Welcome to the IPAC-RS Roundtable!

IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

Designing for a Sustainable Future: Strategies to Address the Device and Delivery System Lifecycle

IPAC-RS Roundtable

April 1, 2025

www.ipacrs.org

This session will be recorded and made available on the IPAC-RS website, post-webinar.

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 drugs and biologics (INDB) by collecting and analyzing data, and conducting joint research and development projects.

Representing the INDB 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
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Our Members

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

AstraZeneca
Bespak
Boehringer Ingelheim
Catalent
Chiesi
GSK
Kindeva Drug Delivery
Lonza
Lupin Pharmaceuticals
Merck & Co., Inc.
Sandoz
Teva
TranspireBio
Vectura Ltd.
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
Harro Höfliger
Honeywell
H&T Presspart
Intertek
invoX Belgium, N.V.
Koura, an Orbia Business
Nemera
PPD
Proveris Scientific Corporation
RxPack

IPAC-RS Progress: 2025

IPAC-RS has been actively working on goals outlined in the 2025-2027 strategic plan.

The Consortium:

1. Engages actively with global regulatory and standard-setting authorities.
2. Provides up-to-date information to the members on relevant developments.
3. Identifies and publicizes INDB industry 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 IPAC-RS Year in Review 2024 and Strategic Plan 2025-2027

Top 5 Reasons to Join IPAC-RS

1. Stay ahead of emerging international regulatory and scientific challenges facing the INDB 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:	*Roundtable: Regulatory and Technical Considerations in Sustainable Lifecycle Approaches for OINDP Device and Container Closure Systems (Part III)*
	WORKSHOP: Inhaled Biologics: Preparing for a Future Beyond Small Molecules – Sept. 4-5, 2024. Recordings and presentations available here.
2025:	***Today – Designing for a Sustainable Future: Strategies to Address the Device and Delivery System Lifecycle***

Housekeeping

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

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

Today's Agenda

I. Welcome and Introduction to IPAC-RS & Overview of Webinar Logistics	10:00 – 10:05 AM	**Mary Devlin Capizzi**, IPAC-RS Secretariat **Lee Nagao**, IPAC-RS Secretariat
II. Designing for the Future	10:05 – 10:15 AM	**Edward Jackson**, Kindeva Drug Delivery **Phil Smith**, Vectura
III. Panel Discussion	10:15 – 11:30 AM	**Edward Jackson,** Kindeva Drug Delivery **Phil Smith,** Vectura **Glenn Svedberg,** Nolato **Alan Harris,** Bespak **Shaun Williams,** Bespak **Mauro Citterio,** Plastiape **Gabriel Bjerner,** AstraZeneca **James King**, GSK

Designing for the Future

See full bios at Roundtable website.

Ed Jackson
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Phil Smith
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Summary of Previous Roundtable discussions – Nov 2022

- ***Introduction into the availability of sustainable grades of resins which can be used now in for our existing and new products.***
  - **Mass Balance approach, switching from fossil feedstocks to circular or bio-based feedstock.**
  - **ISCC certification.**
- ***Presentations and panellists***
  - **Sustainability from a Plastic Raw Material Solutions Perspective - Beate Treffler, Regional Sales Manager Europe, Healthcare Polymer Solutions, Avient Colorants Germany GmbH**
  - **Contributing to More Sustainable Drug Delivery Devices - Marc Severin, Program Manager Sustainability and Innovation, Presspart**
  - **LCA for Devices, Eco-Design, Circularity - Christian Pommereau, Principal Engineer, Technology Platform Development, Sanofi**
  - **Switching to Sustainable Materials for our Current Devices - Edward Jackson, Device Development Team Leader, Kindeva Drug Delivery**

Summary of Previous Roundtable discussions – February 2023

- ***More details regarding the availability of sustainable grades of resins which can be used now in for our existing and new products.***
  - ***Mass Balance approach, switching from fossil feedstocks to circular or bio-based feedstock.***
  - ***Presentations from reason suppliers Borealis, DuPont and Celanese sharing how they approach the switch to sustainable grades of resin***
  - ***ISCC or RedCert certification.***
- ***Presenters***
  - ***Sustainability Drug Deliver Devices - Christian Meusinger, Vice President Global Quality & Regulatory, Nemera***
  - ***Achieve Healthcare Product Circularity - Paulo Cavacas, Business Development Manager, Borealis***
  - ***Delrin Renewable Attributed - Valéry Rebizant, Delrin® Global Sustainability Leader and Sustainability Marketing Leader, DuPont***
  - ***Celanese ECO-B solutions - Rob Haley, Global Director of Program Management – Medical, Drug Delivery Device, Celanese***
- ***Additional Panellists***
  - ***Marc Severin, Program Manager Sustainability and Innovation, Presspart***
  - ***Edward Jackson, Device Development Team Leader, Kindeva Drug Delivery***
  - ***Beate Treffler, Regional Sales Manager Europe, Healthcare Polymer Solutions, Avient Colorants Germany GmbH***

Summary of Previous Roundtable discussions – March 2024

- ***Learning and challenges of recycling Inhalers by Chiesi and Grundon waste management.***
- ***Regulatory and Technical Considerations in Sustainable Lifecyle Approaches for OINDP Device and Container Closure***
- ***Presenters***
  - ***Switch to Mass Balance Circular Resins - Nolwenn Stephan, Nemera***
  - **Managing the end of life of Inhalers though postal recycling scheme, experience sand learnings - *Harriet Lewis, Chiesi***
  - ***The difficulties in recycling Inhalers - Timothy Buxton, Grundon Waste Management, Ltd.***
  - ***Current MHTA position on sustainability themes in device manufacturing - Steven Hoare, MHRA***
  - **Lifecycle management considerations as it includes changes throughout the lifecycle of the product - *Hasmukh Patel, FDA/ CDER***
- ***Additional Panellists***
  - **Rob Haley, Global Director of Program Management – Medical, Drug Delivery Device, Celanese**
  - **Edward Jackson, Device Development Team Leader, Kindeva Drug Delivery**
  - **Edwin Jao, FDA / CDER**

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Phil Smith

Vectura Limited,
part of Phillips Medisize

Set the Scene

Definition of Sustainability

In 1987, the United Nations Brundtland Commission defined sustainability as

> “meeting the needs of the present without compromising the ability of future generations to meet their own needs.”

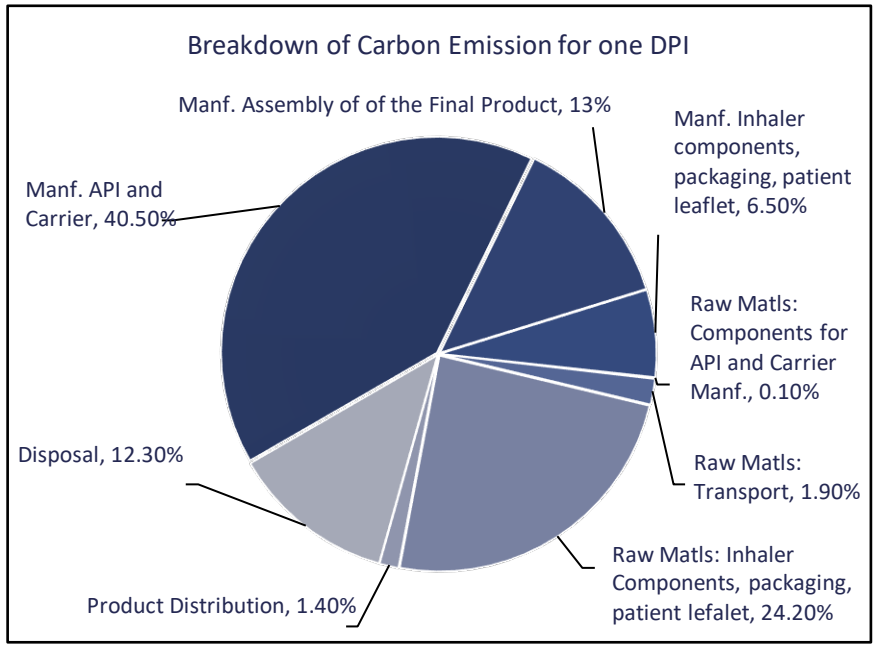
All impacts for The Whole Life-cycle

All Impacts

Greenhouse Gas Emissions		
Fossil depletion	Human Toxicity	Marine eutrophication
Freshwater eutrophication	Ionising radiation	Ozone Depletion
Water depletion	Agricultural land use	Urban land use

Inget M, Hisinger-Mölkänen H, Howard M, Lähelmä S, Paronen N. Cradle-to-Grave Emission Reduction for Easyhaler Dry Powder Inhaler Product Portfolio. Pulm Ther. 2023 Dec;9(4):527-533.

The Whole Life-cycle

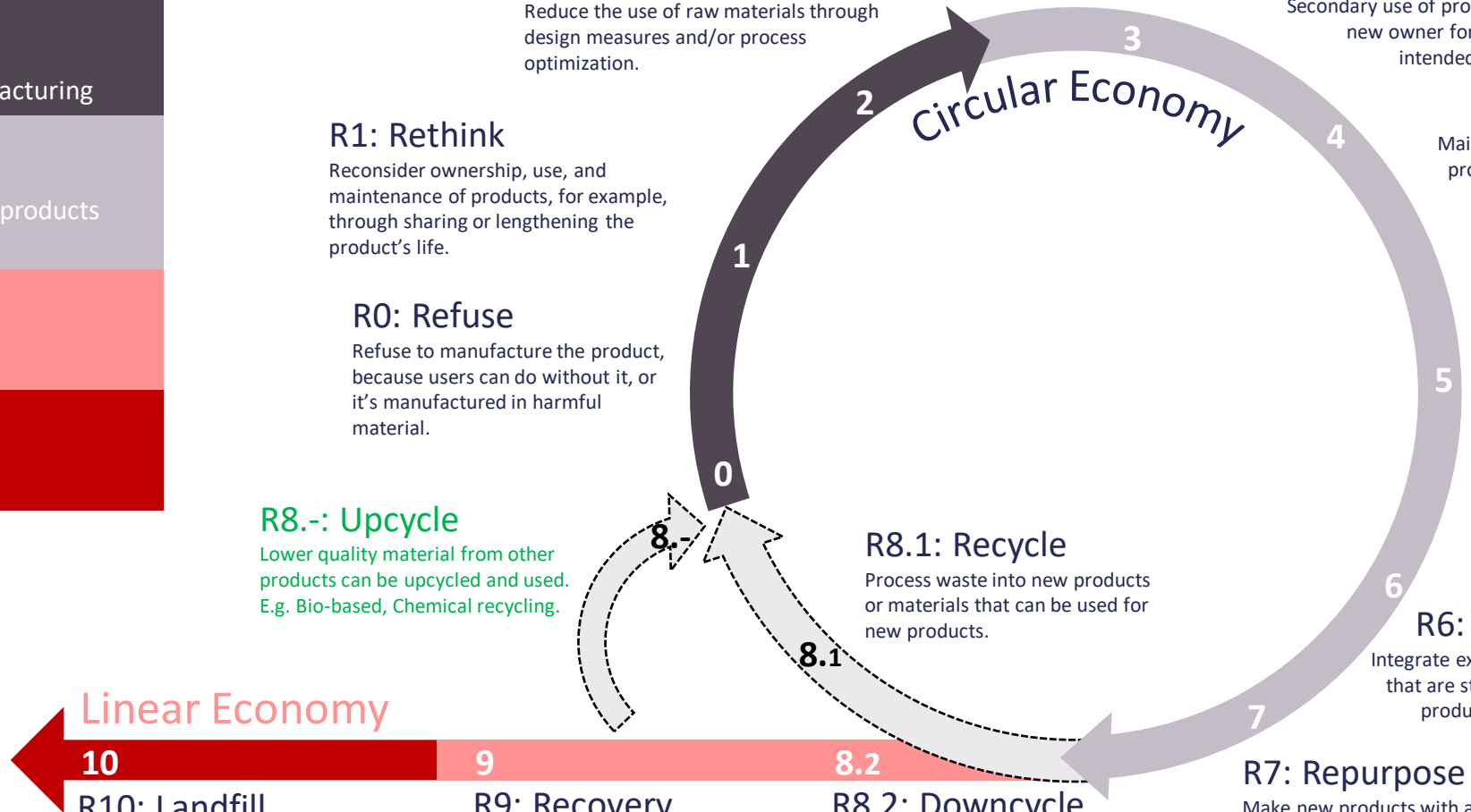


Borenius K, Vartiainen V, Takala A, Haikarainen J, Parker G, Paronen N, Haahtela, T. Life Cycle Assessment (LCA) and Cradle-to-Grave (CTG) Carbon Footprint of a Multidose Reservoir Dry Powder Inhaler. European Respiratory Journal. 2020 56(suppl 64): 3183.

The Circular Approach

R0-R2	Design phase Most sustainable Adds value Responsible use and manufacturing
R3-R8.1	Consumption phase Optimal use Preserve and extend life of products Use materials as a resource
R8.2-R9	End-of-life or return phase Capture and retain value Use waste as a resource
	Loss of resources Value lost Environmental pollution

R-Thinking: Innovating for a Circular Economy
(https://www.nolato.com/en/Stories/R-thinking)



R2: Reduce
Reduce the use of raw materials through design measures and/or process optimization.

R3: Reuse
Secondary use of products by a new owner for the same intended purpose.

R1: Rethink
Reconsider ownership, use, and maintenance of products, for example, through sharing or lengthening the product's life.

R4: Repair
Maintain and repair existing products for extended use.

R0: Refuse
Refuse to manufacture the product, because users can do without it, or it's manufactured in harmful material.

R5: Refurbish
Restore and improve products to a satisfactory condition for extended use.

R8.-: Upcycle
Lower quality material from other products can be upcycled and used. E.g. Bio-based, Chemical recycling.

R8.1: Recycle
Process waste into new products or materials that can be used for new products.

R6: Remanufacture
Integrate existing product components that are still perfectly intact into new products with the same function.

R7: Repurpose
Make new products with a different purpose using discarded products or parts.

R10: Landfill
Disposal of product on a landfill site.

R9: Recovery
Energy recovery through waste incineration or decomposition of biological waste to extract biogas.

R8.2: Downcycle
Lower quality material can still be downcycled and used in new functions but with limitations.

Key Challenges

REGULATORY AND MATERIAL REQUIREMENTS

Meet stringent safety and efficacy standards, which often limits industry willingness innovate with materials and designs.

The industry needs to find biocompatible and durable design approaches that are sustainable.

MEDICAL WASTE MANAGEMENT

Developing recyclable or reusable alternatives and implementing sustainable waste management practices is crucial.

Disposal is difficult due to drug contamination and single use designs.

SUPPLY CHAIN AND CIRCULAR ECONOMY

Adopting circular economy principles, such as reuse, remanufacturing, and recycling, can help reduce waste and resource consumption.

However, implementing these practices requires collaboration across the entire value chain and overcoming safety and regulatory hurdles.

Panel Discussion

See full bios at Roundtable website.

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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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