IPAC-RS Digital Devices Roundtable Series:

DIGITAL DEVICES: REGULATORY CHALLENGES AND CONSIDERATIONS

November 22, 2021
Bios

Moderators:

Fredrik Mannerstråle
Director Regulatory CMC, Medical Devices and Combination Products
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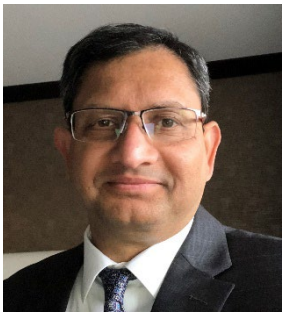
Fredrik has been working in the pharmaceutical industry in various positions for 28 years - mainly within packaging and devices, development engineering, line management and project management. He has spent time working within Manufacturing and within R&D. Prior to joining AZ, Fredrik was Business Area Manager at the company Kronans Droghandel focused on packaging and clinical trials. During this period he was responsible together with Quality when other companies and the Swedish MPA inspected this part of the company. Over recent years at AZ, Fredrik has been developing inhalation devices, both as a line and project manager. Additionally Fredrik was part of the global team that created AZ's current SOP's for device development. Starting in 2014 Fredrik has been part of an ISO working group which has developed a new standard for Device Change Management (ISO 20069). His education background is MSc in Mechanical Engineer. Since January 2019 he has been working within Regulatory CMC, Medical Devices and Combination Products Global Regulatory Excellence mainly with inhalation combination products and inhalation devices. Since 2020 he holds a RAC for device.



S. Prasad Peri, Ph.D.
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S. Prasad Peri, Ph.D. is currently Senior Director, Global Specialty Regulatory Affairs CMC at Teva Branded Pharmaceutical Products R&D Inc., based in West Chester, PA. He and his team are responsible for the regulatory CMC for Small Molecules, Biologics, Combination Products and Devices. Prior to joining Teva Prasad was employed at Merck and Co. as a Director for Global Regulatory Affairs responsible for Combination products and Devices. Prior to joining Merck, Prasad Peri was Branch Chief at the Office of New Drug Quality Assessment in FDA responsible for the CMC review assessment of products submitted to Divisions of Pulmonary, Allergy, Rheumatology, Anesthesia, Analgesia and Addiction. Prasad Peri holds a Ph.D. in Pharmaceutical Chemistry and a BS in Pharmacy.

Speakers:

Robert Berlin, JD, M.P.H
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Rob Berlin is the Head of U.S. Regulatory Policy at GlaxoSmithKline (GSK). Rob leads a team focused on driving U.S. regulatory policy, advocacy, and intelligence activities, to ensure optimal advancement and lifecycle management of GSK's product portfolio. Rob came to GSK from the FDA where he most recently served as the Director of the Division of Clinical Policy within the Office of New Drug (OND) Policy, an office he helped to establish as a founding member of the leadership team. Prior to joining OND Policy, Rob worked in CDRH, FDA's Office of Policy, and in the Office of Chief Counsel. He began his career at Hogan & Hartson (now Hogan Lovells) after completing his law degree and M.P.H. in Epidemiology at the University of Minnesota.

Claudia Vincenzi, Ph.D.
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Claudia Vincenzi is a Quality Specialist at the European Medicines Agency (EMA) in Amsterdam, Netherlands, where she has been working for over 5 years. In her role, she provides scientific peer-review of all quality aspects throughout the life cycle of medicinal products, supporting European Committees, Working Parties as well as the preparation of guidelines. Within the Quality Office Claudia is the topic lead for digital technologies and inhalation products. During the ongoing pandemic she has been involved in several rapid scientific advices for COVID-19 products. Prior to joining EMA, Claudia worked as Regulatory CMC Director at Mylan Global Respiratory Group, U.K., where she led the preparation of the Module 3 for INDs, IMPDs, ANDA on different inhalation products. Claudia came to Mylan from the Medicines and Healthcare products Regulatory Agency (MHRA), U.K., where she worked for over six years as Pharmaceutical Assessor, specialising on inhalation products, among other pharmaceutical form. Claudia holds a Ph. D. in Pharmaceutical Technology from the University of Bradford, U.K., and a pharmacy degree from the University of Trieste, Italy.