Welcome to the IPAC-RS Roundtable!

Organized to explore in further detail a presentation on User Centric Device Design originally presented during the *Regulatory, Science and Technology Innovation: Enabling Novel and Improved OINDP Design, Development and Manufacturing* IPAC-RS/RDD jointly organized session at Respiratory Drug Delivery on Thursday May 5, 2022.

Patient-Centric Product Design

IPAC-RS Roundtable

September 22, 2022

www.ipacrs.org

"A systematic approach to help ensure that patients' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into the development and evaluation of medical products throughout the medical product life cycle."[1]

[1] Patient-Focused Drug Development Glossary | FDA

Today's Agenda

I. Welcome and Introduction to IPAC-RS	5 Minutes	Mary Devlin Capizzi, IPAC-RS Secretariat
II. Overview of Webinar and Logistics	5 Minutes	Jeremy Clarke, GSK
III. Panelist Discussion Questions	60 Minutes	Gregor Anderson, Pharmacentric Solutions Juan Cheng, Merck Sven Stegemann, Graz University Paul Upham, Roche/Genentech Róisín Wallace, Viatris
VI. Open Discussion and Q&A	20 Minutes	All Panelists
Total Time	1.5 hours	

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.

IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

Our Members

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

AstraZeneca
Boehringer Ingelheim
Catalent
Chiesi
Genentech
GSK
Kindeva Drug Delivery
Lonza
Lupin Pharmaceuticals
Merck & Co., Inc.
Novartis
Recipharm
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
PPD
Proveris Scientific Corporation
RxPack

IPAC-RS Successes in 2021 and 2022

During 2022, IPAC-RS continues to actively work on the goals outlined in the 2022-2024 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 2021 for an overview of 2021 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 Roundtable webinar series on digital devices. See the IPAC-RS website for information and recordings from previous webinars.
- In 2022, IPAC-RS is organizing Roundtables to explore in further detail presentations presented during the jointly organized IPAC-RS/RDD *Regulatory, Science and Technology Innovation: Enabling Novel and Improved OINDP Design, Development and Manufacturing* session at Respiratory Drug Delivery on Thursday May 5, 2022.
  - Today's Webinar: ***Patient Centric Product Design***
  - ***Upcoming Webinars***
    - *Sustainability: Alternate Propellants*
    - *Sustainability: Supply Chain Considerations*
    - *Advanced Data Analytics*
    - *Regulatory Evolution*

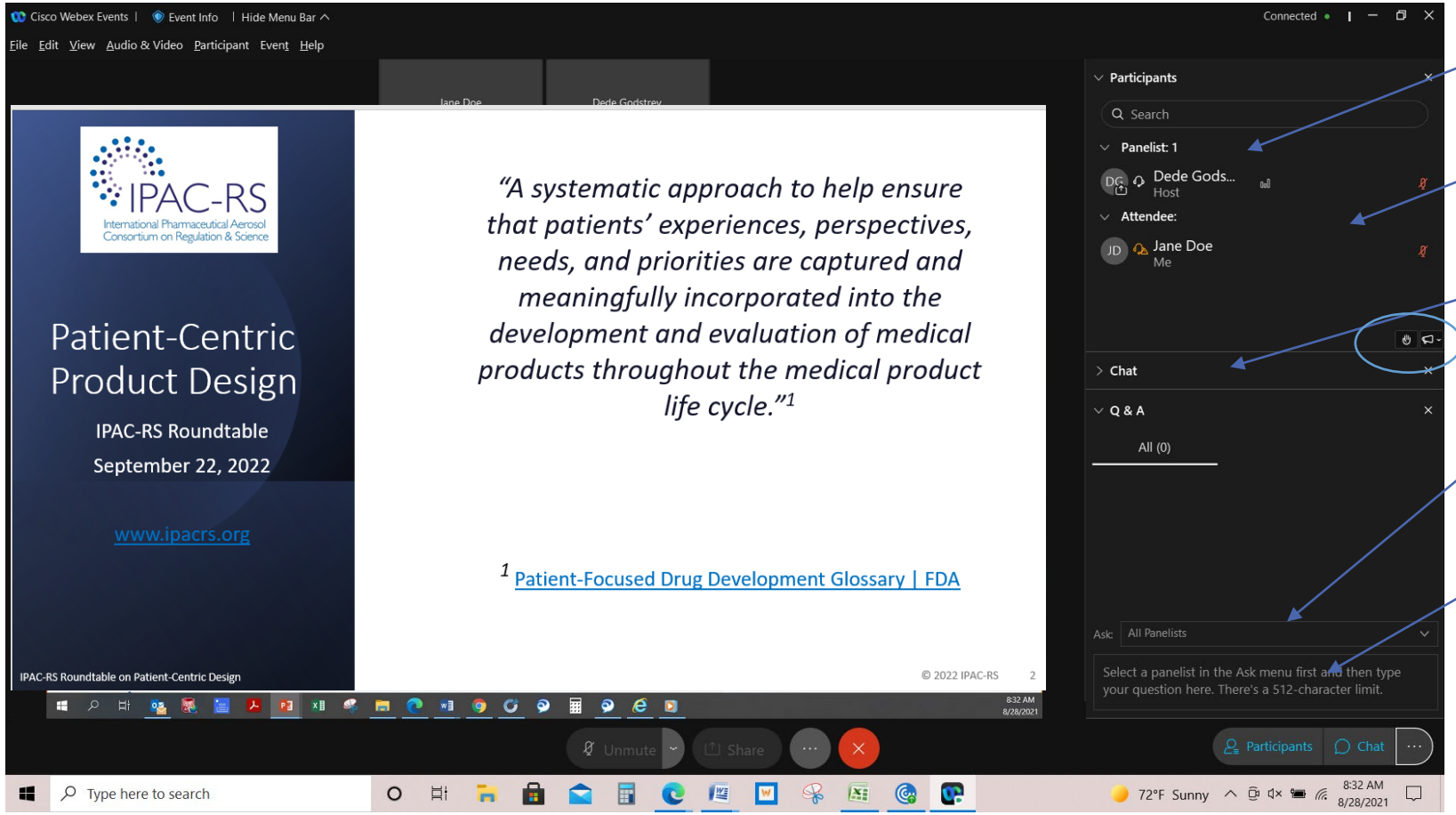
Today's Moderator

Jeremy Clarke, Ph.D.
Senior Fellow
Manufacturing Science & Technology, Global Supply Chain
GSK
jeremy.x.clarke@gsk.com

Jeremy is currently a Senior Fellow in Manufacturing Science and Technology (MSAT), GSK Pharma Supply Chain, supporting technology transfer, industrialisation and filing of late-stage development candidates in the small molecule portfolio, life cycle management programmes for marketed products, internal development of technical experts through the GSK Fellowship programme and external advocacy in pharmaceutical sciences. Jeremy is a Fellow of the Royal Pharmaceutical Society and an Eminent Fellow of the Academy of Pharmaceutical Sciences.

A pharmacist by training, Jeremy obtained his PhD in non-aqueous colloid & interface science at the Welsh School of Pharmacy, University of Cardiff. Following his doctorate studies, Jeremy joined Ciba-Geigy (Novartis) working on OINDPs, where he advanced to leadership of the formulation development group. Subsequently, Jeremy joined Vectura where, as Director of Respiratory Development, he had responsibility for both in-house and contract development programmes. Jeremy then joined Pfizer at Sandwich as matrix/line leader in materials science, formulation, and process development teams, with responsibility for development of new products and technologies for both OINDPs and IR/MR oral solid dosage forms."

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.
- Be sure your Q&A is set to ASK All Panelists
- Type your question in the Q&A box or raise your hand to be unmuted.

All Attendees are muted.

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

Today's Panelists

Gregor Anderson, Msc
Managing Director
Pharmacentric Solutions Ltd
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Juan Cheng, Ph.D., RAC
Device Development, Merck Research Labs (MRL)
Merck
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Prof. Sven Stegemann, Ph.D.
Professor of patient Centric Drug Design and Manufacturing
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Paul Upham
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Roche/Genentech
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Róisín Wallace, BSc., MRSC
Head of Global Device Development
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Q1: How would you define patient centric pharmaceutical drug product design?

Q2: What are the key considerations to successfully implement patient centric drug product design for an OINDP?

Q3: What are the challenges to address and opportunities to exploit to fully embrace patient centric pharmaceutical drug product design for OINDP?

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Thank you for attending the webinar!

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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