martin Forrest, Smithers Rapra, UK
- 10.00 An update of ELSIE activities
Dr Andrew Feilden, Smithers Rapra, UK
- COFFEE
- 11.00 PQRI PODP Extractables & Leachables Working Group: Research project on container closure systems used in parenteral and ophthalmic drug products – accomplishments and next steps
Thomas Egert, Boehringer Ingelheim Pharma GmbH & Co KG, Germany
- 11.30 The simulation study: the replacement of controlled extraction studies for PODP E&L documentation?
Dr Carsten Worsøe, Novo Nordisk A/S, Denmark
- 12.00 Closing the gap between extractables and leachables
Dr Piet Christiaens, Toxikon Europe, Belgium
- 12.30 Q & A SESSION
- 12.45 LUNCH
- 14.00 Extractables and leachables: scientific and regulatory considerations
Dr Ingrid Markovic, Food and Drug Administration, USA (via WebEx)
- 14.30 Extractables and leachables: UK regulatory perspective
Dr Dima Al-hadithi, MHRA, UK
- 15.00 COFFEE
- 15.30 Extractables & Leachables from CCS: life-cycle management and patient safety considerations for parenteral and ophthalmic drugs
Kumudini Nicholas, Health Canada, Canada (via WebEx)
- 16.00 How to set acceptance criteria for leachable studies: selection and toxicological evaluation of analytical targets
Dr Carsten B Senholt, Toxicology & Safety Pharmacology, Novo Nordisk A/S, Denmark
- 16.30 PANEL SESSION
- 17.00 CLOSE OF DAY ONE
- 18.15 EVENING SOCIAL EVENT

Conference Language

Please note that the conference will be conducted in English.

The conference organisers reserve the right to modify or change the above programme if necessary.

Programme correct at time of going to print.

Wednesday 28 September

- 08.15 COFFEE AND HOTEL CHECK-OUT
- 08.45 Current extractables/leachables thinking and its impact on the E&L approach of an elastomeric closure supplier
Dr Bram Jongen, Global Product Support Manager & Dr Renaud Janssen, Global Director of Scientific Affairs, Helvoet Pharma, Belgium
- 09.15 Best practice from a seal manufacturer's view
Dr Till Riehm, Freudenberg Process Seals GmbH & Co KG, Germany
- 09.45 Extractables/leachables from single-use systems components
Dr Weibing Ding, Pall Life Sciences, USA
- 10.15 COFFEE
- 10.45 Extraction studies on the development of packaging materials for dialysis solutions: presentation of a standard procedure and some results
Dr Michael Fünfroeken, Fresenius Medical Care Deutschland GmbH, Germany
- 11.15 Thermodesorption GC/MS as a powerful analytical tool for E&L screenings in pharma or medical grade polymers
Vincent Jeanguyot, Intertek Expert Services, Switzerland
- 11.45 Producing processed plastic materials for controlled extractables testing by the ELSIE Materials Working Group
Dr Roger Pearson & Chris Chapman, Aspen Research Corporation, USA
- 12.15 Q & A SESSION
- 12.30 LUNCH
- 13.45 A control strategy for leachables in a dry powder inhaler
Graham Wilson, GlaxoSmithKlineR&D, UK
- 14.15 Characterisation of drug and drug product related contaminants: when is a leachable not a leachable?
Michael Ludlow, LGC, UK
- 14.45 Extractables & leachables for medical devices: meeting the 510(k) requirements
Dr Kurt Moyer, NSF Pharmalytica, USA
- 15.15 Q & A SESSION
- 15.30 COFFEE
- 15.45 CLOSE OF PROCEEDINGS

For Further Information

Please contact Helen Charlesworth or Sharon Garrington, tel: +44 (0)1939 250383, email conferences@ismithers.net or visit www.polymerconferences.com.

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Delegate Registration

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Registration includes a copy of the proceedings, lunches and refreshments during the day and an evening drinks reception.

- Wallet Service:**
€750 + Irish VAT at 21% (*Insertion of one pen or brochure, up to 6 A4 pages, in every delegate conference bag*)
- Tabletop Exhibition:**
From €2000 + Irish VAT at 21% (*includes one delegate place*)
- Members Discount:**
Rapra Members are entitled to a further discount off the standard registration fee.

If you have a Promotional Code please enter it here

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Cancellation Terms By completing and returning this form delegates are agreeing to be bound by the cancellation terms and conditions of registration. Substitutions can be made at any time, please inform us in writing prior to the conference. If you wish to cancel your registration please do so in writing. A full refund less 20% administration fee will be applicable 28 days before the conference. Cancellations received after this time will be liable for the full registration fee.

Return to:
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