IPAC-RS Roundtable Series 2022:

PATIENT CENTRIC PRODUCT DESIGN

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Moderator:

Jeremy Clarke, Ph.D.
Senior Fellow
Manufacturing Science & Technology, Global Supply Chain
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Jeremy is currently a Senior Fellow in Manufacturing Science and Technology (MSAT), GSK Pharma Supply Chain, supporting technology transfer, industrialisation and filing of late-stage development candidates in the small molecule portfolio, life cycle management programmes for marketed products, internal development of technical experts through the GSK Fellowship programme and external advocacy in pharmaceutical sciences. Jeremy is a Fellow of the Royal Pharmaceutical Society and an Eminent Fellow of the Academy of Pharmaceutical Sciences.

A pharmacist by training, Jeremy obtained his PhD in non-aqueous colloid & interface science at the Welsh School of Pharmacy, University of Cardiff. Following his doctorate studies, Jeremy joined Ciba-Geigy (Novartis) working on OINDPs, where he advanced to leadership of the formulation development group. Subsequently, Jeremy joined Vectura where, as Director of Respiratory Development, he had responsibility for both in-house and contract development programmes. Jeremy then joined Pfizer at Sandwich as matrix/line leader in materials science, formulation, and process development teams, with responsibility for development of new products and technologies for both OINDPs and IR/MR oral solid dosage forms."

Panelists:

Gregor Anderson, Msc
Managing Director
Pharmacentric Solutions Ltd
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Gregor founded Pharmacentric Solutions Ltd in 2017 to deliver consultancy services for the Pharma Industry specialising in device and packaging development and strategies from early concept through to commercial supply. Prior to this Gregor was Senior Design Director at GSK working as a device and packaging specialist and has over 30 years' experience in Pharma and Medical Device design and is a named inventor on over 50 patents and has presented widely on topics such as Digital, Patient Centric Design and Pharma road mapping. He has a B.Sc. in Industrial Design and a M.Sc. in Polymer Science and Engineering. After 3 years at Smiths Medical Systems he joined the Device Development Unit at GSK R&D. He led platform developments including injectable and respiratory devices. In 2009 Greg moved to GSK Manufacturing as Global Head of Technical Packaging. In 2017 he authored the Technology and Innovation road map for UK Pharma.

Juan Cheng, Ph.D., RAC
Device Development, Merck Research Labs (MRL)
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Juan Cheng has over 15 years of working experience in the pharmaceutical and medical device industry. She began her career at Merck as analytical lead in pharmaceutical research and development for solid oral dosage forms. She then worked at the Chindex International as Director of Regulatory Affairs and Government Affairs, responsible for all medical device filing and registration. With extensive experience in both drug and device development, she is currently a Principal Scientist in the Device Development group at Merck, leading combination product development from early concept phase to commercialization and also leading the Human Factors efforts for a variety of combination products such as inhalers, injectors and implantable devices.

Juan obtained her Ph.D. degree in Chemistry from Penn State University, and currently holds Regulatory Affairs Certification (RAC) from Regulatory Affairs Professional Society (RAPS).

Prof. Sven Stegemann, Ph.D.
Professor of patient Centric Drug Design and Manufacturing
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Prof. Dr. Sven Stegemann is professor of patient centric drug design and manufacturing at the Graz University of Technology, Austria. Over the course of his 27-year career in the pharmaceutical industry, he has worked as an advisor to major pharmaceutical companies on ways to improve the design, development and manufacture of pharmaceutical products so they better address the individual needs of patients. In his academic role, he focuses his research on the rational development of patient centric drug products and their associated manufacturing technologies, as well as education and training of students and young scientists.

He is the founder and chair of the AAPS Focus Group on Patient-Centric Drug Development, Product Design, and Manufacturing as well as the founder and President of the Geriatric Medicine Society e.V. He recently started the industrial-academic collaboration partnership Patient Centric Medicine (PaCeMe) to suitable and meaningful guidance for patient centric drug product design. He is the editor of the book “Developing Drug Products in an Aging Society - From Concept to Prescribing”, a multidisciplinary approach towards patient centric drug development for the older and multimorbid patient populations.

Paul Upham
Head, Smart Devices
Roche/Genentech
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Paul is the Head of Smart Devices at Roche / Genentech. Paul has 20+ years of experience in medical device R&D, strategic marketing, product management, clinical research, and medical informatics.

Prior to Roche / Genentech, Paul was with Becton Dickinson(BD), as Worldwide Director of Strategic Marketing in their Pharmaceutical Systems business.

Paul was also the head of Product at WellDoc, Inc., where he led the product management activities for WellDoc's portfolio of mobile health solutions. He was responsible for WellDoc's landmark BlueStar™ product, a class II medical device and the world's first reimbursed, prescription-only software for diabetes.

Paul's prior experience includes 10 years in BD's Diabetes Care business. Paul was responsible for the award-winning BD InterActiv® Diabetes Software and was a member of the BD / Medtronic team that launched ParadigmLink®, the world's first wireless blood glucose meter.

Paul holds four issued patents in medical software and drug delivery devices and has multiple patent applications. He is also an author of numerous peer-reviewed articles in medical informatics and diabetes. His education includes undergraduate studies in cognitive science and graduate work in health informatics and finance at the University of Minnesota and New York University.

Róisín Wallace, BSc., MRSC
Head of Global Device Development
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Róisín Wallace is the Head of Global Device Development at Viatris. In this role Róisín leads the design, development, technical regulatory strategy, commercialisation and lifecycle management of device & drug-delivery technology and combination product development for Viatris's growing branded, biosimilar and generic portfolio. Her focus is on developing products that enable access to high quality, safe, robust and effective device and combination products to meet the worlds' evolving patient healthcare needs.

Róisín graduated with a BSc. in Analytical Science (Chemistry) from Dublin City University, Ireland and subsequently joined Pfizer Global Research & Development in the UK. Róisín held various roles within Analytical Research & Development with responsibility for analytical development of products from Phase I to commercialisation covering API, solid oral and injectable products, before taking a leading role in the establishment of a new Pharmaceutical Sciences organisation in India. She subsequently joined Pfizer's Devices Centre of Emphasis where she was accountable for multiple device programs in Pfizer's injector device portfolio from device concept through development, industrialisation and global registration.

Róisín joined Mylan's newly established Global Respiratory Group in the UK late in 2011 to lead its Device Development Group. She relished the opportunity to move home to Dublin, Ireland during 2012 to establish and lead a new purpose-built R&D Pilot Plant and expand the Device Development Group to support Mylan's growing respiratory portfolio. In January 2016 Róisín took on a new role within Mylan as Head of Global Device Development, leading a group responsible for the design, development, commercialisation and lifecycle management of device and drug-delivery technology and combination product development for Mylan's branded, biosimilar and generic products.