IPAC-RS Digital Devices Roundtable Series

IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

Digital Devices: Manufacturing and Design Considerations

September 29, 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.

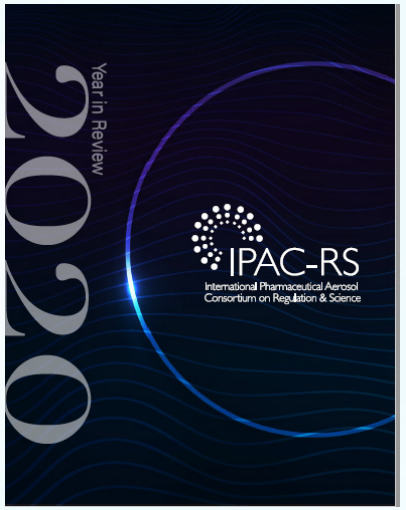
Amcor Flexibles
Aptar Pharma
Copley Scientific
H&T Presspart
Nemera
Oxford Lasers
PPD
Proveris Scientific Corporation
Team Consulting Ltd.

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: ***Digital Devices Manufacturing and Design Considerations***
  - ***Upcoming Webinars***
    - October 4, 2021 (10 AM – 12 PM ET) ***Business Case for Digital Devices***
    - **SAVE THE DATE**: November 22, 2021 (10 AM – 12 PM ET) ***Digital Devices-Regulatory Challenges and Considerations***
  - ***Past Webinars***
    - ***What is a Digital Biomarker and Why Is It Important?***
    - ***Beyond Usability/Human Factors for Digital Healthcare***

Today's Moderators

Daniela Gramaglia, Ph.D., Design Control and Documentation Specialist, Chiesi Group

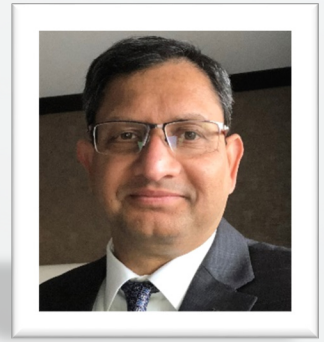
Dr. Gramaglia is a Senior Design Control and Documentation Specialist with 15 years of experience in medical device and pharma R&D.

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 2018, 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.

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.

Agenda

I. Welcome and Introduction to IPAC-RS	5 Minutes	Mary Devlin Capizzi, IPAC-RS Secretariat
II. Overview of Webinar and Logistics	5 Minutes	Daniela Gramaglia Prasad Peri
III. Design of Low Environmental Impact Connected Devices with High Functionality and Ease of Use	25 Minutes	Andreas Meliniotis Phil Swanbury Vectura
VI. Short Q&A	5 Minutes	
V. Practical Considerations for Developing Software in Connected Health Solutions and the Assessment of Sustainability in Respiratory Devices	25 Minutes	Stathis Louridas Brennan Miles Team Consulting
VI. Open Discussion and Q&A	25 Minutes	All Speakers
Total Time	1.5 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.

Today's Presenters

Andreas Meliniotis, Director, Device Development, Vectura

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 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.

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

Today's Presenters

Stathis Louridas, Ph.D., Head of Electronics and Software, Team Consulting

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 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.

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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