

NAVIGATING THE TRANSITION TO LOW GLOBAL WARMING POTENTIAL PROPELLANTS

Day 1 - Session 3: Small Group Working Session

Moderators:

Rik Lostritto, PhD

Christy Gilbert , BS, RAC

Shyamala Ivatury , MS

Uwe Niesner, PhD

Bryan Newman, PhD

Ross Walenga, PhD

Anubhav Kaviratna, PhD

Hailing Zhang, PhD

Ann Purrington, BS, RPh, RAC

Scribes:

Lana Lyapustina, PhD

Lee Nagao, PhD

Jennifer Edeline, MRes, PharmD

Sue Holmes, MS

Liangfeng Han, MD, PhD

Elizabeth Bielski, MS, PhD

Sneha Dhapare, PhD

Susan Boc, PhD

David McChesney, PharmD

Science Advisor, IPAC-RS

Associate Director, CMC Regulatory Affairs, AstraZeneca

Senior Director, Inhalation Product Development, AstraZeneca

Head of Respiratory & Biologics Regulatory Strategy, Viatrix

Lead Pharmacologist, DTP I, ORS, OGD, FDA

Senior Chemical Engineer, DQMM, ORS, OGD, FDA

Biomedical Engineer, DTP I, ORS, OGD, FDA

Division Director, DPQA XII, OPQA II, OPQ, FDA

Regulatory Affairs Director, Kindeva Drug Delivery

Principal, Faegre Drinker - IPAC-RS Secretariat

Principal, Faegre Drinker - IPAC-RS Secretariat

Senior Regulatory Affairs Manager, Aptar

CMC Regulatory Consultant, IPAC-RS

Clinical Analyst, DTP I, ORS, OGD, FDA

Senior Pharmacologist, DTP I, ORS, OGD, FDA

Senior Staff Fellow, DIIP, OCP, OTS, FDA

Pharmacokineticist, DTP I, ORS, OGD, FDA

ORISE Fellow, DTP I, ORS, OGD, FDA

Possible Data to Establish Comparability:

In Vitro Data

- Single Actuation Content(SAC)/Delivered Dose Uniformity (DDU)
- Aerodynamic Particle Size Distribution (APSD)
- Spray Pattern
- Plume Geometry
- Priming/Repriming
- Realistic APSD (rAPSD)
- Dissolution
- Comparative Particle Morphology of Emitted Dose

In Vivo Data

- Pharmacokinetic (PK) Study w/o Charcoal Block
- PK Study with Charcoal Block
- Pharmacodynamic (PD) Study
- Clinical Endpoint (CCEP) Study

In Silico Models

- Computational fluid dynamics (CFD)
- Semi-empirical methods
- Physiologically based pharmacokinetics (PBPK) modeling

Other Studies?

Figure 1