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

Regulatory and Technical Considerations in Sustainable Lifecycle Approaches for OINDP Device and Container Closure Systems (Part III)

IPAC-RS Roundtable

March 14, 2024

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.

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.
Recipharm
Sandoz
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
Intertek
invoX Belgium, N.V.
Koura, an Orbia Business
Nemera
PPD
Proveris Scientific Corporation
RxPack

IPAC-RS Progress: 2024

IPAC-RS has been actively working on goals outlined in the strategic plan.

The Consortium:

1. Engages with regulatory and standard setting authorities.
2. Provides up-to-date information to the members on relevant developments.
3. Identifies and publicizes OINDP industry's positions on key issues of regulatory science
4. Provides a forum for members' discussions.
5. Actively participates in discussions in the wider stakeholder community.

See Strategic Plan 2022-2024 *Also, see IPAC-RS Year in Review 2022 for an overview of 2022 successes.*

Top 5 Reasons to Join IPAC-RS

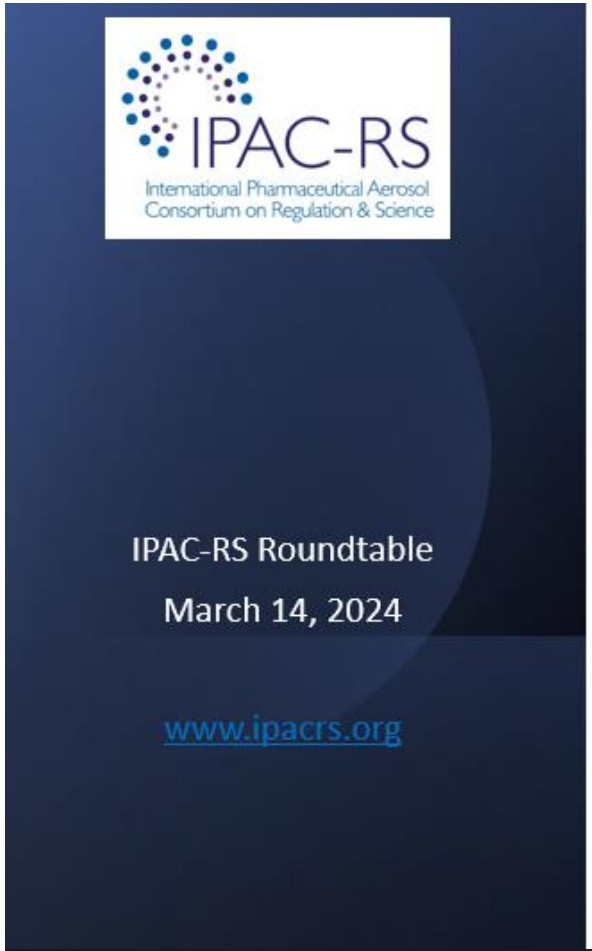
1. Stay ahead of emerging international regulatory and scientific challenges facing the OINDP industry.
2. Participate in joint industry discussions with and guidance commenting to regulators in North America, Europe, Asia, and South America.
3. Join industry leaders in providing feedback to standard-setting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

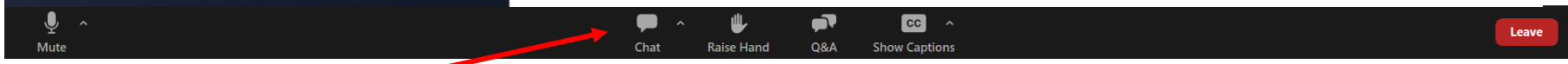
	See the IPAC-RS website for information and recordings from all previous webinars.
2021	***Roundtable series on digital devices.***
2022:	***Roundtable on Patient Centric Product Design*** ***Roundtable on Advancing Sustainability of Device and Container Closure Systems (Part I)***
2023:	***Roundtable on Advancing Sustainability of Device and Container Closure Systems (Part II)***
	WORKSHOP: Transition to Low Global Warming Potential Propellants for Metered Dose Inhalers – October 11, 2023. Recording and presentations available here.
2024:	***Today's Roundtable: Regulatory and Technical Considerations in Sustainable Lifecycle Approaches for OINDP Device and Container Closure Systems (Part III)***

Housekeeping

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



Regulatory and Technical Considerations in Sustainable Lifecycle Approaches for OINDP Device and Container Closure Systems (Part III)



- **The Chat function has been disabled for Attendees.**
- **Type your questions in the Q&A box to be addressed during the final section of the meeting.**
- **All Attendees are on mute**

Today's Agenda

I. Welcome and Introduction to IPAC-RS & Overview of Webinar Logistics *II. Overview of Webinar Agenda & Introduction of Presenters*	5 Minutes	**Mary Devlin Capizzi**, IPAC-RS Secretariat Moderator: **Edward Jackson**, Kindeva Drug Delivery
III. Presentations • Switch to Mass Balance Circular Resins: Need for a Global Understanding and Approval of Material Equivalency at an Industry Level to Safely Achieve a Sustainable Transition • Managing the End of Life of Inhalers through a Postal inhaler Recycling Scheme – Experience and Learnings • The Difficulties In Recycling Inhalers • Current MHRA position on Sustainability themes in Devices manufacturing • Lifecycle Management Considerations	15 Minutes each	**Nolwenn Stephan** (Nemera) **Harriet Lewis** (Chiesi) **Timothy Buxton** (Grundon Waste Management, Ltd.) **Steven Hoare** (MHRA) **Hasmukh Patel** (FDA/CDER)
IV. Moderated Q&A Session with Presenters and Panelists	25 Minutes	Presenters above and the following Panelists **Edward Jackson** (Kindeva Drug Delivery) **Rob Haley** (Celanese) **Edwin Jao** (FDA/CDER)

Today's Moderator

Edward Jackson
Device Development Team Leader
Kindeva Drug Delivery

Edward Jackson has 25 years' experience of actuator and dose counter development, optimization and commercialization at Kindeva, formerly 3M Drug Delivery Systems. He has been the technical lead for the 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. He also has been the technical lead for the commercialization and qualification of these devices. Edward works closely with Kindeva's CDMO's and their customers to ensure all aspects of device development and development supplies from initial batches through to commercialisation meets the needs of their customers. Recently he has been working with Kindeva's partners and the resin suppliers to try and understand what switching to sustainable materials actually means and how complex of a change it is to undertake.

Presenter

Nolwenn Stephan
Materials Engineering Manager - INSIGHT, R&D department
Nemera

Nolwenn Stephan is a polymers scientist by education, and for more than 20 years has been working for the healthcare/medical industry guiding development teams with material selection. In 2001, she started her career at Merck Millipore in the Process Monitoring Tools R&D department and discovered the strong safety and regulatory constrains linked to this area. She has been with Nemera since 2011, and has collaborated with the development, purchasing and regulatory teams to qualify the best materials for own-IP devices and to provide support to Nemera customers.

With raising sustainability concerns, the ambitious ESG objectives of Nemera and the public commitment to reduce its carbon footprint (SBTi), Nolwenn is involved in different projects where alternative fossil-based materials are assessed.

Nolwenn is a member of the IPAC-RS Material Working Group, as well as the MedPharmPlast Europre organization and its Sustainability Working Group. She is convinced that sustainability challenges will be addressed at an industry level with a strong communication and partnership with the relevant authorities.

Presenter

Harriet Lewis
Director of Market Access and Public Affairs
Chiesi Ltd, UK affiliate of Chiesi Group

Harriet Lewis leads Chiesi UK's Government and NHS Advocacy and Communications Programme as well as having responsibility for all Market Access activities, to enable access of Chiesi products to patients. Much of Harriet's external advocacy work showcases the company's extensive sustainability commitments and credentials, including B Corp status gained in 2018 and recertified in 2023, Chiesi's investment in the development of carbon minimal inhalers and her leadership of the award-winning postal inhaler recycling scheme. Harriet uses her advocacy opportunities to encourage and support other businesses to start on their sustainability journeys. She is currently chair of the ABPI Sustainability Group, the UK sub-team of International Pharmaceutical Aerosol Consortium (IPAC) and is a founding member of Circulatory in Primary Pharmaceutical Primary Packaging Accelerator (CiPPPA) .

Harriet studied Pharmacy at University of Manchester followed by Diploma in Public Health. Harriet practised as an NHS pharmacist for over 18 years before moving to NICE as Head of Policy and Implementation, followed by a similar policy focused role with the Association of British Pharmaceutical Industry (ABPI). Harriet joined Chiesi in January 2018 to lead a new team for the UK business, focusing on Public Affairs and NHS Engagement.

Presenter

Tim Buxton
Technical Transfer Station Operations and Development Manager
Grundon Waste Management

Tim Buxton, BSc MCIWM, is the Technical Transfer Station Operations and Development Manager at Grundon Waste Management. With a degree in Chemistry from the University of Warwick, Tim's dedication to environmental improvement has been a driving force throughout his career.

Since 2014, when Grundon opened its state-of-the-art AeroPak - the world's most advanced closed loop aerosol recycling system - Tim has spearheaded technological advancements to accommodate the inhaler recycling market, ensuring propellants are separated and captured for recycling purposes. His efforts have not only pushed the boundaries of waste management but also aligned closely with Grundon's environmental and sustainability commitments.

From entering the waste management industry during a time when landfill was the predominant disposal method, Tim has witnessed and contributed to a number of significant transformations within the sector over the last two decades.

Tim's career underscores a profound passion for environmental stewardship and a relentless pursuit of innovative solutions in waste management, reflecting both his personal values and Grundon's ethos of environmental responsibility.

Presenter

Steven Hoare
Head of Standards and Regulatory Governance, Secretary and Scientific Director for the British Pharmacopoeia Commission.
MHRA

Steve is Head of Standards and Regulatory Governance at the MHRA and acts as Secretary and Scientific Director for the British Pharmacopoeia Commission. Prior to joining the Agency in 2023, Steve was Policy Director at the Association of the British Pharmaceutical Industry (ABPI), leading for Regulatory Science and Sustainability topics. Steve has a background in Quality functions across the medicines lifecycle (early discovery through to manufacturing and distribution).

Presenter

Hasmukh B. Patel
Division Director for the Division of Drug Product Quality Assessment III in the Office of Pharmaceutical Quality Assessment I, OPQ, CDER, FDA

Dr. Hasmukh Patel is the Division Director for the Division of Drug Product Quality Assessment III in the Office of Pharmaceutical Quality Assessment I, OPQ, CDER. His division is responsible for assessment of NDA and ANDA applications submitted to FDA for approval. Prior to this, he was the Division Director in the Division of Postmarketing Activities for NDAs in the Office of Lifecycle Management, OPQ, CDER.

Dr. Patel has more than 25 years of technical, regulatory and managerial experience. His work experience includes review of Investigational New Drug Applications (INDs), New Drug Applications (NDAs) and NDA supplements for a wide variety of dosage forms and drug products. He has also served on various technical committees at CDER drafting Chemistry, Manufacturing and Controls (CMC) guidance documents. Currently he is a member of the Emerging Technology Team (ETT), Platform Technology Team (PTT), Established Conditions Coordinating Committee (ECCC), OPQ Nitrosamines Working Group, and CDER Task Force for nitrosamines impurities. He is also involved in drafting various policies and procedures documents in OPQ. He has several years of industrial research and development experience in the area of natural products and organic synthesis and academic experience in the development of radiopharmaceuticals for medical imaging.

He received his Ph.D. in Organic Chemistry from the University of Georgia, Athens, Georgia and M.Sc. in chemistry from the Indian Institute of Technology, Mumbai, India.

Moderated Q&A with Presenters and Panelists

Edwin Jao
Division Director
Office of Pharmaceutical Quality (OPQ), CDER, FDA

Edward Jackson
Device Development Team Leader
Kindeva Drug Delivery

Rob Haley
Global Director of Program Management – Medical, Drug Delivery Device
Celanese

IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

Regulatory and Technical Considerations in Sustainable Lifecyle Approaches for OINDP Device and Container Closure Systems (Part III)

IPAC-RS Roundtable

March 14, 2024

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

Lana Lyapustina
svetlana.lyapustina@faegredrinker.com

Lee Nagao
Lee.Nagao@faegredrinker.com

Dede Godstrey
Dede.Godstrey@faegredrinker.com

Mary Kate Bielinski
Marykate.bielinski@faegredrinker.com

