

AGENDA

THE GLOBAL REGULATORY LANDSCAPE AND ADVANCES IN DIGITAL TECHNOLOGY: TRANSFORMING THE OINDP-PATIENT EXPERIENCE

THURSDAY, APRIL 30 – FRIDAY, MAY 1, 2020
JW MARRIOTT DESERT SPRINGS, PALM DESERT, CALIFORNIA

Respiratory Drug Delivery (RDD) and the International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) will again collaborate to develop a coordinated program and follow-on symposium that will address *The Global Regulatory Landscape and Advances in Digital Technology: Transforming the OINDP-Patient Experience*. There will be podium presentations and a panel discussion on the morning of Thursday, April 30 as part of the RDD 2020 conference program, and the IPAC-RS Symposium will continue on the afternoon of Thursday, April 30 and run through Friday, May 1.

DATE: Thursday - Friday, April 30 – May 1, 2020

LOCATION: [JW Marriott Desert Springs](#), 74-855 Country Club Drive,
Palm Desert, CA

QUESTIONS: Please contact info@ipacrs.org.

Photos courtesy of JW Marriott Desert Springs



RDD SESSION 9: The Impact of New Technology and Regulation on Inhaler Design, Development and Product Lifecycle

Joint IPAC-RS/RDD Session (Springs Ballroom A-F)

This session will include case studies on the use of connected inhalers in respiratory disease along with the regulatory considerations and challenges of using these technologies to demonstrate potential benefits to patients and clinicians.

Co-Chairs:

Joanne Peart, Virginia Commonwealth University, Richmond, Virginia
Andy Rignall, AstraZeneca, Macclesfield, United Kingdom

<p>8:30 a.m. Rethinking Inhaled Product Development in the Digital World Matthew Bonam, AstraZeneca, Macclesfield, United Kingdom</p> <p>9:00 a.m. User-Centric Design to Identify the Baseline Requirements for a Connected Inhaler Alan Tweedie, Chiesi Limited, Chippenham, United Kingdom</p> <p>9:30 a.m. Connected Ellipta®: A Case Study of Improved Adherence in Uncontrolled Asthma Alison C. Moore, GlaxoSmithKline, Uxbridge, United Kingdom</p> <p>10:00 a.m. Refreshments</p>	<p>10:30 a.m. The Digihaler.™ A New Approach to Manage Airway Diseases Guilherme Safioti, Teva Pharmaceuticals, Helsingborg, Sweden</p> <p>11:00 a.m. Personalized Aerosol Therapies: Understanding the Data Privacy Barrier Mary Devlin Capizzi, Drinker Biddle & Reath, Washington, DC</p> <p>11:30 a.m. Connected Inhalers and Digital Health in the USA: Regulatory Considerations James J. Lee, U.S. Food and Drug Administration, Silver Spring, Maryland</p> <p>12:00 p.m. Panel Discussion: The Impact of New Technology & Regulation on Inhaler Design, Development & Product Lifecycle</p>
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12:30 pm
Luncheon - Sinatra Ballroom
End of RDD 2020

Note: The IPAC-RS Symposium will continue on the afternoon of Thursday, 30 April and run through Friday, May 1.

IPAC-RS SESSION 1: The OINDP Science and Research Agenda

Room: Springs Salon G

This session will exemplify how the latest developments in modelling and predictive tools in the areas of biopharmaceutics, manufacturability, product performance and characterization can enable improved product quality and process robustness of dry powder products.

Moderators: Mariska Kraaij, Chiesi, Italy and Bill Doub, OINDP In Vitro Analysis, USA

<p>2:30 p.m. The iBCS Journey – An Update from the PQRI Working Group Jayne Hastedt, JDP Pharma Consulting, LLC, USA</p> <p>3:00 p.m. Predicting Manufacturability of Inhaled Powders Amrit Paudel, RCPE, Austria</p>	<p>3:30 p.m. Spray Dried Particles for Inhalation: Process Development Following a QbD Approach João Henriques, Hovione, Portugal</p> <p>4:00 p.m. Refreshments</p>
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4:30 p.m. **Deconstructing the Role of Powder Agglomerates in Inhaled Powders (INFORM 2020)**
Darragh Murnane, University of Hertfordshire, UK

5:00 p.m. **Measurement of Dry Powder Inhaler Performance by Cascade Impaction: Multi-laboratory Experimental Study of Flow Rate Rise Time Characteristics and Theoretical Verification Based on Underlying Physical Processes**
Henk Versteeg, Loughborough University, UK
Jolyon Mitchell, Jolyon Mitchell Inhaler Consulting Services Inc, Canada

5:30 p.m. **Break**

Evening Reception: Connecting with the Patient: Developing, Applying and Regulating Smart Inhaler Technology

6:00 p.m. - San Jacinto Ballroom

Moderators: Jen Wylie, Merck, USA and Agnes Colombani, Lupin, USA

Breakout Topics: How Do I Keep Track of All These Inhalers?, Add-In vs. Integral Electronics, Real World Evidence (RWE) and Real World Data (RWD)

This session will be followed by drinks and hors d'oeuvres at The Pointe.

FRIDAY, MAY 1, 2020

IPAC-RS SESSION 2: The Global Regulatory Landscape

Room: Springs Salon G

This session will bring together regulators from across the globe to share current hot topics on the regulation of orally inhaled dosage forms with a focus on digital health and connected inhalers.

Moderators: Hayden Beresford, 3M, UK and Sue Holmes, GlaxoSmithKline, USA

<p>7:30 a.m. Continental Breakfast</p> <p>8:00 a.m. What's Going on With the 2018 CMC Guidance? Current FDA Thinking and Next Steps Richard Lostritto, U.S. Food & Drug Administration (FDA)/CDER, USA</p> <p>8:30 a.m. Combination Products Quandary? CDER and the Office of Combination Products Working Together Kristina Lauritsen, U.S. Food & Drug Administration (FDA)/CDER, USA Maryam Mokhtarzadeh, U.S. Food & Drug Administration (FDA)/OCP, USA</p> <p>9:15 a.m. What's New in the EU: Current Guidance and Advances in Digital Technologies Claudia Vincenzi, European Medicines Agency (EMA), Netherlands</p>	<p>9:45 a.m. Update on MHRA Following UK's Exit from EU, Patient Usage and the MDR Joseph Lim, Medicines and Healthcare Products Regulatory Agency (MHRA), UK</p> <p>10:15 a.m. Refreshments</p> <p>10:45 a.m. ANVISA's Unique OINDP Perspective: How Does it Differ From the Rest of the World? Gustavo Mendes Lima Santos, National Sanitary Surveillance Agency (ANVISA), Brazil</p> <p>11:15 a.m. Who are the National Medical Products Administration (NMPA)? China's New Regulations and Research Priorities Baoming Ning, National Institutes for Food and Drug Control (NIFDC), China</p> <p>11:45 a.m. Panel Discussion: The Global Regulatory Landscape</p>
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12:30 pm
Luncheon - Outside Springs Salon G
End of IPAC-RS Symposium

Current IPAC-RS Members

3M

AstraZeneca

Boehringer Ingelheim

Catalent

Chiesi

GlaxoSmithKline

Hovione

Lupin Pharmaceuticals, Inc.

Merck & Co., Inc.

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Current IPAC-RS Associate Members

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Symposium Organizing Committee Members

Jeremy Clarke, GlaxoSmithKline (Co-Chair)

Andy Rignall, AstraZeneca (Co-Chair)

Hayden Beresford, 3M

Agnes Colombani, Lupin

Bill Doub, OINDP In Vitro Analysis

Dede Godstrey, IPAC-RS Secretariat

Sue Holmes, GlaxoSmithKline

Mariska Kraaij, Chiesi

Lana Lyapustina, IPAC-RS Secretariat

Jolyon Mitchell, Jolyon Mitchell Inhaler Consulting Services Inc.

Lee Nagao, IPAC-RS Secretariat

Joanne Peart, Virginia Commonwealth University/RDD

Stacey Wierzba, IPAC-RS Secretariat

Jennifer Wylie, Merck

About IPAC-RS

IPAC-RS is an association of pharmaceutical and biotech companies that develop, manufacture or market orally inhaled and nasal drug products (OINDPs). IPAC-RS seeks to advance the regulatory science of OINDPs by collecting and analyzing data and best practices, developing improved methods and approaches, monitoring and responding to relevant regulatory developments, and conducting joint research projects.

To learn more or to join, contact us at info@ipacrs.org, call +1-202-230-5607, or visit <http://ipacrs.org/>.