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# Extractables & Leachables for Pharmaceutical Products **2010**

3rd International Conference

14-15 September 2010

Holiday Inn London Kings Cross/Bloomsbury, London\*

*\*Please note: New Venue*

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



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**14-15 September 2010, London**

Impurities originating from any part of the manufacturing or storage of drug products can potentially result in expensive product recalls and damage to a company's reputation – not to mention the serious threat posed to patient safety. Nowadays extractables and leachables assessment of all materials - and especially elastomeric and plastic components - forms an integral part of the submission for approval of a new drug system or medical device.

With regulatory authorities such as the FDA and the MHRA demanding assurance that a product's integrity has been scrutinised – the pharmaceutical industry has formed a range of industry working groups such as the Product Quality Research Institute (PQRI), Parenteral and Ophthalmic Drug Products (PODP), Extractables and Leachables Safety Information Exchange (ELSIE) and Bio-Process Systems Alliance (BPSA) to work towards a common understanding of what extractables and leachables testing should be done and at what stage in the supply chain it is most appropriate.

Smithers third *Extractables & Leachables for Pharmaceutical Products* conference has been developed with ever evolving best practice guidance and region-specific regulations in mind. The conference provides a unique opportunity to learn about the latest developments from industry practitioners and working groups while networking with manufacturers, suppliers and regulators from across the global pharmaceutical industry to meet regulatory requirements and ensure compatibility in drug-package combinations.

## Early Registration Offers

Register before **30 June 2010** to take advantage of the special Early Bird Discount registration fee.

### *Companies sending one or two delegates*

£725 + VAT @ 17.5% per delegate before 30 June 2010

£999 + VAT @ 17.5% per delegate after 30 June 2010

### *Companies sending three or more delegates*

£625 + VAT @ 17.5% per delegate before 30 June 2010

£899 + VAT @ 17.5% per delegate after 30 June 2010

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.

## 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

Holiday Inn London Kings Cross/Bloomsbury  
1 Kings Cross Road,  
London WC1X 9HX  
Tel: +44 (0) 20 7833 3900  
Fax: +44 (0) 20 7917 6163

The Holiday Inn London Kings Cross/Bloomsbury is a central London hotel situated between the City of London and London's West End. Kings Cross, Farringdon and Russell Square underground stations are all within easy walking distance. The new Eurostar terminal at St Pancras is within 15 minutes walk.

The Holiday Inn London Kings Cross provides easy access to key tourist attractions such as Oxford Street, Covent Garden, The British Museum, St Pauls Cathedral and Sadlers Wells Theatre.

## Accommodation

We are holding a number of rooms at the Holiday Inn London Kings Cross/Bloomsbury at a specially negotiated rate of £123.40 including breakfast, excluding VAT, until 18 August, after which point the rooms will be released for general sale. Accommodation booking forms will be sent with your joining instructions on receipt of your completed conference registration form.

For further assistance please contact [conferences@ismithers.net](mailto:conferences@ismithers.net).

## Sponsorship & Exhibition

A limited number of cost effective sponsorship opportunities are available to maximise your corporate profile at this important event. For further information please contact Alix Reeves, [areeves@ismithers.net](mailto:areeves@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](mailto:info@rapra.net)

# Conference Agenda

## Tuesday 14 September

- 08.30 REGISTRATION AND WELCOME COFFEE  
09.25 Welcome and Introduction to Extractables & Leachables for Pharmaceutical Products 2010

### Session 1: Materials

- 09.30 Origins of extractables and leachables from polymer products  
*Dr Martin Forrest, Principal Consultant, Smithers Rapra Technology Ltd, UK*

### Session 2: Regulation of Extractables & Leachables

- 10.00 Regulatory expectations for the toxicological qualification of extractables and leachables in products  
*Dr Rachel Hawkins, MHRA, UK*
- 10.30 Acceptable variability and focused testing on container closure system (CCS) for regulatory flexibility  
*Dr Kumudini Nicholas, Team Leader, Pharmaceutical Quality Review, Health Canada, Canada, TBC*
- 11.00 Leachables in parenteral drug products and responses to these from health authorities  
*Carsten Worsøe, Research Scientist, Novo Nordisk A/S, Denmark*
- 11.30 COFFEE
- 12.00 Extractables and leachables regulation: The FDA perspective  
*Dr Ingrid Markovic, Expert Review Scientist, Center for Drug Evaluation and Research, Food and Drug Administration, USA*
- 12.30 Panel Discussion

### Session 3: Industry Group Updates:

#### PQRI's PODP

- 13.00 PQRI research project on container closures systems used in parenteral and ophthalmic drug products  
*Thomas Egert, Boehringer Ingelheim Pharma GmbH & Co KG, Germany*

#### 13.30 LUNCH

### Extractables and Leachables Safety Information Exchange (ELSIE)

- 14.45 ELSIE: Overview and the value proposition  
*Doug Ball, Research Fellow, Safety Sciences, Pfizer & Lee Nagao, Senior Science Advisor, Drinker Biddle and Reath, LLP, USA*
- 15.15 How the ELSIE database can help de-risk material selection  
*Arthur J Shaw, Associate Research Fellow, Pfizer Inc, USA*
- 15.45 Data from pilot program of ELSIE's Materials Information Working Group  
*Andrew Feilden, Pharmaceutical and Analytical R&D, AstraZeneca, UK*
- 16.15 COFFEE
- 16.45 Toxicology issues in extractables and leachables  
*William P Beierschmitt, Associate Research Fellow, Drug Safety Research & Development, Pfizer, Inc, USA*
- 17.15 Demonstration of ELSIE database  
*Steve Beck, Development Manager, Non-clinical Safety Projects, GlaxoSmithKline Research & Development, USA*
- 17.45 End of Day One
- 18.30 Evening Drinks Reception

### 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.

## Wednesday 15 September

- 08.30 COFFEE

### Session 3: Industry Group Updates (Continued)

#### IPAC-RS Initiatives

- 09.00 The IPAC-RS OINDP Materials Working Group: Opportunities for improving materials quality  
*Jason Creasey, Andrew Feilden, Mike Hodgson, Jamie Mullis, Lee Nagao, Gaby Reckzuegel, Cheryl L M Stults on behalf of the IPAC-RS OINDP Materials Working Group, USA*

#### BPSA Update

- 09.30 BPSA consensus recommendations for extractables testing of single-use process equipment  
*Jerald Martin, Chairman, Bio-Process Systems Alliance (BPSA) & Senior VP Scientific Affairs, Pall Life Sciences, USA*

### Session 4: E&L Testing: Industry Best Practice

- 10.00 Routine method development: perils, pitfalls and triumphs  
*Dr Cheryl L M Stults, Novartis Pharmaceuticals Corp, USA*
- 10.30 COFFEE
- 11.00 How to speed up extractable and leachable testing to achieve quality by design  
*Dr Andrew Feilden, Pharmaceutical and Analytical R&D, AstraZeneca R&D, UK*
- 11.30 Comparison of the application of a risk-based approach to the design of an extractables and leachables programme for a biopharmaceutical product and a dry powder inhaler product  
*Jason Creasey, GlaxoSmithKline, UK*
- 12.00 The role of L&E tests within a risk management framework  
*Carsten B Senholt, Research Scientist, Toxicology & Safety Pharmacology, Hans Holmegaard Sørensen, CMC Project Support & Sourcing & Jytte Pedersen, Protein Characterization, Novo Nordisk A/S, Denmark*
- 12.30 LUNCH
- 13.45 Application of Quality by Design (QbD) principles to extractables/leachables assessment: Establishing a design space for terminally sterilized aqueous drug products stored in plastic packaging system  
*Dr Dennis Jenke, Principal Scientist, Baxter Technology Resources, USA*

### Session 5: Medical Grade Polymers

- 14.15 E&Ls - A converter's view  
*John Toynbee & Peter Warren, James Walker Ltd, UK*
- 14.45 Use of blister material and their validation for DPI  
*Peter Claessens & Thorsten Schmeck, Amcor Flexibles, Germany*
- 15.15 COFFEE
- 15.45 A pharmaceutical rubber formulation based on an unconventional elastomer – extractables behaviour before and after gamma irradiation  
*Dr Ir Renaud Janssen, Global Director of Scientific Affairs, Helvoet Pharma, Belgium*
- 16.15 Clean and effective curing vital for elastomer applications in pharmaceutical packaging  
*Dr Wai Keung Wong, ExxonMobil Chemical Europe, Belgium*
- 16.45 CONFERENCE CLOSES

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**Wallet Service:**  
 £685 + VAT at 17.5% (*Insertion of one pen or brochure, up to 6 A4 pages, in every delegate conference bag*)

**Tabletop Exhibition:**  
 From £1800 + VAT at 17.5% (*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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**Return to:**  
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