IPAC-RS
International Pharmaceutical Aerosol Consortium on Regulation & Science

DDL2018
DRUG DELIVERY TO THE LUNGS

Global Regulatory Topics in Orally-Inhaled and Nasal Drug Product Development

DDL/IPAC-RS workshop

12 December 2018

Edinburgh, UK

Today's Programme

TOPIC	PRESENTER	TIMING
Registration (& Coffee)		*From 08:00*
Introduction to IPAC-RS Membership, structure, strategic priorities, overview of workstreams, accomplishments and impact	Jeremy Clarke, GSK	09:00-09:10
Delivery Systems Workstream - activity update Medical Device Regulations Human Factors Instructions for use	 Tim Chesworth, AZ Roisin Wallace, Mylan Julian Dixon, Team Consulting	 09:10-09:35 09:35-10:00 10:00-10:25
Coffee Break		*10:25-10:50*
General workstream - activity update A review of FDA draft guidance on Metered Dose Inhaler and Dry Powder Inhaler Drug Products--Quality Considerations	Gustavo Marco, GSK	10:50-11:25
CMC and Product Development Test Workstream - activity update Cascade Impaction testing and data analysis, regulatory and pharmaceutical developments	Adrian Goodey, Merck +/or Jolyon Mitchell, Independent OIP Consultant	11:25-12:00
Close of workshop		

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DDL2018
DRUG DELIVERY TO THE LUNGS

Science and Regulation of Orally Inhaled and Nasal Drug Products (OINDPs) Worldwide

An introduction to IPAC-RS

Jeremy Clarke, Senior Fellow, GSK

12 December 2018

Edinburgh, UK

IPAC-RS

Vision

IPAC-RS is and will remain the leading technical resource and advocate of the OINDP industry, with a focus on Chemistry, Manufacturing and Controls aspects.

Mission

Advance scientifically driven approaches to enhancing product quality of OINDPs for the benefit of patients.

IPAC-RS

Advances

regulatory science of aerosol drug products through joint research and experimental work, benchmarking surveys, and technical publications.

Provides

members with timely regulatory and scientific updates and analyses, access to the IPAC-RS research results, networking opportunities, representation at the national and international level.

Works

with regulatory agencies and standard-setting bodies:

- **US FDA**
- **EMA**
- **Health Canada**
- **Ph. Eur., USP**
- **ISO**
- **CFDA**
- **ANVISA**

Engages Stakeholders

broader industry, trade associations, patient advocacy groups, clinicians, academicians, etc. to discuss key regulatory science topics of OINDPs

IPAC-RS Members

(develop, manufacture or contract to manufacture OINDPs)

3M, Chiesi, Merck, Sunovion, AstraZeneca, GlaxoSmithKline, Mylan, teva, Boehringer Ingelheim, Hovione, Catalent, Lupin Pharmaceuticals, Inc., Novartis, vectura

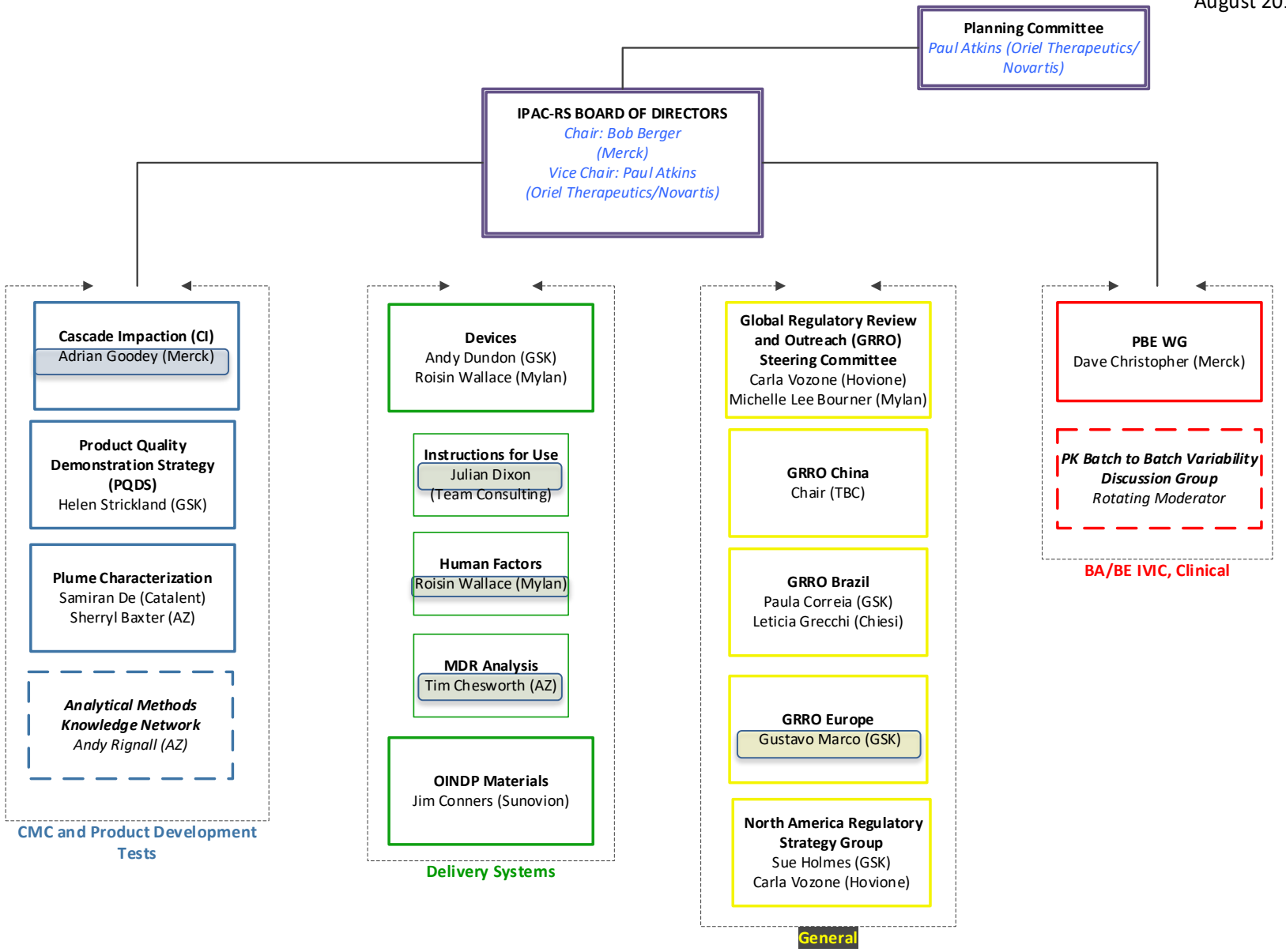
IPAC-RS Associate Members

(develop or manufacture components and/or devices for OINDPs or provide scientific or technical services relating to development and manufacture of OINDPs)

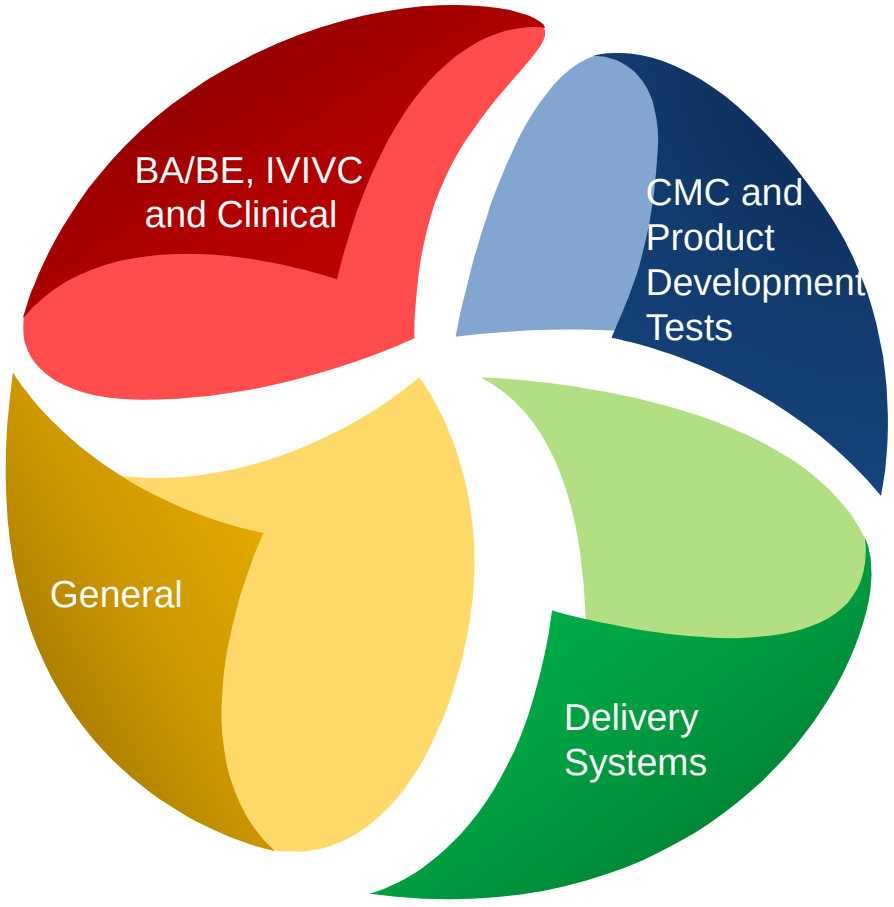
Aptar pharma, Copley Scientific, Proveris Scientific, West, amcor, H&T Presspart, team

IPAC-RS Organizational Chart

August 2018



IPAC-RS Workstreams



Activities organized into workstreams.

Working Groups within workstreams produce member resources, publications and presentations

This output informs scientific and regulatory dialogue.

General Workstream

Objectives

- Stay abreast of regulatory developments in countries with well-established regulatory systems.
- Understand requirements in emerging markets.
- Initiate outreach to regulatory agencies, pharmacopeias and other standard-setting bodies worldwide.
- Collaborate with other trade groups.

Activities

- Global Regulatory Review and Outreach (GRRO)
  - China Subgroup
  - Brazil Subgroup
  - European Union Subgroup
  - North America Regulatory Strategy Group

BA/BE and IVIVC Workstream

Objectives

- Monitor, evaluate and engage in discussions related to research and regulatory recommendations for:
- Bioavailability (BA), bioequivalence (BE), in-vitro/in-vivo correlations (IVIVC), clinical inputs for Quality-by-Design (QBD) and similar topics.
- Stay abreast of clinical research, and collaborate with other organizations pursuing clinical topics for orally inhaled and nasal drug products (OINDPs)

Activities

- Population bioequivalence (PBE) and modified chi-square ratio: evaluation of approaches
- Pharmacokinetics (PK) Batch to Batch Variability Discussion Group

CMC and Product Development Test Workstream

Objectives

- Monitor, assess and respond to regulatory developments related to CMC and product development requirements.
- Develop improved approaches, “best industry practices” and other recommendations for CMC and product development tests, such as delivered dose uniformity, aerodynamic particle sizing, material characterization and others.

Activities

- Cascade Impaction (CI)
- Product Quality Demonstration Strategy (PQDS – formerly Delivered Dose Uniformity, and Aggregate Approaches to DDU Testing)
- Plume Characterization
- QBD for Analytical Methods Knowledge Network

Delivery Systems Workstream

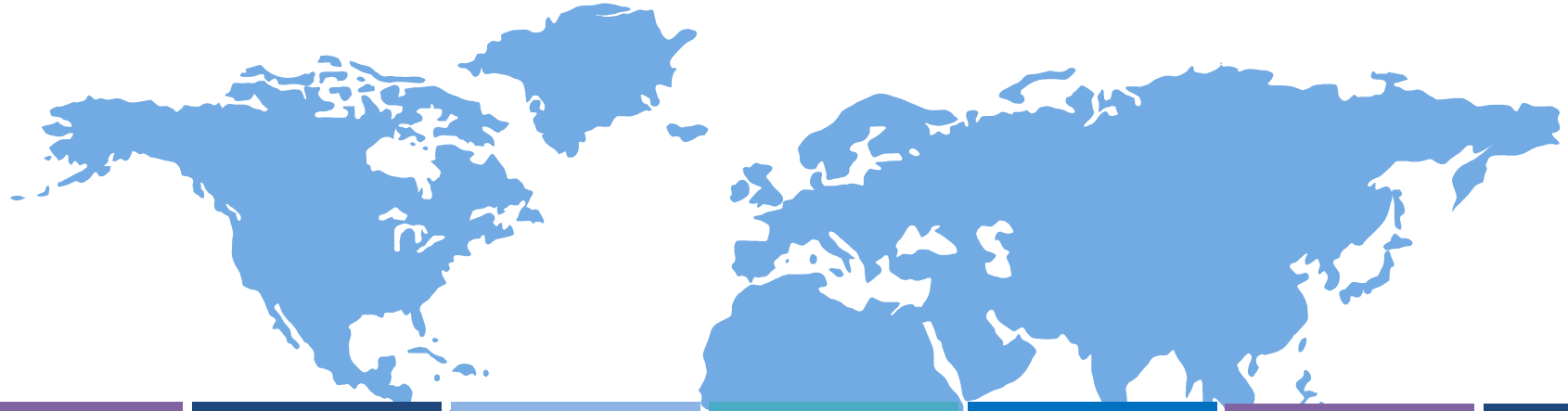
Objectives

- Study industry practices and regulatory developments related to OINDP devices and device-patient interface.
- Develop recommendations for industry, device manufacturers, regulators, health-care providers, patients and other potential stakeholders

Activities

- Devices
  - Instructions for Use Subgroup
  - Human Factors Subgroup
  - European Medical Device Regulations (MDR) Analysis Subgroup
- OINDP Materials
  - 08 November, 2018 - Supplier/Pharma workshop on device and container closure system quality

IPAC-RS Accomplishments and Impact



- Active engagement with US regulators and standard setting bodies
- Collaborative relationships with regulators and informing regulatory decision-making in other world regions including emerging markets by sharing scientific knowledge and experience on OINDP
- Evaluating bioequivalence approaches proposed by regulators
- Advancing streamlined approaches to human factors testing and device change management and risk based approaches for materials quality, for OINDPs
- Advancing scientifically and statistically sound approaches to control of DDU and APSD.
- Active outreach to increase public visibility of IPAC-RS work and positions
- Improved and modernized internal communications among IPAC-RS members

Recent and Ongoing Collaborations

- **With Drug Delivery to the Lungs (DDL)**
  - Joint workshop on Dec 12, 2018, Global Regulatory Topics in Orally-Inhaled & Nasal Drug Product (OINDP) Development
- **With ISAM**
  - Joint Workshop on Jun 3, 2017, New Frontiers in Inhalation Technology
  - Planning a joint workshop at ISAM 2019
- **With RDD**
  - Joint Symposium Apr 2016, Meeting the Quality Challenge for Orally Inhaled Products
  - Planning a joint session at RDD 2020
- **With Inhalation Asia**
  - Presented at Sep 2017 Inhalation Asia conference, Materials quality & Cascade Impaction
- **With University of Florida**
  - Collaborative research of the modified chi-square ratio statistic recommended by FDA for in-vitro comparisons of Aerodynamic Particle Size Distributions
- **With North Carolina State University**
  - IPAC-RS work with NCSU graduate student on PBE approach for OINDPs

Educational Webinars for IPAC-RS Members

- **2016**
  - July: Digital health and privacy
  - July (in person): jointly with IPAC: Mexichem presentation on novel propellants
  - November: Regulatory Framework and Key Guidelines in Brazil for OINDP
  - December: Dr. Darragh Murnane (University of Hertfordshire), a webinar on his recent EPSRC grant “INFORM 2020 - Molecules to Manufacture: Processing and Formulation Engineering of Inhalable Nanoaggregates and Microparticles.”
- **2017**
  - April: State of Affairs in Washington DC
  - May: Jointly with IPAC: An update on environmental laws for propellants
  - December: Dr. Bassil Akra, TÜV SÜD: The New Medical Device Regulation
- **2018**
  - May: Population Bioequivalence (PBE) Test
  - Summer: Privacy updates
  - Fall: Brazil

IPAC-RS

A voice and source of knowledge for the OINDP industry

For further information, or to join, please contact:
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www.ipacrs.org