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

IPAC-RS Roundtable

February 7, 2023

www.ipacrs.org

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

Today's Agenda

I. Welcome and Introduction to IPAC-RS and Overview of Webinar and Logistics *II. Introduction of Presenters*	5 Minutes	Mary Devlin Capizzi, IPAC-RS Secretariat Jacqueline Green, H&T Presspart
III. Presentations	15 Minutes each	Christian Meusinger, Nemera Paulo Cavacas, Borealis Valéry Rebizant, DuPont Rob Haley, Celanese
IV. Moderated Q&A Session with Presenters and Panelists	55 Minutes	Presenters above and Panelists from Part I Beate Treffler, Avient Colorants Germany GmbH Marc Severin, H&T Presspart Edward Jackson, Kindeva
Total Time	2 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
Teva
TranspireBio
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.

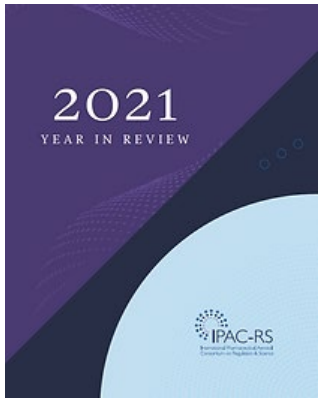
Aptar Pharma
Copley Scientific
H&T Presspart
Impel Pharmaceuticals
Nemera
PPD
Proveris Scientific Corporation
RxPack

IPAC-RS Successes in 2022

During 2022, IPAC-RS continued 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

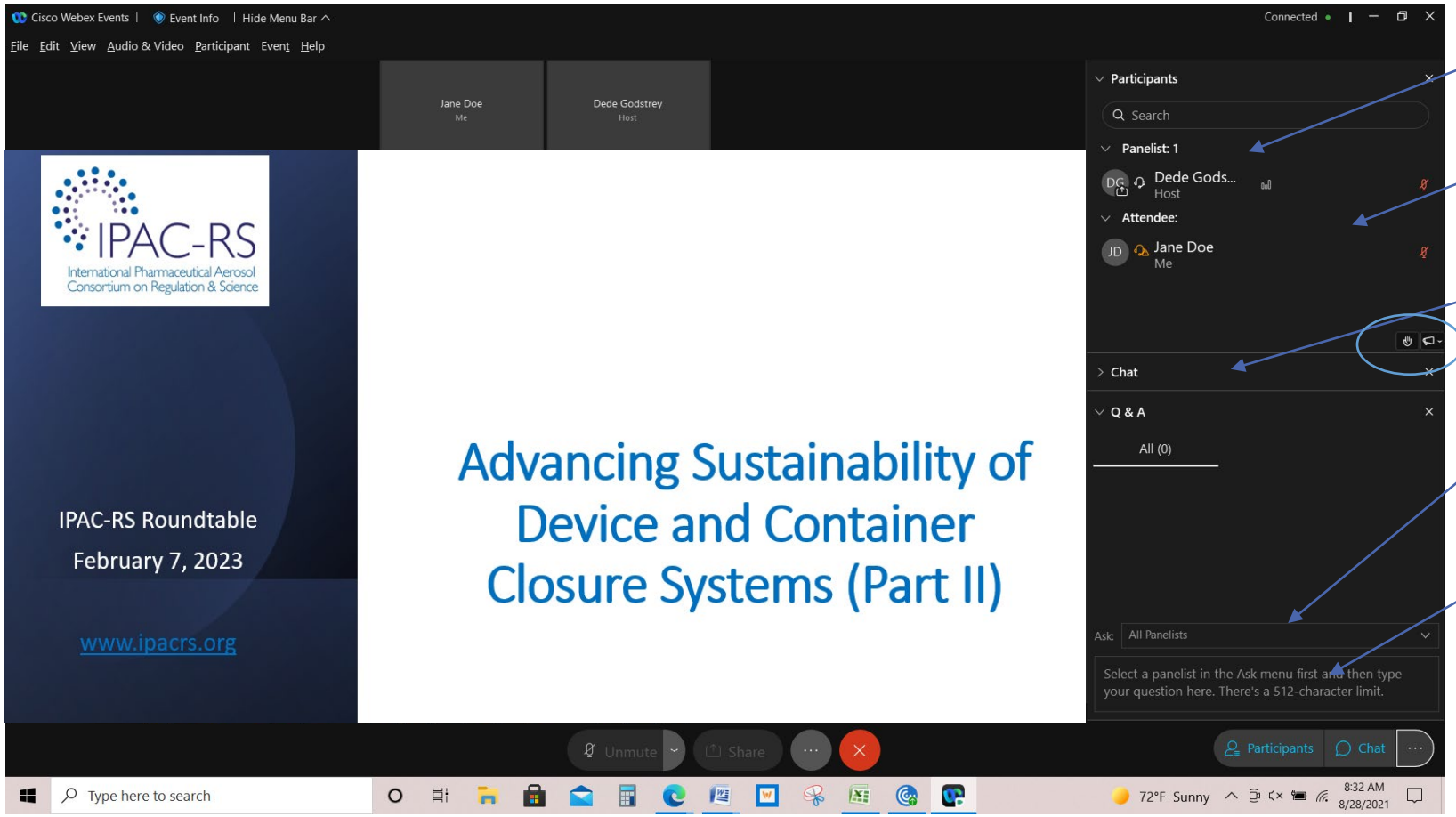
1. Stay ahead of emerging international regulatory and scientific challenges facing the OINDP industry.
2. Participate in joint industry discussions with and guidance commenting to regulators in North America, Europe, Asia, and South America.
3. Join industry leaders in providing feedback to standard-setting 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

See the IPAC-RS website for information and recordings from all previous webinars.

- In 2021, IPAC-RS developed a Roundtable webinar series on digital devices.
- In 2022, IPAC-RS organized 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 RDD in May 2022.
  - Patient Centric Product Design – held on September 22, 2022
  - Advancing Sustainability of Device and Container Closure Systems (Part I) – held on November 30, 2022
- In 2023, IPAC-RS is continuing its Roundtable series supplementing the podium presentations held at the IPAC-RS/RDD Joint session.
  - **Today's Webinar: *Advancing Sustainability of Device and Container Closure Systems (Part II)***
  - ***Upcoming Webinars***
    - *Advancing Sustainability of Device and Container Closure Systems (Part III) - to be scheduled in Spring 2023*
    - *Sustainability: Alternate Propellants*
    - *Advanced Data Analytics*
    - *Regulatory Evolution*

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 Moderator

Jacqueline Green
Global Business Development Manager
H&T Presspart
jacqueline.green@presspart.com

With a strong pharmaceutical and analytical background, Jacqueline has worked in the pharmaceutical industry, specifically with inhalation products, for more than 10 years. She is currently based at H&T Presspart's Blackburn, UK site and works within the Business Development team. In her role, she provides technical expertise and support on every aspect of Metered Dose Inhalers (MDI), other respiratory products, as well as metal components applicable to the pharmaceutical industry.

Within this role, Jacqueline is also responsible for providing technical support on Presspart's patented plasma canisters, particularly in terms of the sustainability advantage over other canister types. Jacqueline also oversees all cannabis related projects across the globe.

Jacqueline previously worked within H&T Presspart's Inhalation Product Technology Centre (IPTC), undertaking a wide range of in vitro analytical testing for inhalation products and formulations to support Presspart's customer product development. She is now the interface between customers and IPTC, which is also more recently supporting customers with their low Global Warming Potential (GWP) MDI propellant filling and testing services.

Presenter

Christian Meusinger
Vice President Global Quality & Regulatory
Nemera
christian.meusinger@nemera.net

Christian Meusinger is Vice President of Quality, Regulatory at Nemera with over 25 years of experience within the Medical Device and Combination Product Industry.

At Nemera he is responsible for building comprehensive forward looking Quality Systems and implementing MDR and GMP compliant processes across the organizations. This includes since 2006, the transformation of Nemera into a CMO and OiP combination product and medical device company, with up to 14 sites including two development centers worldwide and two “green field” GxP facilities in India and Poland. Within this scope, he is forming and leading global improvement strategies as part of the Nemera Leadership team.

In his regulatory role, he is responsible for all regulatory subjects such as compliance oversight, initiatives and registrations. As well for all early phase developments, the launch and the entire lifecycle of the product. During a former Sustainability Strategy program led by Christian, ESG principles and technical Eco Design principles have been implemented and are now key pillars and are embedded within each new development project and change control process.

Former technical engineering, project management and supply chain roles were helping him strongly to understand what makes a global program workable and therefore successful.

Presenter

Paulo Cavacas
Business Development Manager
Borealis
paulo.cavacas@borealisgroup.com

Paulo Cavacas has over 25 years' experience in the polymer industry, having started as process engineer at a polyolefin unit and developed his career into product, application development, marketing and circular economy solutions developer in consumer packaging for Polyolefin's.

For the last 5 years, he heads the global healthcare marketing team at Borealis, with the objective to support business growth opportunities at partners, delivering long term sustainable polyolefin medical grade solutions, global reliability of supply and regulatory support. The increasing relevance of environmental sustainability in healthcare became Paulo's focus, looking to establish value chain partnerships to deliver on circular economy solutions, from design for recycling application development, to renewable based solutions to reduce carbon foot print and end of life solutions based on chemical recycling.

Presenter

Valéry Rebizant, Ph.D.
Delrin® Global Sustainability Leader and Sustainability Marketing Leader
DuPont
valery.rebizant@dupont.com

Valéry Rebizant, Ph.D., has over 20 years of experience in Engineering Resins. He joined DuPont in 2003 after finalizing his Ph.D. in chemistry, and has held several roles in R&D / Technology, manufacturing technology, global continuous improvement along the supply chain (as certified Six Sigma Black Belt) and global project management, before joining the Delrin® acetal (= POM) homopolymer team in 2018 as Global Product Technical Specialist, which included coordination of the portfolio of new product developments.

Valéry also took the lead of Delrin® global Sustainability in September 2020, using his structured, cross-functional approach to tackle this broad subject and drive the launch and promotion of the new Delrin® Renewable Attributed portfolio. Since July 2022, he added a Marketing aspect to his role by taking the lead on Sustainability Marketing, building and implementing longer-term plans.

Presenter

Rob Haley
Global Director of Program Management – Medical, Drug Delivery Device
Celanese
rob.haley@celanese.com

Rob Haley is the Global Marketing Director for Medical and Drug Delivery Device at Celanese. In this role, he helps develop and lead the strategic vision of the Celanese Medical Organization to keep the team positioned with high value products, clearly defined value propositions and opportunities to realize a healthy growth plan. He has been working in the medical device, pharmaceutical and drug delivery device space for over 14 years serving in a range of technical and commercial leadership roles. He holds a B.S. in Business Management from Salem State University (MA, US) and is currently completing an MBA from the same institution.

Moderated Q&A with Presenters and Panelists from Roundtable Part I

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

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

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

IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

Advancing Sustainability of Device and Container Closure Systems Part II

IPAC-RS Roundtable

February 7, 2023

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

