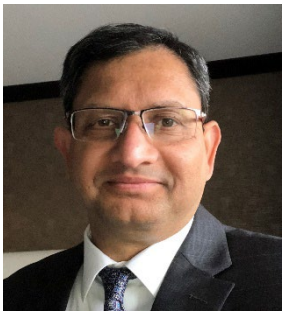
IPAC-RS Digital Devices Roundtable Series:

DIGITAL DEVICES: MANUFACTURING AND DESIGN CONSIDERATIONS

September 29, 2021

Bios

Moderators:



S. Prasad Peri, Ph.D.
Senior Director, Global Specialty Regulatory Affairs CMC
Teva Branded Pharmaceutical Products R&D Inc.
Prasad.Peri@tevapharm.com

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.

Robyn Parker, MS
Associate Director, Global Regulatory Affairs
Sunovion
Robyn.Parker@sunovion.com

Robyn Parker, MS, is an Associate Director, Global Regulatory Affairs at Sunovion Pharmaceuticals, Inc. headquartered in Marlborough, MA. Her experience encompasses not only regulatory strategy, but also Regulatory CMC, Advertising and Promotional review, and drug product labeling. In addition, Robyn has extensive knowledge and involvement in addressing Health Authority inspection responses worldwide. She has global and regional responsibilities for phase 1 clinical studies through post approval life cycle management covering Cardiovascular and Renal, Neurology, Psychology, and Respiratory therapeutic areas. She also serves as a preceptor for Doctor of Pharmacy Fellows.

Robyn's pharmaceutical career spans Manufacturing, Quality Assurance, Regulatory Compliance, and Regulatory Affairs. She holds a MS in Regulatory Affairs and Quality Assurance, and a BS in Chemistry.

Speakers:

Ulf Ericsson, MS
Vice President Drug Development
Nanologica
ulf.ericsson@nanologica.com

Ulf Ericsson is an experienced leader in Marketing and Business Development with 25-years experience in the Pharmaceuticals industry, whereof twenty in inhaled medicine. In all, seventeen years in AstraZeneca managing product portfolios in all stages from pre-launch to launch and LCM as well as managing all inhalation devices both on market and in development. Ulf have also extensive experience in working with the environmental sustainability aspects of our business, especially from an inhaler device and formulation perspective. Up to just recently Ulf was leading the Global Inhaled Device strategy work for AstraZeneca's inhaled portfolio, as well as leading the commercial part in the development of future inhalation devices, formulations and platforms, including digital pharma. In the past five to six years there has been an increasing interest and focus on how to use and develop novel digital technology to further improve clinical outcomes of our already existing medicines as well as improving the patient experience and user interface. Ulf have been deeply involved in the business development and strategies in this field especially from a commercial and business perspective, e.g., user interface, business models, business cases and ROI. Ulf recently joined Nanologica, a nanotechnology company developing nano porous particles for applications in life science, e.g. delivering oral and inhaled drug products, where he is leading the Drug Development organisation and strategy. Ulf holds a Master of Science in Business Administration, Business Economics and Marketing Management from the University of Lund, Sweden.

David Pettigrew, DPhil
VP Global Accounts
BrightInsight
david.pettigrew@brightinsight.com

David Pettigrew, DPhil has 15 years of experience in medical device and pharmaceutical product development. Prior to joining BrightInsight, he was Managing Director of Sagentia, a technology and product development consulting firm. During his time at Sagentia, he served a range of large multinational healthcare clients, with particular focus on development strategies for integrating connectivity into higher risk medical devices such as in vitro diagnostic instruments, implantable neurostimulators and autoinjectors. He has also participated in FDA discussion panels on (regulated) mobile medical apps.

His early career focused on developing sensors for point of care microfluidic diagnostic instruments, most notably the world's first clinical analyzer for measuring the anaesthetic propofol in whole blood. His work in diagnostics has resulted in several CE mark and FDA 510k approvals.

David holds a DPhil from the University of Oxford, UK in Molecular Biophysics, where he used X-Ray Crystallography and Electron Microscopy to explore host-pathogen interactions at the molecular level.