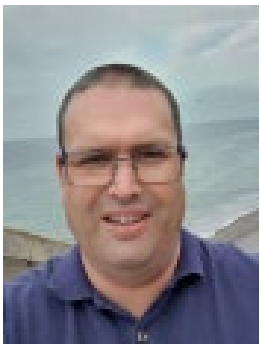
IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

IPAC-RS Roundtable Series 2023:

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

March 14, 2024 – Bios

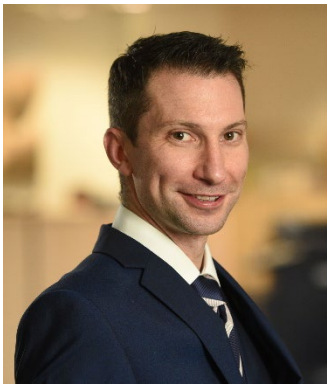
Moderator:



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.

Presenters and Panelists:



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

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

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.

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).

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

Edwin Jao serves as the Division Director within the Center for Drug Evaluation and Research (CDER)'s Office of Pharmaceutical Quality (OPQ)/ *Office of Pharmaceutical Manufacturing Assessment (OPMA)* at the FDA, where he oversees the evaluation of drug product manufacturing processes and facility assessments. With over 20 years of experience at the Agency, Jao possesses extensive regulatory expertise in the realm of small molecule drug applications, encompassing Investigational New Drug (IND) applications, New Drug Applications (NDA)/Abbreviated New Drug Applications (ANDA), and their supplements. He is particularly knowledgeable about issues related to extractables and leachables that may arise from manufacturing, packaging, and delivery systems.

He worked for major pharmaceutical companies with various responsibilities prior to joining the Agency. His education background includes chemical engineering (BS), organic synthesis (MS), and medicinal chemistry (PhD).

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.

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.

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.