NAVIGATING THE TRANSITION TO LOW GLOBAL WARMING POTENTIAL PROPELLANTS

Session 2: Current Industry Experience with New Drug LGWP MDI Development

Introductions:	**Christy Gilbert, BS, RAC**	Associate Director, CMC Regulatory Affairs, AstraZeneca
Presenters:	**Ann Purrington, BS, RPh, RAC**	Regulatory Affairs Director, Kindeva Drug Delivery
	Richard (Rik) Lostritto, PhD	Consultant, Lostritto Consulting, LLC
	Helen Strickland, MS	Sr. Statistical Consultant, Manufacturing Science and Technology, GSK
	Laura Clow, MChem	Medicine Development Leader, GSK
	Poonam Gulati, PhD, MBA, PGCert	Sr. Director and Team Lead, Global Regulatory Affairs, GSK
	David Lechuga-Ballesteros, PhD	Head of Innovation, Inhalation Product Development, AstraZeneca
	Angelo Benedetto Matturo, MS	R&D Global Technical Leader, CHIESI Farmaceutici

FDA U.S. FOOD & DRUG ADMINISTRATION

Hybrid Public Workshop
December 4-5, 2024

CENTER FOR RESEARCH ON COMPLEX GENERICS at the University of Maryland, Baltimore and the University of Michigan

NAVIGATING THE TRANSITION TO LOW GLOBAL WARMING POTENTIAL PROPELLANTS

Session 2: Current Industry Experience with New Drug LGWP MDI Development

Moderators:	**Christy Gilbert, BS, RAC**	Associate Director, CMC Regulatory Affairs, AstraZeneca
	Sue Holmes, MS	CMC Regulatory Consultant, Sue Holmes CMC Consulting LLC
Panelists:	**Laura Clow, MChem**	Medicine Development Leader, GSK
	Poonam Gulati, PhD, MBA, PGCert	Sr. Director and Team Lead, Global Regulatory Affairs, GSK
	Sheryl Johnson, CChem, MChem	Pharma Application Development Lead, Orbia Fluor & Energy Materials, Koura
	David Lechuga-Ballesteros, PhD	Head of Innovation, Inhalation Product Development, AstraZeneca
	Richard (Rik) Lostritto, PhD	Consultant, Lostritto Consulting, LLC
	Markham Luke, MD, PhD	Director, DTP I, ORS, OGD, FDA
	Angelo Benedetto Matturo, MS	R&D Global Technical Leader, CHIESI Farmaceutici
	Ann Purrington, BS, RPh, RAC	Regulatory Affairs Director, Kindeva Drug Delivery
	Helen Strickland, MS	Sr. Statistical Consultant, Manufacturing Science and Technology, GSK

What is IPAC-RS?

- 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, webinars, and discussions with regulatory bodies.

- IPAC-RS advances and supports science-based regulatory approaches for OINDPs to ensure their availability, safety, efficacy, and quality.

- IPAC-RS works collaboratively across the industry and with external experts from regulatory agencies, standard-setting bodies, academia, pharmacopeias, healthcare providers, patient groups, and other stakeholders.

- IPAC-RS members are based around the world, and its activities are global, with region-specific projects in North America, South America, Europe, and Asia.

- IPAC-RS shares its findings with the larger scientific and regulatory community through publications, online tutorials, in-person training courses, webinars, and conferences.