IPAC-RS Digital Devices Roundtable Series

IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

Beyond Usability/Human Factors for Digital Healthcare

September 21, 2021

www.ipacrs.org

Who We Are

The International Pharmaceutical Aerosol Consortium on Regulation & Science (IPAC-RS) is an international association that seeks to advance the science, and especially the regulatory science, of orally inhaled and nasal drug products (OINDPs) by collecting and analyzing data, and conducting joint research and development projects.

Representing the OINDP industry since 2000, IPAC-RS aims to build consensus and contribute to effective regulations and standards by sharing the results of its research through conferences, technical journals, and discussions with regulatory bodies.

Our Members

- **Members** - corporations that develop, manufacture or contract to manufacture OINDPs

AstraZeneca
Boehringer Ingelheim
Catalent
Chiesi
Genentech
GlaxoSmithKline
Hovione
Kindeva Drug Delivery
Lupin Pharmaceuticals, Inc.
Merck & Co., Inc.
Novartis
Sunovion
Teva
Vectura
Viatris

- **Associate Members** – corporations that (1) develop or manufacture components and/or devices for OINDPs or (2) provide scientific or technical services relating to development and manufacture of OINDPs or (3) are eligible for full membership but have annual revenues of less than seventy-five million US dollars.

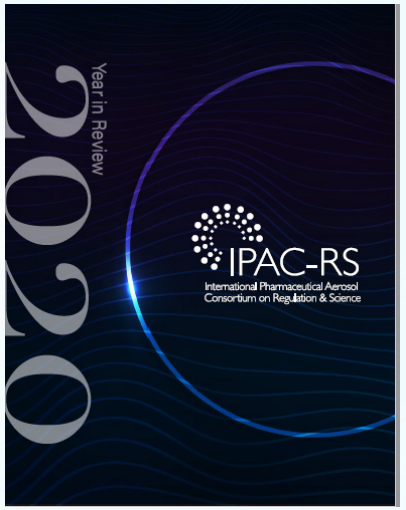
Amcor Flexibles
Aptar Pharma
Copley Scientific
H&T Presspart
Nemera
Oxford Lasers
PPD
Proveris Scientific Corporation
Team Consulting Ltd.

IPAC-RS Successes in 2021

During 2021, IPAC-RS continues to actively work on the goals outlined in the 2019-2021 Strategic Plan.

The Consortium:

1. Engaged with regulatory and standard setting authorities.
2. Provided up-to-date information to the members on relevant developments.
3. Identified and publicized OINDP industry's positions on key issues of regulatory science
4. Provided forum for members' discussions.
5. Actively participated in discussions in the wider stakeholder community.



See the IPAC-RS Year in Review 2020 for an overview of 2020 successes.

Top 5 Reasons to Join IPAC-RS

1. Stay ahead of emerging international regulatory and scientific challenges facing the OINDP industry.
2. Participate in joint industry discussions with and guidance commenting to regulators in North America, Europe, Asia, and South America.
3. Join industry leaders in providing feedback to standard-setting bodies and international pharmacopoeia.
4. Share knowledge, information and experiences with other industry leaders.
5. Stay abreast of pertinent development and also shape national and international trends and requirements.

IPAC-RS Roundtables

- In 2021, IPAC-RS developed a new Roundtable webinar series on digital devices for 2021. Presented by subject matter experts in the pharmaceutical sciences, this is a unique opportunity to learn about the latest research and regulatory trends focused on digital devices. See the IPAC-RS website for details, registration information and recordings for previous webinars.
  - Today's Webinar: ***Beyond Usability/Human Factors for Digital Healthcare***
  - ***Upcoming Webinars***
    - September 29, 2021 (8:30 – 10 AM US ET) ***Digital Devices Manufacturing and Design Considerations***
    - October 4, 2021 (10 AM – 12 PM ET) ***Business Case for Digital Devices***
  - ***Past Webinars***
    - ***What is a Digital Biomarker and Why Is It Important?***

Today's Moderators

Marta Lombardini, Ph.D., Device Development Manager, Chiesi Group

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 AstraZeneca

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.

Agenda

I. Welcome and Introduction to IPAC-RS	5 Minutes	Mary Devlin Capizzi, IPAC-RS Secretariat
II. Overview of Webinar and Logistics	5 Minutes	Marta Lombardini Fredrik Mannerstråle
III. Designing Digital Healthcare; HFE and UX in Partnership	30 Minutes	Julian Dixon, Team Consulting
IV. Questions	5 Minutes	
V. Evolution of HF Test Methods for Digital Healthcare Systems	30 Minutes	Ian Culverhouse, Rebus Medical Ltd.
VI. Open Discussion and Q&A	45 Minutes	All Speakers
Total Time	2 hours	

Webex Housekeeping

- Panelists will be listed here.
- The Attendee list is only available to Panelists and Host. (You will only see your name listed.)
- The Chat function has been disabled for Attendees. You may receive chats from the Host, but you cannot reply.
- Type your question in the Q&A box or raise your hand to be unmuted.

Be sure your Q&A is set to ASK All Panelists

All Attendees are muted.

The recording will be posted on the IPAC-RS website after the webinar.

Presenter

Julian Dixon, HF Consulting Director
Team Consulting

Julian is HF Consulting Director at Team Consulting. Since Team Consulting's first significant user research project in 1999, he has been core to the development of our human factors engineering capability. Julian also takes an active role in understanding emerging FDA expectations/practices with regard to human factors, particularly as they apply to combination products.

During his time at Team, Julian has worked on a large number of drug delivery device development projects, particularly in the respiratory and parenteral sectors. He has fulfilled a range of consultancy roles for clients including facilitation, decision support, technical problem solving and, of course, user research/human factors.

Julian joined Team in 1998 and has degrees in both Mechanical Engineering (from the University of Cambridge) and Psychology. Prior to his current role, Julian worked as a design engineer and then as a consultant within an international innovation management practice.

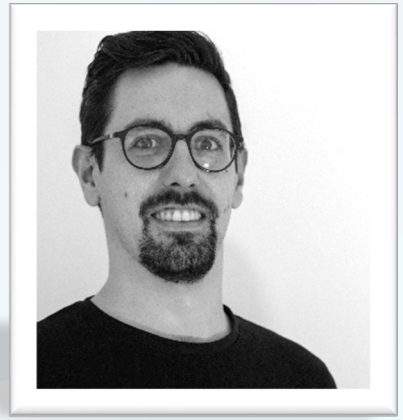
Julian has been a regular presenter at international conferences on topics related to HFE, particularly of combination products and with a regulatory focus. He is a science advisor to the inhalation products industry group, IPAC-RS.

Short Q&A Session

- Type your question in the Q&A box or raise your hand to be unmuted.

Be sure your Q&A is set to ASK All Panelists

Presenter



Ian Culverhouse, Ph.D., Co-Founder, Rebus Medical Ltd.

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.

Thank you for attending the webinar!

- Type your question in the Q&A box or raise your hand to be unmuted.

Be sure your Q&A is set to ASK All Panelists

Secretariat Contacts

For further information regarding membership or other questions about IPAC-RS, please contact a member of the Secretariat below. You can also learn more by visiting www.ipacrs.org.

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