Welcome to the IPAC-RS Roundtable!

Organized to explore some of the sustainability concepts 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.

IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

<354073419>

IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

Advancing Sustainability of Device and Container Closure Systems (Part I)

IPAC-RS Roundtable

November 30, 2022

www.ipacrs.org

Today's Agenda

I. Welcome and Introduction to IPAC-RS *II. Overview of Webinar and Logistics*	15 Minutes	Lee Nagao, IPAC-RS Secretariat
III. Presentations	15 Minutes each	Beate Treffler, Avient Colorants Germany GmbH Marc Severin, H&T Presspart Christian Pommereau, Sanofi Edward Jackson, Kindeva
IV. Moderated Q&A Session with Presenters	20 Minutes	All Presenters
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

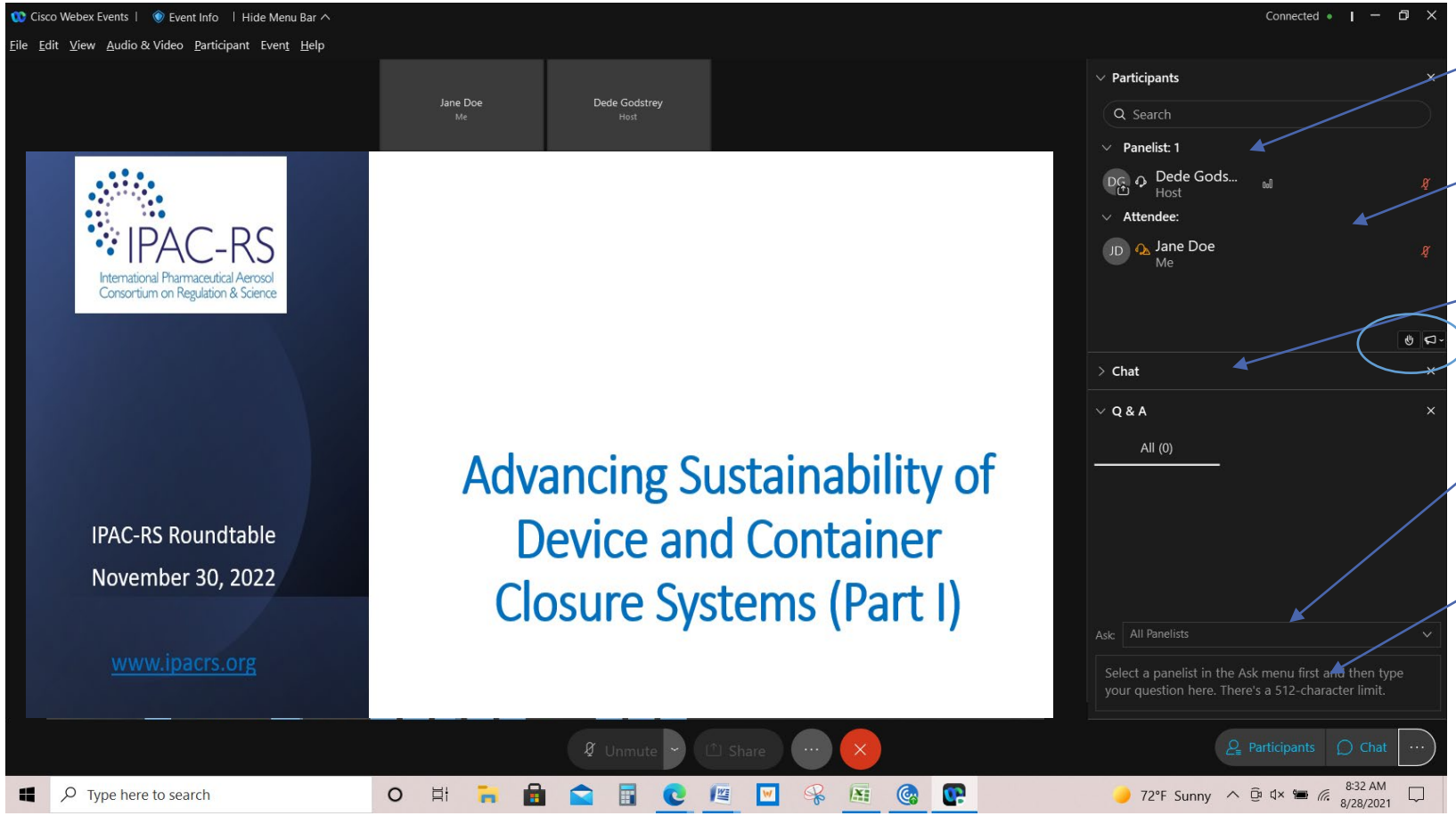
- In 2021, IPAC-RS developed a Roundtable webinar series on digital devices. See the IPAC-RS website for information and recordings from previous webinars.
- In 2022, IPAC-RS is organizing Roundtables to explore in further detail presentations presented during the jointly organized IPAC-RS/RDD *Regulatory, 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: *Advancing Sustainability of Device and Container Closure Systems (Part I)***
  - ***Upcoming Webinars***
    - *Advancing Sustainability of Device and Container Closure Systems (Part II) - to be scheduled in Jan 2023*
    - *Sustainability: Alternate Propellants*
    - *Advanced Data Analytics*
    - *Regulatory Evolution*
  - ***Past Webinars***
    - Patient Centric Product Design – held on September 22, 2022

Today's Moderator

Lee M. Nagao, Ph.D.
Senior Director - Science, Regulatory & Policy
Faegre Drinker Biddle & Reath LLP, IPAC-RS Secretariat
lee.nagao@faegredrinker.com

Lee M. Nagao, Ph.D., is a Senior Director of Science, Regulation and Policy at the law firm of Faegre, Drinker, Biddle and Reath, LLP, and is a member of the Firm's Life Sciences Consortium Management and Regulatory Affairs Practice Group. The Group works extensively with pharmaceutical, biopharmaceutical and medical device companies on a range of scientific and regulatory collaborations and provides strategic and regulatory guidance to individual life sciences companies. Lee plays a lead role serving scientific and regulatory consortia including the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS), the Extractables and Leachables Safety Information Exchange (ELSIE), and the International Pharmaceutical Consortium on Innovation and Quality (IQ). Lee has extensively published and presented on many aspects of pharmaceutical development including supply chain, CMC, and translational sciences. She has represented various industry groups before regulatory and scientific agencies and organizations in the US, Europe and Asia, including the FDA, EMA, China NIFDC, Chinese Pharmacopoeia, ANVISA, Taiwan CDE, Japan PMDA, and USP.

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.

Presenter

Beate Treffler
Regional Sales Manager Europe, Healthcare Polymer Solutions
Avient Colorants Germany GmbH
beate.treffler@avient.com

Beate Treffler has over 25 years of experience in additives for plastic applications and processing. In March 2015 she joined the Business Unit Masterbatches of Clariant as Regional Head Europe Segment Healthcare Polymer Solutions being responsible for Marketing & Sales. On 1st of July 2020 the former PolyOne Corp. acquired Clariant's BU Masterbatches to form the new company Avient Corporation, a leading provider of color- and performance-enhancing concentrates and compounds. Since October 2021 she leads the HC Sales in EMEA and together with the dedicated team they provide polymer solutions for pharma packaging, medical - and drug delivery devices. These polymer solutions comprise pre-tested and changed controlled concentrates/masterbatches as well as ready-to-use compound solutions.

Before joining BU Masterbatches, she was heading the global technical marketing team for waxes in the Business Unit Additives of Clariant. Furthermore, she was involved in project management for new developments and for the Clariant Commercial Excellence program (Lean Sigma; certified Green Belt).

Presenter

Marc Severin
Program Manager Sustainability and Innovation
H&T Presspart
marc.severin@presspart.com

Marc Severin has over 10 years of experience in engineering and project management. He joined H&T Presspart in 2017 and has taken over several responsibilities in business development, key account project management and is driving the sustainability program with the H&T Presspart Division, world leader and specialist in manufacturing drug-delivery systems and pharmaceutical components, since 2021. In this program Marc manages the strategic sustainability objectives and networks throughout the organization to intensify H&T Presspart's endeavors to become a key driver in the market for more sustainable supply chains.

Holding a bachelor's degree in engineering and a master's degree in international management, Marc adores finding practical and tangible solutions for the challenges we are facing like resource scarcity and climate change. Over the past months he started initiatives and discussions with customers and supplies the evaluate future potentials and cooperations along the supply chain. In his role as a project manager, he worked on changes with H&T Presspart's key customers to optimize packaging's, production processes and supported the quality management along the supply chain.

Presenter

Christian Pommereau
Principal Engineer Platform Technology
Sanofi
christian.pommereau@sanofi.com

Almost 25 years of experience in design and production of complex disposable devices for Diagnostics and Healthcare

20 years with SANOFI, a large pharmaceutical company, for DDC and Medical Device working with increasing responsibilities in Design, Industrialization, Supplier Management, Program Management, Sustainability, etc.

(Board-) Member of various associations and guidelines working groups: MPPE, KiM e.V, VDI 2017 and VDI 2023

New position as of Jan 1st 2023 to develop and drive Eco-Design activities for Sanofi devices, across the value chain.

Presenter

Edward Jackson
Device Development Team Leader
Kindeva Drug Delivery
edward.jackson@kindevadd.com

Ed Jackson has 25 years' experience of actuator and dose counter development, optimisation and commercialisation at Kindeva, formerly 3M Drug Delivery Systems.

He has been the technical lead for our actuator with integrated dose counter platforms with responsibility from feasibility testing, design verification through to regulatory submission on several successful programs for US and European product launches.

Ed has also been our technical lead for the commercialisation and qualification of these devices. I work closely with our CDMO's through to our customers to ensure all aspects of device development and development supplies from initial batches through to commercialisation meets the needs of our customers.

Over the last 18 months he has been working with our partners and resin suppliers to trying and understand what switching to sustainable materials actually means and how complex of a change is it to undertake.

IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

Advancing Sustainability of Device and Container Closure Systems Part I

IPAC-RS Roundtable

November 30, 2022

www.ipacrs.org

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.

Mary Devlin Capizzi
Mary.DevlinCapizzi@faegredinker.com

Dede Godstrey
Dede.Godstrey@faegredrinker.com

Lana Lyapustina
svetlana.lyapustina@faegredrinker.com

Lee Nagao
Lee.Nagao@faegredrinker.com