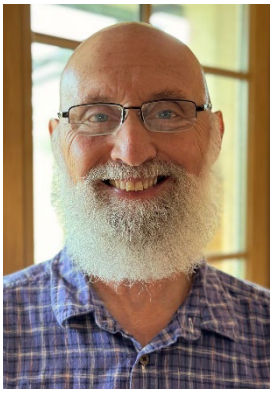
IPAC-RS WORKSHOP ON THE TRANSITION TO LOW GLOBAL WARMING POTENTIAL PROPELLANTS FOR METERED DOSE INHALERS

October 11, 2023 - Bios



Richard (Rik) Lostritto, Ph.D.
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Richard (Rik) Lostritto has over 46 years professional experience in pharmacy practice, education, and research in pharmaceutical science. After receiving his B.S. Pharmacy from the University of Connecticut and working as a hospital pharmacist, Rik attended and received this M.S. and Ph.D. degrees in pharmaceutical chemistry from the University of Michigan, after which he served on the faculty of UCONN's School of pharmacy for nine years. In 1992, Rik joined Boehringer Ingelheim in Ridgefield CT where he led a group developing HFA alternate propellant MDI formulations. In 1995, he joined the FDA in the (then) Division of Pulmonary and Allergy Drug Products as a Chemist where he served as the sole primary Chemistry reviewer for the first HFA-based MDI and first DPI approved in the United States. Rik went on to serve as Team Leader and Division Director in multiple therapeutic areas including OINDPs. From 2015 onward, he served as the Associate Director for Science in the Office of Policy for Pharmaceutical Science which included regulatory and policy oversight of combination drug products such as MDIs. After 27 years at FDA, Rik retired in 2022 and has since been working as an Independent Consultant and serving as Science Advisor to IPAC-RS.

Sue Holmes
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Sue Holmes has 35 years' experience in the pharmaceutical industry, leading cross-functional teams in both product development activities and regulatory focused activities. She started her career as an analytical chemist with GSK and quickly moved into the area of analytical development of inhaled products, then, over 20 years ago, moved into CMC Regulatory Affairs. Sue has experience working on clinical trials, initial marketing applications and from 2019 to 2023 led the CMC Regulatory Mature Product Respiratory team, who were responsible for GSKs global post-approval change programs for the respiratory portfolio and medical devices. Since July 2023, Sue has been working as a consultant with GSK, and as such continues to represent GSK in IPAC-RS activities. Within IPAC-RS, Sue has been GSKs board representative for 16 years, participating on various Working Groups; and is currently the co-chair for the Global Regulatory Outreach on Alternate Propellants Working Group who organized this workshop.

Craig M. Bertha
Chemist, Division of New Drug Products (DNDP) II, Office of New Drug Products (ONDP) OPQ, CDER, U.S. Food and Drug Administration
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Craig received his B.A. degree in Chemistry from the University of Maryland, Baltimore County in 1986, and M.S. and Ph.D. degrees in Organic Chemistry from the University of Maryland Graduate School at Baltimore in 1989 and 1992, respectively. He was a postdoctoral fellow in the Laboratory of Medicinal Chemistry at the National Institutes of Health under the direction of Kenner Rice, Ph.D. from 1992-1995. Craig then joined the FDA as a CMC reviewer co-located in the Division of Pulmonary and Allergy Drug Products (DPADP) in 1995 and currently serves as a reviewer in ONDP, supporting both the Division of Pulmonology, Allergy, and Critical Care (DPACC) and the Division of Rheumatology and Transplant Medicine (DRTM). Craig currently serves on the working group revising the 2018 draft quality guidance for MDIs and DPIs, the internal Agency working group for ICH Q3E guidance for extractables/leachables, and several Agency working groups involved in regulatory aspects related to the changing of propellants for MDIs to reduce global warming.

Karolina Törneke
Associated Professor
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Dr. Karolina Törneke is a pharmacologist with more than 20 years' experience as clinical assessor at the Medicinal Products Agency (MPA). She is a senior expert with a main focus on respiratory medicine including approval of orally inhaled products. She is involved in guideline work at the European Medicines Agency acting vice chair of the Rheumatology and Immunology Working Party with responsibility for the revision of the guideline for orally inhaled products.

Dan Dohmeier, Ph.D
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Dan has more than 17 years' experience in drug product development, spanning several of Kindeva's delivery platforms including metered dose inhalers, transdermal patches, and intradermal microneedle delivery. Dan currently leads the Extractables & Leachables lab at Kindeva, where he manages a team focused on development and validation of methods to characterize materials extractables profiles and drug product leachables profiles. Dan has been engaged with IPAC-RS as a member of the Materials Working Group for 5+ years, and is currently the co-chair of the Materials & Propellants Working Group.