IPAC-RS Roundtable Series 2022:

ADVANCING SUSTAINABILITY OF DEVICE AND CONTAINER CLOSURE SYSTEMS

PART I - November 30, 2022

Bios

Moderator:

Lee M. Nagao, Ph.D.
Senior Director - Science, Regulatory & Policy
Faegre Drinker Biddle & Reath LLP, IPAC-RS Secretariat
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Lee M. Nagao, Ph.D., is a Senior Director of Science, Regulation and Policy at the law firm of Faegre, Drinker, Biddle and Reath, LLP, and is a member of the Firm's Life Sciences Consortium Management and Regulatory Affairs Practice Group. The Group works extensively with pharmaceutical, biopharmaceutical and medical device companies on a range of scientific and regulatory collaborations and provides strategic and regulatory guidance to individual life sciences companies. Lee plays a lead role serving scientific and regulatory consortia including the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS), the Extractables and Leachables Safety Information Exchange (ELSIE), and the International Pharmaceutical Consortium on Innovation and Quality (IQ). Lee has extensively published and presented on many aspects of pharmaceutical development including supply chain, CMC, and translational sciences. She has represented various industry groups before regulatory and scientific agencies and organizations in the US, Europe and Asia, including the FDA, EMA, China NIFDC, Chinese Pharmacopoeia, ANVISA, Taiwan CDE, Japan PMDA, and USP.

Presenters:

Edward Jackson
Device Development Team Leader
Kindeva Drug Delivery
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Ed Jackson has 25 years' experience of actuator and dose counter development, optimisation and commercialisation at Kindeva, formerly 3M Drug Delivery Systems.

He has been the technical lead for our 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.

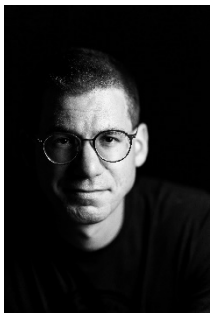
Ed has also been our technical lead for the commercialisation and qualification of these devices. I work closely with our CDMO's through to our customers to ensure all aspects of device development and development supplies from initial batches through to commercialisation meets the needs of our customers.

Over the last 18 months he has been working with our partners and resin suppliers to trying and understand what switching to sustainable materials actually means and how complex of a change is it to undertake.

Beate Treffler
Regional Sales Manager Europe, Healthcare Polymer Solutions
Avient Colorants Germany GmbH
beate.treffler@avient.com

Beate Treffler has over 25 years of experience in additives for plastic applications and processing. In March 2015 she joined the Business Unit Masterbatches of Clariant as Regional Head Europe Segment Healthcare Polymer Solutions being responsible for Marketing & Sales. On 1st of July 2020 the former PolyOne Corp. acquired Clariant's BU Masterbatches to form the new company Avient Corporation, a leading provider of color- and performance-enhancing concentrates and compounds. Since October 2021 she leads the HC Sales in EMEA and together with the dedicated team they provide polymer solutions for pharma packaging, medical - and drug delivery devices. These polymer solutions comprise pre-tested and changed controlled concentrates/masterbatches as well as ready-to-use compound solutions.

Before joining BU Masterbatches, she was heading the global technical marketing team for waxes in the Business Unit Additives of Clariant. Furthermore, she was involved in project management for new developments and for the Clariant Commercial Excellence program (Lean Sigma; certified Green Belt).



Marc Severin
Program Manager Sustainability and Innovation
H&T Presspart
marc.severin@presspart.com

Marc Severin has over 10 years of experience in engineering and project management. He joined H&T Presspart in 2017 and has taken over several responsibilities in business development, key account project management and is driving the sustainability program with the H&T Presspart Division, world leader and specialist in manufacturing drug-delivery systems and pharmaceutical components, since 2021. In this program Marc manages the strategic sustainability objectives and networks throughout the organization to intensify H&T Presspart's endeavors to become a key driver in the market for more sustainable supply chains.

Holding a bachelor's degree in engineering and a master's degree in international management, Marc adores finding practical and tangible solutions for the challenges we are facing like resource scarcity and climate change. Over the past months he started initiatives and discussions with customers and supplies the evaluate future potentials and cooperations along the supply chain. In his role as a project manager, he worked on changes with H&T Presspart's key customers to optimize packaging's, production processes and supported the quality management along the supply chain.

Christian Pommereau
Principal Engineer Platform Technology
Sanofi
christian.pommereau@sanofi.com

Almost 25 years of experience in design and production of complex disposable devices for Diagnostics and Healthcare

20 years with SANOFI, a large pharmaceutical company, for DDC and Medical Device working with increasing responsibilities in Design, Industrialization, Supplier Management, Program Management, Sustainability, etc.

(Board-) Member of various associations and guidelines working groups: MPPE, KiM e.V, VDI 2017 and VDI 2023

New position as of Jan 1st 2023 to develop and drive Eco-Design activities for Sanofi devices, across the value chain.