IPAC-RS Digital Devices Roundtable Series

IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

Business Case for Digital Inhaler Devices

October 4, 2021

www.ipacrs.org

Who We Are

The International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) is an international association that seeks to advance the science, and especially the regulatory science, of orally inhaled and nasal drug products (OINDPs) by collecting and analyzing data, and conducting joint research and development projects.

Representing the OINDP industry since 2000, IPAC-RS aims to build consensus and contribute to effective regulations and standards by sharing the results of its research through conferences, technical journals, and discussions with regulatory bodies.

Our Members

- **Members** - corporations that develop, manufacture or contract to manufacture OINDPs

AstraZeneca
Boehringer Ingelheim
Catalent
Chiesi
Genentech
GlaxoSmithKline
Hovione
Kindeva Drug Delivery
Lupin Pharmaceuticals, Inc.
Merck & Co., Inc.
Novartis
Sunovion
Teva
Vectura
Viatris

- **Associate Members** – corporations that (1) develop or manufacture components and/or devices for OINDPs or (2) provide scientific or technical services relating to development and manufacture of OINDPs or (3) are eligible for full membership but have annual revenues of less than seventy-five million US dollars.

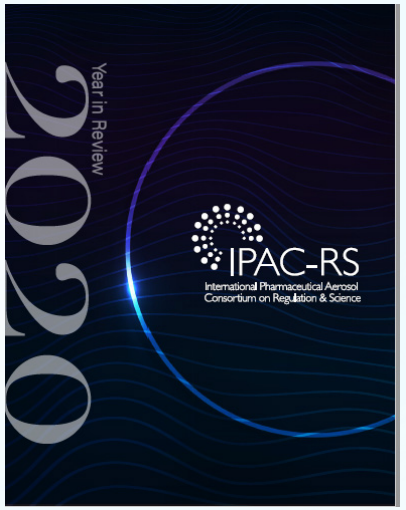
Amcor Flexibles
Aptar Pharma
Copley Scientific
H&T Presspart
Nemera
Oxford Lasers
PPD
Proveris Scientific Corporation
Team Consulting Ltd.

IPAC-RS Successes in 2021

During 2021, IPAC-RS continues to actively work on the goals outlined in the 2019-2021 Strategic Plan.

The Consortium:

1. Engaged with regulatory and standard setting authorities.
2. Provided up-to-date information to the members on relevant developments.
3. Identified and publicized OINDP industry's positions on key issues of regulatory science
4. Provided forum for members' discussions.
5. Actively participated in discussions in the wider stakeholder community.



See the IPAC-RS Year in Review 2020 for an overview of 2020 successes.

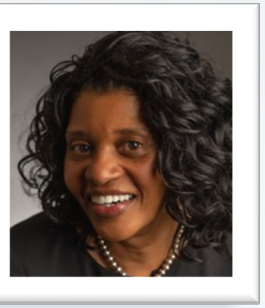
Top 5 Reasons to Join IPAC-RS

1. Stay ahead of emerging international regulatory and scientific challenges facing the OINDP industry.
2. Participate in joint industry discussions with and guidance commenting to regulators in North America, Europe, Asia, and South America.
3. Join industry leaders in providing feedback to standard-setting bodies and international pharmacopoeia.
4. Share knowledge, information and experiences with other industry leaders.
5. Stay abreast of pertinent development and also shape national and international trends and requirements.

IPAC-RS Roundtables

- In 2021, IPAC-RS developed a new Roundtable webinar series on digital devices for 2021. Presented by subject matter experts in the pharmaceutical sciences, this is a unique opportunity to learn about the latest research and regulatory trends focused on digital devices. See the IPAC-RS website for details, registration information and recordings for previous webinars.
  - Today's Webinar: ***Business Case for Digital Inhaler Devices***
  - ***Upcoming Webinars***
    - **SAVE THE DATE**: November 22, 2021 (10 AM – 12 PM ET) ***Digital Devices- Regulatory Challenges and Considerations***
  - ***Past Webinars***
    - ***What is a Digital Biomarker and Why Is It Important?***
    - ***Beyond Usability/Human Factors for Digital Healthcare***
    - ***Digital Devices Manufacturing and Design Considerations***

Today's Moderators



Robyn Parker, MS, Associate Director, Global Regulatory Affairs, Sunovion

Robyn Parker, MS, is an Associate Director, Global Regulatory Affairs at Sunovion Pharmaceuticals, Inc. headquartered in Marlborough, MA. Her experience encompasses not only regulatory strategy, but also Regulatory CMC, Advertising and Promotional review, and drug product labeling. In addition, Robyn has extensive knowledge and involvement in addressing Health Authority inspection responses worldwide. She has global and regional responsibilities for phase 1 clinical studies through post approval life cycle management covering Cardiovascular and Renal, Neurology, Psychology, and Respiratory therapeutic areas. She also serves as a preceptor for Doctor of Pharmacy Fellows.

Robyn's pharmaceutical career spans Manufacturing, Quality Assurance, Regulatory Compliance, and Regulatory Affairs. She holds a MS in Regulatory Affairs and Quality Assurance, and a BS in Chemistry.

S. Prasad Peri, Ph.D., Senior Director, Global Specialty Regulatory Affairs CMC, Teva Branded Pharmaceutical Products R&D Inc.

S. Prasad Peri, Ph.D. is currently Senior Director, Global Specialty Regulatory Affairs CMC at Teva Branded Pharmaceutical Products R&D Inc., based in West Chester, PA. He and his team are responsible for the regulatory CMC for Small Molecules, Biologics, Combination Products and Devices.

Prior to joining Teva Prasad was employed at Merck and Co. as a Director for Global Regulatory Affairs responsible for Combination products and Devices. Prior to joining Merck, Prasad Peri was Branch Chief at the Office of New Drug Quality Assessment in FDA responsible for the CMC review assessment of products submitted to Divisions of Pulmonary, Allergy, Rheumatology, Anesthesia, Analgesia and Addiction. Prasad Peri holds a Ph.D. in Pharmaceutical Chemistry and a BS in Pharmacy.

Agenda

I. Welcome and Introduction to IPAC-RS	5 Minutes	Mary Devlin Capizzi, IPAC-RS Secretariat
II. Overview of Webinar and Logistics	5 Minutes	Robyn Parker, Sunovion Prasad Peri, Teva
III. Business Case for Digital Inhaler Devices: A pharma company perspective	30 Minutes	Ulf Ericsson, Nanologica
VI. Short Q&A	5 Minutes	
V. Business Case for Digital Inhaler Devices: A platform provider's perspective on creating a compelling user experience and driving adoption.	30 Minutes	David Pettigrew, BrightInsight
VI. Open Discussion and Q&A	45 Minutes	All Speakers
Total Time	2 hours	

Webex Housekeeping

- Panelists will be listed here.
- The Attendee list is only available to Panelists and Host. (You will only see your name listed.)
- The Chat function has been disabled for Attendees. You may receive chats from the Host, but you cannot reply.
- Type your question in the Q&A box or raise your hand to be unmuted.

Be sure your Q&A is set to ASK All Panelists

All Attendees are muted.

The recording will be posted on the IPAC-RS website after the webinar.

Presenter

Ulf Ericsson, MS, Vice President Drug Development, Nanologica

Ulf Ericsson is an experienced leader in Marketing and Business Development with 25-years experience in the Pharmaceuticals industry, whereof twenty in inhaled medicine. In all, seventeen years in AstraZeneca managing product portfolios in all stages from pre-launch to launch and LCM as well as managing all inhalation devices both on market and in development.

Ulf have also extensive experience in working with the environmental sustainability aspects of our business, especially from an inhaler device and formulation perspective. Up to just recently Ulf was leading the Global Inhaled Device strategy work for AstraZeneca's inhaled portfolio, as well as leading the commercial part in the development of future inhalation devices, formulations and platforms, including digital pharma.

In the past five to six years there has been an increasing interest and focus on how to use and develop novel digital technology to further improve clinical outcomes of our already existing medicines as well as improving the patient experience and user interface. Ulf have been deeply involved in the business development and strategies in this field especially from a commercial and business perspective, e.g., user interface, business models, business cases and ROI.

Ulf recently joined Nanologica, a nanotechnology company developing nano porous particles for applications in life science, e.g. delivering oral and inhaled drug products, where he is leading the Drug Development organisation and strategy. Ulf holds a Master of Science in Business Administration, Business Economics and Marketing Management from the University of Lund, Sweden.

Short Q&A Session

- Type your question in the Q&A box or raise your hand to be unmuted.

Be sure your Q&A is set to ASK All Panelists

Presenter

David Pettigrew, DPhil, VP Global Accounts, BrightInsight

David Pettigrew, DPhil has 15 years of experience in medical device and pharmaceutical product development. Prior to joining BrightInsight, he was Managing Director of Sagentia, a technology and product development consulting firm. During his time at Sagentia, he served a range of large multinational healthcare clients, with particular focus on development strategies for integrating connectivity into higher risk medical devices such as in vitro diagnostic instruments, implantable neurostimulators and autoinjectors. He has also participated in FDA discussion panels on (regulated) mobile medical apps.

His early career focused on developing sensors for point of care microfluidic diagnostic instruments, most notably the world's first clinical analyzer for measuring the anaesthetic propofol in whole blood. His work in diagnostics has resulted in several CE mark and FDA 510k approvals.

David holds a DPhil from the University of Oxford, UK in Molecular Biophysics, where he used X-Ray Crystallography and Electron Microscopy to explore host-pathogen interactions at the molecular level.

Thank you for attending the webinar!

- Type your question in the Q&A box or raise your hand to be unmuted.

Be sure your Q&A is set to ASK All Panelists

Secretariat Contacts

For further information regarding membership or other questions about IPAC-RS, please contact a member of the Secretariat below. You can also learn more by visiting www.ipacrs.org.

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