



2017 IPAC-RS/ISAM Joint Workshop

New Frontiers in Inhalation Technology

Saturday, June 3, 2017 in Santa Fe, New Mexico, USA

Held in conjunction with the ISAM-2017 Congress: <http://www.isamcongress.com/>

Updated April 19, 2017

| Timing | Title and Topics | Speakers |
|--|--|---|
| Morning Session CHAired BY PAUL ATKINS | | |
| 8:55-9:00 am | Welcome and overview | Paul Atkins* and Franz-Josef Rehmann** *Novartis and **AstraZeneca |
| 9.00-9.35 am | New delivery technologies for orally inhaled products (OIPs) Review of recent technology enhancements in the space and what the future might hold – focus on patient-friendly features, e.g., BAIs, Smart MDIs. | Hugh Smyth University of Austin, Texas |
| 9.35 – 10.10 am | New inhaler monitoring technologies, what they do and how they are used The use of smart inhalers that have an e-connect features; Discuss if expense is justified, benefits to patients or pharma? What about privacy issues. | Paul Colthorpe Global Program Lead TeleHealth, Novartis Pharma |
| 10.10-10.30 am | BREAK | |
| 10.30-11.05 am | User perspectives on innovation in inhalers Pros and cons of new technologies & device add-ons from the perspective of patients & caregivers. | Maureen George Columbia University School of Nursing |
| 11.05-11.40 am | FDA CDER perspective on new technologies in inhaler products. | Irene Chan FDA CDER |
| 11.40-12.15 | FDA CDRH perspective on new technologies in inhaler products. | Linda Ricci (by phone) FDA CDRH |
| 12.15-12.30 | PANEL DISCUSSION What are the challenges when introducing new technologies? Do they improve clinical outcomes? How do they play out in the real world? | Speakers from Morning Session, moderated by Paul Atkins |
| 12.30-1.30 pm | LUNCH | |



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| Afternoon Session CHAired BY FRANZ-JOSEF REHMANN | | |
| 1.30-2.05 pm | Update from ISO working group on device change management | Paul Jansen ISO WG |
| 2:05-2.40 pm | Challenges in the manufacturing of OIPs in the new technology world including complex mechanical/electronic devices (e.g. Ellipta, RespiClick or Respimat), flexible, agile & adaptable production facilities, other challenges | Herbert Wachtel Boehringer Ingelheim |
| 2.40-3.15 pm | Globally divergent regulatory strategies for OIPs? What are the worldwide similarities and differences as the complexity of inhaled products gets greater? With focus on combination products, their regulatory requirements, and the challenges innovators and generic companies are currently facing. | Anders Fuglsang Fuglsang Pharma |
| 3.15-3.30 pm | BREAK | |
| 3.30-4.05 pm | Industry view on validation/regulation of <u>novel</u> devices Regulatory aspects for new inhaler technology from the industry perspective/experience. How do they get validated? What Human Factors studies look like for novel devices? | Stéphane Baronnet AstraZeneca |
| 4.05-4.40 pm | US and European regulatory considerations on cybersecurity and patient privacy for digital-health technologies | Katherine E. Armstrong Drinker, Biddle & Reath LLP |
| 4.40-5.00 pm | PANEL DISCUSSION | Afternoon Speakers, moderated by Franz-Josef Rehmann |
| 5.00 pm | ISAM CONGRESS RECEPTION | |

For questions or comments, contact info@ipacrs.org.