IPAC-RS Digital Devices Roundtable Series:

BEYOND USABILITY/HUMAN FACTORS FOR DIGITAL HEALTHCARE

September 21, 2021

Bios

Moderators:

Marta Lombardini, Ph.D.
Device Development Manager
Chiesi Group
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Dr. Marta Lombardini is an Experienced Device Development Manager with a demonstrated history of working in the pharmaceuticals industry. Skilled in Device development processes, Agile Design, Human factors sciences, Product and process Validation, Documentation generation, Regulations and Product submissions. Enthusiastic professional with a Doctor of Philosophy (PhD) focused in Electronics and Biomedical/Medical Engineering from University of Bologna. Marta's aim is to develop products to improve quality of life. Since she firstly joined Chiesi in 2016 she has strongly contributed at spreading the Customer Centric design approach. She has experience in developing diverse type of device constituent part in combination products naming Syringes, Nebulizers and other electromechanics delivery systems. She is particularly interested in studying and collecting behavioral data that can be used to explain, influence, and predict health-related outcomes and she enjoys managing the diversity of the different projects which can include digital devices. Marta has always had a strong focus at standardizing the approach to get to the best outcome and performance of the systems we design. Prior to joining Chiesi she has been part of the Philips healthcare Respironics group and learned how to enhance medical products development using the human factors and risk based approach as a competitive advantage for achieving what is really needed in the market creating loyalty and ensuring it can be safely, efficaciously and pleasantly used by the final customers.

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.

Speakers:

Ian Culverhouse, Ph.D.
Co-Founder
Rebus Medical Ltd.
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Dr. Ian Culverhouse is Co-Founder of Rebus Medical Ltd, an ISO 13485 certified human factors consultancy based in the UK. During his career, Ian has worked with many global medical device and pharmaceutical companies including as Roche, AstraZeneca, Smith and Nephew, Eli Lilly and Bosch Healthcare. Ian has a wealth of experience in applying HF to the design of medical devices throughout the development process, supporting manufacturers maximize their return on integrating HF into their business. His knowledge and experience has supported products and devices achieve both FDA and European approval including connected drug delivery devices, combination drug products, patient monitoring systems for in-home and ICU settings, as well as surgical devices.

Ian has a PhD in the application of early stage interactive prototyping techniques. Today he advocates the philosophy of inclusion of early stage user testing to maximize the opportunity for learning and influencing design decisions.

Haydyn Phillips
User Experience (UX) Lead
AstraZeneca
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Haydyn leads a User Experience (UX) team at AstraZeneca solving messy problems across healthcare and life sciences. He's successfully integrated user experience and human factors practices into real world projects to examine how, beyond safety and reducing risk, digital healthcare outcomes truly can be meaningful to those using them. His current role draws on over 13 years of experience over industries that span Telco, FinTech & Healthcare. With a multi-disciplinary background in HCI & Research, Haydyn is a keen advocate of integrating and enabling HF/UX & research teams to come together to build better products and understand problems more efficiently. This is especially true in the complex world of digital healthcare where it's often challenging and difficult to create truly meaningful and impactful products for patients, beyond just safety and risk management.