Conference Presentations

2014 Orlando Inhalation Conference: Approaches in International Regulation

Day 1

Are We Open to Innovation?

- Opening Remarks – Martin Oliver
- The Future of Regulatory Science Research – Lawrence Lesko
- Evolving FDA’s Approach to Pharmaceutical Quality - Lawrence Yu
- Carpe Diem: Opportunities in Inhaled Therapy – Anthony Hickey

Devices and Patient Interface

- Key Challenges in Device Design and Manufacturing – Orest Lastow
- Emerging and Established Inhaler Markets: Can One Size Fit All? – David Howlett
- Patient Factors Consideration – Dave Parkins
- Is BE Just Math? The Importance of Handling Patient Feedback for BE Assessments – Stefan Leiner

General Risk Assessment and Development of Affordable OIPS

- New OGD OIP Guidelines – Sau (Larry) Lee
- Considerations for Generic OIPs in Brazil – Gustavo Mendes Lima Santos
- flutiform® pMDI: Development Continues After Approval – A Global Perspective – Geraldine Venthoye
- Comparison of OIP Experiences in Different Markets – David Waite
- Challenges in the Development of Affordable Orally Inhaled Products - Juliet Rebello
- Industry Panel
  Moderators: Ying Li and Martin Oliver
  Panelists: Geraldine Venthoye, David Waite, Juliet Rebello, Shuguang Hou

Day 2

- Welcome to Day 2 - Mike Hindle

New Approaches to In Vitro Testing for Pharmaceutical Development

- Moving to More Realistic In Vitro Testing of OIPS – Renish Delvadia
- In-silico OIP Development – Worth Longest
- The Role of Particle Dissolution and Cellular Uptake Testing in OIP Bioequivalence Determinations – Ben Forbes
- Critical Device and Formulation Controls Required in Achieving In Vitro Comparability of OIPS – Robert Price

In Vitro and PK Generic

- In Vitro and PK Studies for Generics Based on European Experience – Alfredo García Arieta
- Role of PK Studies in Bioequivalence of Orally Inhaled Drugs – Robert Lionberger
- Modified Chi-Square Ratio for Comparing Aerodynamic Particle Size Distribution Profiles – Benjamin Weber
- A Real Case Comparison of Average and Population Bioequivalence for Evaluation of APSD Data – Dennis Sandell

Development Considerations

- Statistical Considerations in Design and Analysis of Equivalent Studies Using PD and Clinical End Points – Scott Haughie
- **Handling Reference Product Variability in PK/PD Trials** – Patrick Darken
- "Best Practices" Bioequivalence Testing for pMDIs with spacer/VHC – Myrna B. Dolovich
- **Developing First to Market or 505b2** – Prasad Peri
- **Scientific and Regulatory Considerations for Development of Generic OIPs via 505j** – Bhawana Saluja
- A Panel on New In Vitro Approaches
  - Moderators: Craig Davies-Cutting and Mike Hindle
  - Panelists: Ben Forbes, Günther Hochhaus, Worth Longest, Rob Price, Renish Delvadia, Prasad Peri, Larry Lee

**Day 3**

**How to In Vitro, PK/PD, and Device Data Fit Together?**
- **Lesson Learned from Approval of Generic Nasal Products** – Julie Suman
- **FDA Views on Nasal Products** – Bing Li
- **In Vitro/In Vivo Comparisons of Formoterol Fumarate MDI to Formoterol Fumarate DPI: Lessons Learned** – Colin Reisner
- **IVIVC in Pediatric OIPs** – Herbert Wachtel
- **Predictive Modeling of Deposition, Dissolution, Absorption, and System Exposure** – Per Bäckman

**PD to Demonstrate Efficacy and Safety**
- **OIP BE Case Study** – Stephen Horhota
- **Evaluation of the Feasibility of Pharmacodynamic BE Studies of OIPs through Monte Carlo Simulations** – Bhargava Kandala
- **Study Designs and PD/Clinical End Points to Demonstrate Therapeutic Equivalence: European Views** – Alfredo García Arieta
- **Use of Bronchoprovocation to Determine Bioequivalence of Beta Agonists** – Leslie Hendeles
- **Biomarkers of Anti-inflammatory Effects in the Airways and the Evaluation of Therapeutic Equivalence** – Peter Daley

**PD Biomarkers and Safety**
- **A Double Blind Placebo Controlled Study Using Novel Biomarkers** – Jan DeBacker
- **Points to Consider in Design/Conduct of HPA-axis Studies Comparing the Systemic Safety of ICS-Products** – Robert Hermann
- **Assessment of Beta-Agonist Safety** – Sanjeeva Dissanayake
- A Regulatory Panel
  - Moderator: Günther Hochhaus
  - Panelists: Eva Agurell, Alfredo García Arieta, Gustavo Mendes Lima Santos, Rob Lionberger, Bing Li
IPAC-RS 2011 Conference: Bringing Value to the Patient in a Changing World

On March 29-31, 2011, IPAC-RS hosted its third open public conference entitled "Bringing Value to the Patient in a Changing World" where industry, regulators and other interested parties discussed best scientific and regulatory approaches for orally inhaled and nasal drug products.

The Conference program is posted here: Final Program

A Conference Report is available here: Conference Report

Day 1

- Welcome – Sue Holmes
- Keynote Address: Asthma and its Many Unmet Needs: Directions for Novel Therapeutic Approaches – William W. Busse
- COPD Patient’s Needs – Stephen I. Rennard
- It’s Easy, Just Take Two Puffs: A Global Perspective on Patient Educational Requirements and Needs Related to Inhaled Therapies – Monica Fletcher
- Matching Patient to the Device – Søren Pedersen
- FDA Efforts on Liaising with Patients – Deborah J. Miller
- Summary of the 2010 ISAM/IPAC-RS Equivalence Workshop, with a Focus on Patient-Related Aspects – Dennis O’Connor
- The MDI – In Vitro Measures to Confirm Patient Perceptions: HFA vs CFC – Bill Doub
- Lifting Medication Adherence: Lessons from Internet Connected Packaging – Joshua Wachman
- Talking Packs: Making Packaging Part of the Treatment – Tim Chesworth
- Regulatory Expectations for User Testing – Paul Lucas
- Human Factors and the Design of Inhalation Devices – Stephen Eason and Julia Dixon
- Human Factors "Usability" in the Review of New Medical Devices at FDA’s Center for Devices and Radiological Health (CDRH) – Ronald D. Kay

Day 2

- Keynote Address: FDA View on Assessing Quality of Inhaled Products and Links to Efficacy and Safety – Prasad Peri
- Applying Quality by Design Principles to Analytical Methods Associated with OINDPs – Andy Rignall
- So You Want to Use Parametric Tolerance Testing for Control of Delivered Dose Uniformity? – Greg Larner
- Overview of Effective Data Analysis – Terry Tougas
- Dissolution Testing for Inhaled Products – Trevor Riley and Dave Christopher
- Strong Foundations: Building Quality Through the Supply Chain – Barbara Falco
- Collaborating with the Global Supply Chain on Materials Requirements and a Rationalized Testing Paradigm – James Mullis
- Supply Chain Approaches to Ensuring Component Quality – Ken Chesney
- Regulatory Perspectives on Supply Chain Quality and Security – Vibhakar Shah

Day 3

Workshop #1: Leachables & Extractables – Experience to Date with PQRI Recommendations (Qualification and Analytical Evaluation Thresholds)

- Brief Overview of PQRI Recommendations Challenges and Successes – Daniel Norwood
- Leachables and Extractables: Evolution of Regulatory Aspects and Perspectives on PQRI Recommendations – Guirag Poochikian
- **Work of the PQRI PODP** – Tom Feinberg
- **Case Study: A Problematic Extractable for a Pulmonary Delivery Device System** – William Beierschmitt
- **A Step-wise Approach for Leachables & Extractables Evaluation in pMDI Product Development** – Andrea Mieth
- **Experiences with Adoption of the PQRI Best Practice Guidelines When Applied to Development of an E&L Development Package for DPI** – Jason Creasey

**Workshop #2: Abbreviated Impactor Measurements and Effective Data Analysis - Implementing a New Best Practice for OIP Aerosol Particle Size Analysis**

- **Lifecycle Strategies for Using EDA, AIM and Full Resolution Impactor** – Terry Tougas
- **Control Strategies for APSD** – Rajni Patel
- **Equipment Options for AIM and Beyond** – Jolyon Mitchell
- **Precision and Accuracy of AIM** – Dave Christopher and Rajni Patel
- **Considerations for Applying EDA to an Existing Product** – Helen Strickland
- **Road to Adopting AIM/EDA as a Standard** – Adrian Goodey

**Workshop #3: Ensuring Patient Success: Improving Adherence Through Concordance**

- **The Voice of the Patient** – Nancy Sander
- **Patient Perspective** – Sandra Fusco-Walker
- **Patient Perspective** – John Walsh
- **Health Care Provider Perspective** – Barbara Yawn and Suzanne Lareau
- **Disease Management and Health Outcomes Perspective/Purchaser Perspective** – Len Fromer

**IPAC-RS 2011 Conference Posters**

<table>
<thead>
<tr>
<th>Title</th>
<th>Authors</th>
</tr>
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<tbody>
<tr>
<td>Albuterol in situ Bioadhesive Nasal Inserts of Albuterol Sulphate</td>
<td>Mohamed Etman, Raga Farid, Abdelazim Ebian, Aly Nada</td>
</tr>
<tr>
<td>Oral Inhalation Therapy for Broncho-Constrictive Disease Management: Meeting the Challenge of Developing More Patient Appropriate Devices</td>
<td>Jolyon Mitchell</td>
</tr>
<tr>
<td>In Vitro Evaluation of Poorly Soluble Inhalation Compounds: Effect of Media, Lactose, Drug Particle Size and Concentration</td>
<td>Susan Heimbecher, Nastaran Sigari and Nishit Patel</td>
</tr>
<tr>
<td>Summary of Techniques for Measuring Dissolution of Orally Inhaled Products: Review of Published Applications</td>
<td>Andrew Cooper, Trevor Riley, Dave Christopher, Jan Arp, Agnes Colombani, Svetlana Lyapustina, Janet Maas, Jolyon Mitchell, Maria Reiners, Frank Thielmann, Terrence Tougas</td>
</tr>
<tr>
<td>Application of the Abbreviated Impactor Measurement (AIM) concept: A Reduced Extraction Method for the Andersen Cascade Impactor</td>
<td>Shari Sellers, Jennifer Wylie, Brent Donovan</td>
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<tr>
<td>Influence of Stability Effects on Delivered Dose PTIT Acceptance Probabilities</td>
<td>Hans-Joachim Delzeit and Stefan Leiner</td>
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<tr>
<td>In Vivo Nasal Deposition from Different Delivery Devices and Formulations</td>
<td>Samir Shah, Chris George, Robert Berger, Pranav Gupta, Jason Wan, David Monteith, Alyson Connor, John McDermott, Wu Lin</td>
</tr>
<tr>
<td>Design of Experiments to Optimize an In Vitro Nasal Cast to Predict Human Nasal Drug Deposition</td>
<td>Samir Shah, Chris George, Walter Horodnik, Joel Sequeira, David Monteith, Colin Dickens, Anna Banaszek, David Ward</td>
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<tr>
<td>Influence Of Gamma-Radiation On Additives In HDPE – Used For Primary Packaging Components</td>
<td>Daniela Marx, Dr. Holger-Thorsten Steinführer</td>
</tr>
<tr>
<td>Application and Limitation of QbD principles in method development and validation</td>
<td>Heike Gottschalg, Rüdiger Gössl, Dr. Holger Memmesheimer</td>
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<td>Novel Adaptation of a Laser Diffraction Measurement Technique</td>
<td>Chad Smutney, Benoit Adamo, Art Hamfeldt, Saiyam Shah</td>
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<tr>
<td>Pressure Profiling In Development of a Dry Powder Delivery System</td>
<td>Chad Smutney, Benoit Adamo, John Polidoro, Brendan Laurenzi, Carl Sahi</td>
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<tr>
<td>Considerations For Human Factors In Developing A Pulmonary Drug/Device Delivery System</td>
<td>P. Spencer Kinsey and Chad Smutney</td>
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<td>Imaging deposited particles in airways of laboratory animals</td>
<td>Anthony Wexler, Praveen Srirama, Chris Wallis, and DongYoub Lee</td>
</tr>
<tr>
<td>How Do We Ensure Material Quality for OINDP?</td>
<td>James Mullis, Gaby Reckzuegel, Andrew Feilden, Jason M. Creasey, Mike Hodgson, Bobbijo Redler, Cheryl L. M. Stults, Daniel Dohmeier, Lisa Dick, Fred Adair, Lee Nagao, Maggie Liu</td>
</tr>
<tr>
<td>How PTI-TOST, Control Strategy Principles and Acceptance Sampling Consensus Standards can Work Together to Achieve an Appropriate Quality Assessment Strategy of Delivered Dose Uniformity of OIPs</td>
<td>Helen Strickland, Lee Clewley and DDU Working Group</td>
</tr>
<tr>
<td>Non-Impactor-Based Methods for Sizing of Aerosols Emitted from Oral and Nasal Inhaler Drug Products (OINDP)</td>
<td>Richard Bauer, Jolyon Mitchell, Svetlana Lyapustina, Terrence Tougas</td>
</tr>
<tr>
<td>A Risk Based Approach to Device Design, Development &amp; Industrialisation</td>
<td>Mike D Hodgson, Declan Reilly, Charles Godfrey, Stuart Broughton &amp; Ian Vaughan</td>
</tr>
<tr>
<td>Analytical methods Quality by Design (AM-QbD) approach implemented within GlaxoSmithKline (Inhaled Product and Device Technology) for Orally Inhaled Drug Products</td>
<td>Geoffrey E Daniels, Andrew J Crumpton</td>
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<tr>
<td>Advantages of Atmospheric Pressure Gas Chromatography (APGC) Ionization in Extractable Identification</td>
<td>Baiba Cabovska, Douglas Stevens, John Cunningham, Sam Shum, and Arthur Bailey</td>
</tr>
<tr>
<td>Development of Dissolution Methodology for Dry Powder Inhalation Aerosols</td>
<td>Jason Mees, Craig Fulton, Suzanne Wilson, Nicola Bramwell, Marilyn Lucius &amp; Andrew Cooper</td>
</tr>
<tr>
<td>Drug Delivery to the Sinuses via Pulsating Aerosols - Results from a Scintigraphic Deposition Study in Healthy Volunteers</td>
<td>Winfried Möller, Uwe Schuschnig, Gülnaz Khadem Saba, Karl Häussinger, Manfred Keller, Lisa Cambridge</td>
</tr>
<tr>
<td>An Investigational Patient Monitoring System to Generate Objective Information on Patients Drug Adherence to Inhaled Medications</td>
<td>Carola Fuchs, Lisa Cambridge, Wolfgang Achtzehner, Robert P Notifiedorski, Stefan Seemann and Martin Knoch</td>
</tr>
<tr>
<td>Principle Component Analysis as a tool for description of Aerodynamic Particle Size Distribution</td>
<td>Alan Silcock, Rachel Brody</td>
</tr>
<tr>
<td>Determination of Particle Size Distribution of an Orally Inhaled Drug Product: Automated Microscopy and Raman Spectroscopy</td>
<td>Linda H. Kidder, Kenneth S. Haber, Janie Dubois, and E. Neil Lewis</td>
</tr>
<tr>
<td>The EPAG Workshop on the Abbreviated Impactor Concept (AIM) in December 8th 2010 in Edinburgh, UK: Status, Key Results and Future Needs in Oral Inhaled Product (OIP) Testing</td>
<td>Jolyon Mitchell and Steve Nichols</td>
</tr>
<tr>
<td>Dissolution Testing for Inhaled Products</td>
<td>Maria Reiners, Birte Jensen, Markus Wolkenhauer, Petra Ritzheim, Marc Egen</td>
</tr>
<tr>
<td>Regulatory Science and Guidance for Orally Inhaled and Nasal Drug Products</td>
<td>Jackie Schumacher, Ray Ormiston, Bettina Berner, Nicholas Childerhouse, Jeffrey Ding, Greg Howe, Michael James, J.R. Keegstra, Rosella Musa, Tiziana Peveri, Andy Rignall, Mary Ann Smith, Eileen Wyka, Svetlana Lyapustina, Ilse Peterson, Chihiro Ikegami</td>
</tr>
<tr>
<td>FDA Approval Times for OINDPs: A Review 2000-2010</td>
<td>Ray Ormiston</td>
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IPAC-RS Satellite Conference at RDD Europe 2011: Perspectives on Efficient Data Analysis Methods and Abbreviated Impactor Measurements as Quality Assessment Tools

The IPAC-RS Satellite Conference, held on Friday, 6 May 2011, included short presentations from representatives of regulatory agencies, pharmacopeias and industry followed by interactive discussions with the audience around technical and statistical aspects of EDA and AIM, and the lifecycle approach to incorporating EDA and AIM in product development, registration and manufacturing.

The program for the conference and a summary report are available.

- Introduction and Questions & Answers about Technical Aspects of EDA and AIM: Incorporating EDA and AIM into the Development Cycle - Terrence P. Tougas, Ph.D.
- Detecting Differences in APSD APSD: Efficient Data Analysis (EDA) vs. Stage Groupings - David Christopher
- Pharmaceutical Perspectives on EDA and AIM - European Viewpoint - Steven C. Nichols, Ph.D.
- Pharmacopeial Perspective on EDA and AIM - US Viewpoint - Paul Curry, Ph.D.
- European Regulatory Perspectives on EDA and AIM - Marjolein Weda, Ph.D.
- USA Regulatory Perspectives on EDA and AIM - Prasad Peri, Ph.D.
ISAM/IPAC-RS 2010 Equivalence Considerations EU Workshop

On 12-13 October 2010 IPAC-RS and The International Society for Aerosols in Medicine (ISAM) hosted a joint 2-day Workshop European Workshop on Equivalence Considerations for Orally Inhaled Products for Local Action in Frankfurt, Germany.

The Conference program is [posted here](#).

**Day 1**

- [Introduction to Workshop](#) – Sue Holmes
- [Overview of Plenary 1 Session](#) – Gur Jai Pal Singh
- [Generic Medicines: Understanding the Legal Framework in the EU, US and Canada](#) – Mary Devlin Capizzi
- [Experience with OIP Equivalence Determinations in the Netherlands – Focus on In-vitro Aspects](#) – Marjolein Weda
- [MHRA/UK Experience – Focus on In-vivo, Design of Clinical Studies, Biomarkers, PK/PD](#) – Sanjeeva Dissanayake
- [MPA/Swedish Experience with OIP Equivalence Determinations](#) – Eva Agurell
- [Spanish Interpretation and Application of the OIP Guideline](#) – Alfredo García Arieta
- [Experience with Canadian Guidance: Similarity and Distinction Relative to European Approach](#) – Myrna Dolovich
- [An Overview of the FDA Position and Experience with Equivalence of Respiratory Drugs](#) – Dale Conner
- [Overview of Plenary 2 Session](#) – Michael Golden and David Cipolla
- [Synopsis of the RDD/PQRI PK Workshop](#) – Dennis O'Connor
- [Dose-Response and Related Mathematical Considerations](#) – Gur Jai Pal Singh
- [Equivalence of OIPs in Europe: Present and Past Approval Principles](#) – Anders Fuglsang
- [Subject Populations and Study Designs](#) – Richard Ahrens
- [Review of the EMEA Guidelines’ In-Vitro Equivalence Criteria for Cascade Impaction Data](#) – Dennis Sandell
- [Use of In Vitro vs In Vivo Data To Conclude Equivalence of Two Inhaled Products](#) – Dave Parkins
- [Some unresolved issues in the use of PK for equivalence of OIPs](#) – Günther Hochhaus

**Day 2**

Moderators: Colin Reisner, Richard Ahrens, Sanjeeva Dissanayake
- [Track A: Considerations for Design of Equivalence Studies](#)
- [Summary Slides from Track A](#)
- [Track B: In Vivo Tests (PK, PD and Biomarkers)](#)
- [Summary Slides from Track B](#)
Moderators: Myrna Dolovich, Bill Doub, Dave Parkins, Marjolein Weda
- [Track C: “In-Vitro Only” Equivalence](#)
- [Track C Extra Slides](#)
- [Summary Slides from Track C](#)
Moderators: Dennis Sandell, Tim Chesworth, Paul Lafferty, Robert Price
- [Track D: Device Design Similarity & Testing Needed to Support Device Changes](#)
- [Summary Slides from Track D](#)
IPAC-RS 2008 Conference

On September 22-24, 2008 IPAC-RS hosted its second open public conference entitled "Doing the Right Thing" in the Changing Culture of Design and Development of Inhalation and Nasal Drug Products: Science, Quality, and Patient-Focus where industry, regulators and other interested parties discussed best scientific and regulatory approaches for orally inhaled and nasal drug products.

The Conference Program and an Executive Summary are available here.

Day 1

- **Keynote Address: Embracing Challenges & Opportunities to Enhance Quality of OINDP** - Jim Spavins
- **Quality by Design and OINDP: Setting the Stage** - John Berridge
- **Panel - Lessons Learned from Implementation of ICH Q8, Q9 and Q10 - Regulatory Agency Perspectives**
  - Co-Moderators: Carol DeSain and Bill Paulson
  - Panelists: John Berridge, Michael Golden, Chris Marriott, Moheb Nasr, Krishnan Tirunellai
- **Patient Perspective** - John Walsh (Alpha-1 Foundation)
- **Evolving Regulatory Developments** - Stefan Leiner
- **Role of Standards in Drug and Device Development** - Pat Picariello
- **Panel - Application of Evolving Regulatory Landscape to OINDP**
  - Moderator: Michael Golden
  - Panelists: John Berridge, Blair Fraser, Sabina Hoekstra-van den Bosch, Stefan Leiner, Joseph Lim
- **Day 1 Summary Slides**

Day 2

- **Keynote Address: Changing the Culture: Why Walking the Green Walk Globally Matters** - Paul Narog
- **Panel - Potential for Green Chemistry and Green Engineering in OINDP: Design for Environment**
  - Sharon Austin
  - David Constable
  - Buzz Cue
- **Industry Roundtable Discussion: Green Product Development is Good Business - Highlighting Industry's Best Green Practices**
  - Moderator: Barbara Falco
  - Panelists: Paul Atkins, David Constable, Joanne Jaeger, Paul Narog, Elizabeth Girardi Schoen
- **Patient Perspective** - Nancy Sander (Allergy & Asthma Network - Mothers of Asthmatics)
- **Panel - Design Control for OINDP**
  - Moderator: John Hart
  - Panelists: Guillaume Brouet, Tim Chesworth and Paul Lafferty, Dave Christopher
- **Polling Results**
- **Practical Perspectives in the Application of QbD to OINDP** - Dave Parkins
- **Day 2 Summary Slides**
Day 3

- **Keynote Address: Future Opportunities in OINDP Development** - Paul Huckle
- **Lessons Learned from Other Industries - Overcoming Supplier-Manufacturer Challenges: Perspectives from Toyota North America and ArvinMeritor, LVS** - Dennis Cuneo and Sherry Welsh
- **QbD & Manufacturer-Supplier Partnerships** - Barbara Falco and Jo Ward
- **Lifecycle Approach to Specification Setting** - Dave Christopher
- **Patient Perspective** - Suzanne Pattee (Cystic Fibrosis Foundation)
- **QbD & Manufacturer-Supplier Partnerships** - Barbara Falco and Jo Ward
- **Lifecycle Approach to Specification Setting** - Dave Christopher
- **Patient Perspective** - Suzanne Pattee (Cystic Fibrosis Foundation)
- **Panel - Application of QbD to Clinical Trial Design for OINDP: Regulatory CMC & Clinical Perspectives**
  - Moderator: Don Chambers
  - Panelists: Wally Adams, Badrul Chowdhury, Ken Furnkranz, Joseph Lim, Prasad Peri, Jun Zhang
- **Clinical Relevance of Aerosol Quality Attributes: Exubera Case Study** - Nancy Harper
- **Moving Towards the Desired State - Roundtable: Regulatory and Industry Perspectives**
  - Moderator: Andy Rignall
  - Panelists: Sabina Hoekstra-van den Bosch, Chuck Hoiberg, Rich Levy, Joseph Lim, Rik Lostritto, Reggie Saraceno, Terry Tougas

**IPAC-RS 2008 Conference Posters**

The Conference plenary sessions were supplemented by a scientific poster session that addressed a wide range of topics such as bioequivalence requirements for OINDP, optimized cascade impaction and other analytical methods, statistical design of experiments for device-drug combination products, extractables and leachables, and approaches to managing the supply chain.

<table>
<thead>
<tr>
<th>Title</th>
<th>Authors</th>
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</thead>
<tbody>
<tr>
<td><strong>Regulatory Issues</strong></td>
<td></td>
</tr>
<tr>
<td><strong>IPAC-RS Strategic Vision</strong></td>
<td>David Cipolla, Terrence Tougas, Mary Devlin Capizzi, Don Chambers, Dave Parkins, Andy Rignall, Jackie Schumacher, Mary Ann Smith</td>
</tr>
<tr>
<td><strong>Establishing the Shelf Life of Pharmaceutical Products</strong></td>
<td>Terrence Tougas, Suntara Cahya, David Christopher, Dennis Sandell</td>
</tr>
<tr>
<td><strong>Points to Consider for a Pharmaceutical Development &quot;P2&quot; Report for OINDP: An Industry View</strong></td>
<td>Jackie Schumacher, Alex Bell, Mark Broughton, Mukul Dalvi, John Hart, Susan Holmes, Terry Kosobud, Paul Lucas, Lee Nagao, Tilo Schönbrodt, Mary Ann Smith, Terrence Tougas, Tony Wilkinson, Xian-Ming Zeng</td>
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<tr>
<td><strong>Requirements for Orally Inhaled and Nasal Drug Products (OINDPs) Based on Risk Management</strong></td>
<td></td>
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<tr>
<td><strong>Risk Management Interactive Poster</strong></td>
<td>Anthony Hickey and Kahkashan Zaidi</td>
</tr>
<tr>
<td><strong>USP Aerosols Experts Committee: Responsibilities and Activities</strong></td>
<td></td>
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<tr>
<td><strong>Aerodynamic Particle sizing</strong></td>
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<tr>
<td><strong>Comparative Analysis of Manual Versus Automated Actuation Parameters for Droplet Size Determination by Laser Diffraction for Spray Devices</strong></td>
<td>Robin Spivey and LaMonica Ware</td>
</tr>
<tr>
<td><strong>A Comparison of Different Approaches to Estimating the Mass Median Aerodynamic Diameter (MMAD) of OINDP Aerosols from Cascade Impactor Data</strong></td>
<td>Terrence Tougas, David Christopher, Monisha Dey, Jolyon Mitchell, Svetlana Lyapustina, Michael Van Oort, Stephen Stein</td>
</tr>
<tr>
<td><strong>Controlling Variability during Aerodynamic Particle Size Measurement</strong></td>
<td>Sarah Walker, Debbie Kraus, Tamsin Jenkins, Liz Clift</td>
</tr>
<tr>
<td><strong>Lean Data Analysis for Cascade Impaction Measurements</strong></td>
<td>Terrence Tougas, Dave Christopher, Svetlana Lyapustina, Jolyon Mitchell, Helen Strickland, Bruce Wyka</td>
</tr>
<tr>
<td><strong>Utilization of a climate box for optimization of cascade impaction measurements ensuring control of impactor temperature</strong></td>
<td>Ellen Bitterle, Anke Luithlen, Karin Reul, Albert Bucholski, Manfred Keller</td>
</tr>
<tr>
<td><strong>Analytical Methods – General</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Analytical Methods Quality by Design (AM-QbD) Risk Assessments undertaken within GlaxoSmithKline (World Wide Inhaled Product Development) for Orally Inhaled and Nasal Drug Products</strong></td>
<td>Andrew J. Crumpton, Geoffrey E. Daniels, Karl M. Ennis, and Nick C. Turner</td>
</tr>
<tr>
<td><strong>The Discrimination of Robustness and Ruggedness Factors During the Evaluation of Analytical Methods for Orally Inhaled and Nasal Drug Products</strong></td>
<td>Andy Rignall, David Christopher, Andrew Crumpton, Kevin Hawkins, Sebastian Kaerger, Svetlana Lyapustina, Holger Memmesheimer, Adrian Parkinson, Mary Ann Smith</td>
</tr>
<tr>
<td><strong>Quality by Design for Analytical Methods Intended for Use with Orally Inhaled and Nasal Drug Products</strong></td>
<td>Andy Rignall, David Christopher, Andrew Crumpton, Karl Ennis, Kevin Hawkins, Sebastian Kaerger, Svetlana Lyapustina, Holger Memmesheimer, Adrian Parkinson, Mary Ann Smith</td>
</tr>
<tr>
<td><strong>Quality by Design Systematic Chromatographic Method Development</strong></td>
<td>Oscar Liu, Justin Pennington, Tina Masiuk, Zhenyu Wang, Honggen Zhang, Kevin DeBoyace, Pallavi Mehta, Brent Donovan</td>
</tr>
<tr>
<td><strong>Extractables &amp; Leachables</strong></td>
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<tr>
<td><strong>The Extractables and Leachables Safety Information Exchange (ELSIE): Developing an Extractables/Leachables</strong></td>
<td>Douglas Ball, Steve Beck, Arthur Shaw</td>
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<tr>
<td><strong>How Low can we Go? Sensitivity and the Analytical Evaluation Threshold for Leachables</strong></td>
<td>James Mullis, Scott Pennino, Daniel Norwood</td>
</tr>
<tr>
<td><strong>Tackling the Extractables and Leachables Challenge: Managing Extractables Along the Supply Chain</strong></td>
<td>Cheryl Stults, Barbara Falco, Matthew Coates, Jason Creasey, Daniel Dohmeier, Andrew Feilden, Simon Kaar, James Mullis, Lee Nagao, Daniel Norwood, Gaby Reckzuegel, Bobbijo Redler, Andy Rignall, Caesar Snodgrass-Pilla, Xian-Ming Zeng</td>
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<td><strong>Use of Designed Experiments to Understand and Control Variability of Extractables</strong></td>
<td>Nathan Knotts, William Duffield, Arthur J. Shaw, Suzette Roan, Cheryl L.M. Stults</td>
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<th>Formulation &amp; Process development</th>
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<td><strong>Development of Robust Capsule based Dry Powder Inhalation Formulations: Moving towards Quality by Design</strong></td>
<td>Angela Armanni, Ruth Leu Marseiler, Mukul Dalvi, Markus Otz, Jean-Daniel Bonny</td>
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<td><strong>From Understanding to Control: A Successful Application of Multivariate Modeling in Commercial Manufacturing</strong></td>
<td>Beth Morgan, Chris Wong, Wilvan Wee, Brad Flynn, Mike Bowley</td>
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<td><strong>Predicting bronchodilator response of a short acting beta-2-agonist from aerodynamic particle size data using artificial neural networks</strong></td>
<td>M. de Matas, Q. Shao, M. Biddiscombe, H. Chrystyn, P.J. Barnes, O.S. Usmani</td>
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<td><strong>Detecting Siliceous Flakes in Glass Containers using Microscopic Techniques</strong></td>
<td>Frank Bales, Brian Mitchell</td>
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<td><strong>Foreign Particles Method Development and Identification in Inhalable Drug Products with Single Particle Explorer in the QbD Paradigm</strong></td>
<td>Oliver K. Valet, Markus Lankers</td>
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<td><strong>Simultaneous Raman micro-spectroscopy and Morphological analysis of Particles from an Orally Inhaled Product – A Novel Analytical Approach for QbD</strong></td>
<td>E. Neil Lewis, Kenneth S. Haber, Linda H. Kidder, Janie Dubois</td>
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IPAC-RS 2006 Conference

On November 6-8, 2006, IPAC-RS hosted its first open public conference entitled "Inhalation and Nasal Drugs: The Regulatory Landscape", where industry, regulators and other interested parties discussed best scientific and regulatory approaches for orally inhaled and nasal drug products. The Conference program is available here.

Day 1

- IPAC-RS Conference Welcome - Liuda Shtohryn
- Evolution of Regulatory Paradigm for OINDP - Industry Perspective - Gordon Hansen
- QbD for OINDP - FDA Perspective - Rik Lostritto
- Quality by Design for OINDP - Michael Golden
- Quality Risk Management and Design Space in Device Development - Laurence Huxham
- Change Protocols - Jon Clark
- Quality by Design - Jon Clark
- IPAC-RS Model OINDP Initiative - Terry Tougas

Day 2

- Keynote Day 2 - Roger Williams
- Track A Breakout Feedback - OINDP Industry's Use of PAT in Submissions
- Track B Breakout Feedback - Applying Risk Management, Risk Assessment and Design Space to OINDP Development and Regulation
- Track C Breakout Feedback - Q&A on Control Strategies and linking Quality, Safety & Efficacy in a QbD Development Program
- Control of Suppliers, Component Quality and QbD - David Cummings
- Role of the IPAC-RS GMP Guideline in Promoting OINDP Component Quality - Barbara Falco
- Promoting Quality OINDP Components-Supplier Perspective - Tom Gaspar
- What Do Cascade Impaction Measurements Tell Us - Jolyon Mitchell
- Clinical Relevance of In-vitro Particle Sizing Data - Steve Newman
- ISO Process and Standards Under Development - Steve Nichols
- Linking Safety & Quality - Examples from L&E and Foreign Particles in OINDP - Tim McGovern
- Considerations for Foreign Particulates in a QbD Environment - Mikael Sundahl
- Considerations for Leachables & Extractables in a QbD Environment - Dan Norwood
- Track D - Progress Report and Q&A on ISO Standards for MDI-DPI - Hal Yeager
- Track D - Progress Report and Q&A on ISO Standards for Nebulizers - Ann Graham
- Track E - Application of PTI Tests – Dave Christopher, Walter Hauck

Day 3

- Keynote Day 3 - Igor Gonda
- Track D Breakout Feedback - Progress Report and Q&A on ISO Standards for MDI-DPI and Nebulizers
- Track E Breakout Feedback - Application of PTI Tests
- Track F Breakout Feedback - Q&A and Discussion on Supplier QC for OINDP
- Canadian Approach to Regulation of OINDP - Caroline Vanneste
- European Approach to Regulation of OINDP - Diana van Riet
- Industry Perspectives on OINDP Regulatory Challenges in a Global Environment - Ray Ormiston
- Development of Inhalation Products for Systemic Applications - Regulatory Challenges - Sally Seymour
- Case Study 1 - Development of Inhaled Insulin for Diabetes - Nancy Harper
• **Case Study 2 - Systemic Delivery of Small Molecules via the Lungs** - Jim Blanchard (substituting for Tunde Otulana)
• **Closing Remarks** - Liuda Shtohryn