IPAC-RS Digital Devices Roundtable Series:

DIGITAL DEVICES: MANUFACTURING AND DESIGN CONSIDERATIONS

September 29, 2021

Bios

Moderators:

Daniela Gramaglia, Ph.D.
Design Control and Documentation Specialist
Chiesi Group
d.gramaglia@chiesi.com

Dr. Daniela Gramaglia is a Senior Design Control and Documentation Specialist with 15 years of experience in medical device and pharma R&D.

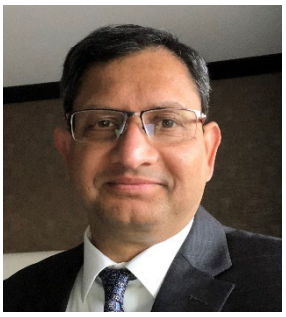
Skilled in development of pure medical device and combination products used in different areas such as cardiovascular, respiratory and neonatology with experience gained in development of coronary and peripheral angioplasty devices, syringes used for oral and injectable administration, respiratory devices such as pMDI and DPI.

Daniela supported different companies to improve their quality and documentation management systems. She was actively involved in quality audits and documents preparation for regulatory submissions. She believes in design control as a powerful tool to collect know-how, improve traceability, share information between cross-functional and interdisciplinary team and reduce the effort during the preparation of the technical documentation for regulatory submission.

Since joining Chiesi in 2017, she has provided design development experience and she supported the bridging between Quality assurance, R&D CMC development activities and industrial manufacturing.

Daniela supervises the delivery of project development documents, she acts as a reference for a risk based approach and platform approach and she is the moderator during project design reviews.

Daniela has a Master Degree in Chemical and pharmaceutical technology from the University of Pavia (Italy) with technical final project conducted at Aston University in Birmingham (UK) concluded with the publication of an article in the International Journal of Pharmaceutics.



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.

Speakers:

Stathis Louridas, Ph.D.
Head of Electronics and Software
Team Consulting
Stathis.Louridas@team-consulting.com

Stathis is head of software and electronics at Team Consulting, where he leads work in system design, software development and hardware design. Stathis has extensive experience in the development of medical devices and IVD point of care instruments, leading projects from initial concept through to manufacture. Stathis has a keen interest in connected devices, safety critical software, cybersecurity and the regulation of medical software.

More than 20 years of experience working in the medical device, consumer, and aerospace industry.

Prior to Team, he previously worked as a consultant at Sagentia and has had senior engineering roles in various companies, including CSR and as manager of the development systems group at Samsung in Cambridge. Stathis has a first-class degree in Medical Electronic Engineering, MSc in Bioengineering and a PhD in electronics.

Brennan Miles
Managing Consultant – Drug Delivery
Team Consulting
brennan.miles@team-consulting.com

Brennan is an accomplished medical device expert with an extensive background in managing and delivering innovative, high-value programmes across a range of medical technology and pharmaceutical delivery routes. These include infusion, injection, intranasal, implantable, ocular, oral, respiratory, and topical applications. He also has hands-on experience of gaining device approval within the regulatory frameworks.

With his direct experience of product development and industry knowledge, Brennan co-ordinates Team Consulting's drug delivery activities to ensure we continue to create exciting technologies and deliver exceptional services for our clients.

Prior to his appointment at Team, Brennan worked on the development of medical devices for the pharmaceutical company Pfizer as well as senior roles in other sectors for several large multi-national companies. Brennan has a BSc (Hons) degree in Product Design and Engineering and is the named inventor on several patents.

Andreas Meliniotis
Director, Device Development
Vectura
andreas.meliniotis@vectura.com

Andreas Meliniotis is Director of Device Development at Vectura, leads the mechanical engineering team and the Vectura engineering facility located on the Cambridge Science Park. Andreas has been working at Vectura since 2003, studied Mechanical Engineering at the University of Nottingham and is a Chartered Mechanical Engineer and Chartered Manager.

Andreas has lead the design and development of several multi-dose DPIs, from initial concept through to scaled-up commercialized products, in addition to working on hand-held mesh nebulizers and more latterly on novel connected devices. Andreas has a passion for focusing on simplistic design, in particular simplification at the conceptual level in order to achieve simple, user centric, easy to manufacture products.

Prior to joining Vectura Andreas worked for the Cambridge Design Partnership developing a novel lancet and glucose measurement device and for The Technology Partnership developing large scale industrial printing technology.

Phil Swanbury
Director, Device Development
Vectura
phil.swanbury@vectura.com

Phil Swanbury is a Director of Device Development at Vectura, leading the design assurance team, and responsible for developing the company strategy for digital health. He has worked in various roles at Vectura since 2005.

Phil has led various device development projects within Vectura, including the later phases of GyroHaler and GyroPLUS, which are now successfully launched in multiple territories by our licensee Sandoz as AirFluSal® Forspiro® and AirBuFo® Forspiro® respectively. Recent projects have included devices with electronics and software and various connectivity projects.

Phil has worked in the medical devices sector for over 20 years; at GSK on their portfolio of pMDIs and DPIs, and at Weston Medical on the Intraject needle-free injector, the technology which was eventually commercialised as Sumavel® DosePro® by Zogenix. He is a Mechanical Engineering graduate from the University of Nottingham.