FDA-CRCG Workshop on Navigating the Transition to Low Global Warming Potential Propellants

Public Workshop
December 4-5, 2024
Agenda

Day 1 December 4

8:30 AM – 8:40 AM	**Welcome and Opening Remarks**	
	James Polli, PhD	Co-Director, CRCG
	Anna Schwendeman, PhD	Co-Director, CRCG
8:40 AM – 8:50 AM	**FDA Opening Remarks**	
	Markham Luke, MD, PhD	Director, DTP I, ORS, OGD, FDA
8:50 AM – 8:55 AM	***Workshop Day 1 Overview***	
	Markham Luke, MD, PhD	Director, DTP I, ORS, OGD, FDA

Session 1: LGWP Propellant Transition for New Drug Product Metered Dose Inhalers (MDIs)

In this session, regulators will discuss the current propellant transition including lessons learned from previous transitions and scientific considerations for the LGWP propellants. FDA presenters will cover the scientific and regulatory considerations for new drug LGWP propellant MDI development programs and expectations for the pharmacology/toxicology, quality, pharmacokinetics, pharmacodynamics, efficacy, and safety data to support a new drug application.

8:55 AM – 9:00 AM	***Speaker Introductions***	
	Sally Seymour, MD	Director, DPACC, OII, OND, FDA
9:00 AM – 9:20 AM	***The Global Phasedown of HFC: A U.S. Regulatory Perspective***	
	Luke Hall-Jordan, MPH	Supervisory Environmental Policy Analyst, Phasedown Implement Branch, EPA
9:20 AM – 9:30 AM	***Lessons Learned from CFC Transition***	
	Sally Seymour, MD	Director, DPACC, OII, OND, FDA
9:30 AM – 9:55 AM	***Propellant Properties and the Impact on Product Development***	
	Stephen Stein, MS	Scientific Director, Inhalation Product Development, Kindeva Drug Delivery
9:55 AM – 10:10 AM	***Coffee Break***	
10:10 AM – 10:20 AM	***Introduction to OND Framework for LGWP Transition***	
	Stacy Chin, MD	Clinical Team Leader, DPACC, OII, OND, FDA
10:20 AM – 10:30 AM	***Nonclinical Considerations for LGWP Transition***	
	Luqi Pei, PhD	Master Pharmacologist, DPT II, OII, OND, FDA
10:30 AM – 10:40 AM	***Quality Considerations for LGWP Propellant Transitions***	
	Craig Bertha, PhD	CMC Reviewer, DPQA VII, OPQA II, OPQ, FDA
10:40 AM – 10:55 AM	***Clinical Pharmacology Considerations for LGWP Transition***	
	Sneha Dhapare, PhD	Senior Clinical Pharmacologist, DIIP, OTS, FDA
10:55 AM – 11:10 AM	***Clinical Considerations for LGWP Transition***	
	Aishah Ali, MD	Senior Physician, DPACC, OII, OND, FDA
11:10 AM – 12:00 PM	***Q&A Session with Panel***	
Moderator:	**Sally Seymour, MD**	Director, DPACC, OII, OND, FDA
Panelists:	**Aishah Ali, MD**	Senior Physician, DPACC, OII, OND, FDA
	Craig Bertha, PhD	CMC Reviewer, DPQA VII, OPQA II, OPQ, FDA
	Stacy Chin, MD	Clinical Team Leader, DPACC, OII, OND, FDA
	Sneha Dhapare, PhD	Senior Clinical Pharmacologist, DIIP, OTS, FDA

	Luke Hall-Jordan, MPH	Supervisory Environmental Policy Analyst, Phasedown Implement Branch, EPA
	Luqi Pei, PhD	Master Pharmacologist, DPT II, OII, OND, FDA
	Stephen Stein, MS	Scientific Director, Inhalation Product Development, Kindeva Drug Delivery
	Hailing Zhang, PhD	Division Director, DPQA XII, OPQA II, OPQ, FDA

12:00 PM – 12:50 PM ***Lunch Break***

Session 2: Current Industry Experience with New Drug LGWP MDI Development

This session will include industry presentations on their experiences with new drug LGWP propellant MDI development, including development strategy and challenges encountered thus far.

12:50 PM – 12:55 PM ***Speaker Introductions***

Christy Gilbert, BS, RAC Associate Director, CMC Regulatory Affairs, AstraZeneca

12:55 PM – 1:10 PM ***An Introduction to the IPAC-RS Scenarios - Transition to LGWP Propellants in MDIs: Proposed Pathways to U.S. FDA Approval***

Ann Purrington, BS, RPh, RAC Regulatory Affairs Director, Kindeva Drug Delivery

1:10 PM – 1:30 PM ***Statistical Considerations for the In Vitro Comparisons of Critical Product Performance Attributes for an Approved MDI Product Transitioning to LGWP Propellant***

Richard (Rik) Lostritto, PhD Consultant, Lostritto Consulting, LLC
Helen Strickland, MS Sr. Statistical Consultant, Manufacturing Science & Technology, GSK

1:30 PM – 1:50 PM ***Case Study: Development Considerations for Transitioning MDI Products to LGWP Propellant***

Laura Clow, MChem Medicine Development Leader, GSK
Poonam Gulati, PhD, MBA, PGCert Senior Director & Team Lead, Global Regulatory Affairs, GSK

1:50 PM – 2:10 PM ***Engineered Excipient Particles Facilitate Transition to LGWP Propellants in Combination MDI Products***

David Lechuga-Ballesteros, PhD Head of Innovation, IPD, AstraZeneca

2:10 PM – 2:30 PM ***Innovative Drug Development Approach to Address the Transition to LGWP Propellant Using HFA 152a, for a Triple Combination MDI Product Targeting Small Airways***

Angelo Benedetto Matturo, MS R&D Global Technical Leader, CHIESI Farmaceutici

2:30 PM – 3:00 PM ***Q&A Session with Panel***

Moderators:	**Christy Gilbert, BS, RAC**	Associate Director, CMC Regulatory Affairs, AstraZeneca
	Sue Holmes, MS	CMC Regulatory Consultant, Sue Holmes CMC Consulting LLC
Panelists:	**Laura Clow, MChem**	Medicine Development Leader, GSK
	Poonam Gulati, PhD, MBA, PGCert	Senior Director & Team Lead, Global Regulatory Affairs, GSK
	Sheryl Johnson, CChem, MChem	Pharma Application Development Lead, Orbia Fluor & Energy Materials, Koura
	David Lechuga-Ballesteros, PhD	Head of Innovation, IPD, AstraZeneca
	Richard (Rik) Lostritto, PhD	Consultant, Lostritto Consulting, LLC
	Markham Luke, MD, PhD	Director, DTP I, ORS, OGD, FDA
	Angelo Benedetto Matturo, MS	R&D Global Technical Leader, CHIESI Farmaceutici
	Ann Purrington, BS, RPh, RAC	Regulatory Affairs Director, Kindeva Drug Delivery
	Helen Strickland, MS	Sr. Statistical Consultant, Manufacturing Science & Technology, GSK

3:00 PM – 3:05 PM ***Closing Remarks for the Virtual Session*** **(End of Virtual Session for Day 1)**

Yan Wang, PhD Acting Deputy Division Director, DTP I, ORS, OGD, FDA

3:05 PM – 3:15 PM ***Coffee Break***

Session 3: Small Group Working Sessions (In-Person Only)

3:15 PM –4:45 PM

Lead:	**Elizabeth Bielski, PhD**	Senior Pharmacologist, DTP I, ORS, OGD, FDA
Moderators:	**Richard (Rik) Lostritto, PhD**	Consultant, Lostritto Consulting, LLC
	Christy Gilbert, BS, RAC	Associate Director, CMC Regulatory Affairs, AstraZeneca
	Shyamala Ivatury, MS	Senior Director, IPD, PT&D, AstraZeneca
	Anubhav Kaviratna, PhD	Biomedical Engineer, DTP I, ORS, OGD, FDA
	Uwe Niesner, PhD	VP, Head Respiratory & Biologics Regulatory Strategy, Viatris
	Bryan Newman, PhD	Lead Pharmacologist, DTP I, ORS, OGD, FDA
	Ross Walenga, PhD	Senior Chemical Engineer, DQMM, ORS, OGD, FDA

	Hailing Zhang, PhD	Division Director, DPQA XII, OPQA II, OPQ, FDA
4:45 PM – 5:00 PM	***Closing Remarks (Day 1)***	
	James Polli, PhD	Co-Director, CRCG
	Anna Schwendeman, PhD	Co-Director, CRCG

Day 2 December 5

8:30 AM – 8:35 AM — ***Workshop Day 2 Overview***
Bryan Newman, PhD — Lead Pharmacologist, DTP I, ORS, OGD, FDA

Session 1: Generic LGWP MDI Development and the Generic Industry Experience

This session will include presentations from FDA on the scientific and regulatory considerations for generic LGWP propellant MDI development programs from the quality and bioequivalence perspectives. Industry presentations will then discuss the current experiences and challenges encountered by generic developers for an LGWP propellant MDI.

8:35 AM – 8:40 AM — ***Speaker Introductions***
Bryan Newman, PhD — Lead Pharmacologist, DTP I, ORS, OGD, FDA

8:40 AM – 9:00 AM — ***Summary of Small Group Working Sessions on Day 1***
Bryan Newman, PhD — Lead Pharmacologist, DTP I, ORS, OGD, FDA

9:00 AM – 9:20 AM — ***Policy Considerations for Generic MDIs Transitioning to an LGWP Propellant***
Rachael Dippold, PhD, JD — Regulatory Counsel, DPD, OGDP, OGD, FDA

9:20 AM – 9:40 AM — ***Generic MDI LGWP Propellant Transition: OGD Framework and Data Submission Recommendations***
Elizabeth Bielski, PhD — Senior Pharmacologist, DTP I, ORS, OGD, FDA

9:40 AM – 10:00 AM — ***Coffee Break***

10:00 AM – 10:20 AM — ***Alternative In Vitro Bioequivalence Approaches for the Low GWP Propellant Transition***
Lucas W. S. Silva, BSc — Senior Specialist, Analytical Development, Nanopharm, An Aptar Pharma Co.

10:20 AM – 10:40 AM — ***No Time to Lose: Adopting a Science-Based Approach to Ensure Continued Access to Generic pMDI Products***
Rupi Pannu, PhD — Senior Director, Respiratory R&D Project Leader, Respiratory R&D, Viatris

10:40 AM – 11:00 AM — ***Perspective on Generic LGWP MDI Development***
Siva Vaithiyalingam, PhD — Senior Vice President/Head of US Regulatory Affairs, Cipla, Ltd

11:00 AM – 11:50 AM — ***Q&A Session with Panel***

Moderator:	**Bryan Newman, PhD**	Lead Pharmacologist, DTP I, ORS, OGD, FDA
Panelists:	**Pradeep Bhadauria, MPharm**	President and Global Chief Scientific Officer, Cipla Ltd
	Andrew Clerman, MD, PhD	Acting Lead Physician, DTP I, ORS, OGD, FDA
	William Feldman, MD, DPhil, MPH	Assoc. Physician, Pulmonary & Critical Care Med, Faculty, Regulation Program Therapeutics & Law, Pharmacoepidemiology & Pharmacoeconomics, Assoc. Dir., Ethics Service, Brigham & Women's Hosp., Asst. Prof, Harvard Med School
	Dhaval Gaglani, MS	Supervisor, DPQQ V, OPQA I, OPQ, FDA
	Bing Li, PhD	Associate Director for Science, OB, OGD, FDA
	Rupi Pannu, PhD	Senior Director, Respiratory R&D Project Leader, Respiratory R&D, Viatris
	Lucas W. S. Silva, BSc	Senior Specialist, Analytical Development, Nanopharm, An Aptar Pharma Co.
	Siva Vaithiyalingam, PhD	Senior Vice President/Head of US Regulatory Affairs, Cipla, Ltd
	Ross Walenga, PhD	Senior Chemical Engineer, DQMM, ORS, OGD, FDA

11:50 AM – 12:50 PM — ***Lunch Break***

Session 2: The Global LGWP Propellant Transition

This session will cover the global perspective on the LGWP propellant transition. Presentations will include discussion on how similarities and differences in regulatory thinking may impact LGWP propellant MDI development strategies and areas for study harmonization that could minimize potential challenges for drug developers seeking approval in different markets.

12:50 PM – 12:55 PM — ***Speaker Introductions***
Sarah Ibrahim, PhD — Associate Director, Stakeholder and Global Engagement, OGD, FDA

12:55 PM – 1:10 PM — ***Considerations from the Global Propellant Transition***
Karolina Törneke, DVM — Assistant Prof and Senior Clinical Assessor, Swedish Medical Products Agency

1:10 PM – 1:25 PM — ***Current MHRA Approach on Data Requirements for the Transition to Low GWP Propellants in pMDIs***
Nithyanandan Nagercoil, MBBS, MD — Senior Medical Assessor, MHRA

	Orla Ní Ógáin, PhD, PGDip Stat QI	Senior Pharmaceutical Assessor, Medicines & Healthcare Products, MHRA
1:25 PM – 1:40 PM	***Navigating the Regulatory Landscape: Sustaining Patient Care with Next-Gen LGWP MDI Propellants***	
	Mark Boelens, PhD	Global Senior Director, Product Stewardship & Toxicology, Honeywell
1:40 PM – 1:55 PM	***Key Considerations in the Business Decision to Reformulate a HFA-based pMDI with LGWP***	
	Geraldine Venthoye, PhD, BPharm, MRPharmS	Chief Scientific Officer & EVP Inhaled Technology Platforms, Vectura Group
1:55 PM – 2:10 PM	***Considerations and Challenges Facing Generic Manufacturers Transitioning to LGWPs***	
	Giuseppe Randazzo, MS	Senior Vice President, Sciences and Regulatory Affairs Association for Accessible Medicines (AAM)
2:10 PM – 2:55 PM	***Q&A Session with Panel***	
Moderator:	**Sarah Ibrahim, PhD**	Associate Director, Stakeholder and Global Engagement, OGD, FDA
Panelists:	**Mark Boelens, PhD**	Global Senior Director, Product Stewardship & Toxicology, Honeywell
	Nithyanandan Nagercoil, MBBS, MD	Senior Medical Assessor, MHRA
	Orla Ní Ógáin, PhD, PGDip Stat QI	Senior Pharmaceutical Assessor, Medicines & Healthcare Products, MHRA
	Giuseppe Randazzo, MS	Senior Vice President, Sciences and Regulatory Affairs Association for Accessible Medicines (AAM)
	Sally Seymour, MD	Director, DPACC, OII, OND, FDA
	Karolina Törneke, DVM	Assistant Prof and Senior Clinical Assessor, Swedish Medical Products Agency
	Geraldine Venthoye, PhD, BPharm, MRPharmS	Chief Scientific Officer & EVP Inhaled Technology Platforms, Vectura Group
	Paul Wielowieyski, MSc	Sr. Drug Evaluator, Division of Biopharmaceutics Evaluation, Health Canada
	Lei Zhang, PhD, FAAPS	Deputy Director, ORS, OGD, FDA
2:55 PM – 3:05 PM	***Coffee Break***	

Session 3: Lessons Learned and Closing Remarks

Following the presentations across both Day 1 and 2, this panel discussion will cover the lessons learned, along with identifying the areas where the FDA can provide additional guidance on areas that are most needed to address the ongoing challenges affecting LGWP propellant MDI development.

3:05 PM – 3:50 PM	***Holistic Panel Discussion***	
Moderator:	**Darby Kozak, PhD**	Deputy Director, OGD, FDA
Panelists:	**Mark Boelens, PhD**	Global Senior Director, Product Stewardship & Toxicology, Honeywell
	Poonam Gulati, PhD, MBA, PGCert	Senior Director & Team Lead, Global Regulatory Affairs, GSK
	Markus Laubscher, PhD	Head Business Unit Pharma, Orbia Fluor & Energy Materials, Koura
	Richard (Rik) Lostritto, PhD	Consultant, Lostritto Consulting, LLC
	Uwe Niesner, PhD	VP, Head Respiratory & Biologics Regulatory Strategy, Viatris
	Lucas W. S. Silva, BSc	Senior Specialist, Analytical Development, Nanopharm, An Aptar Pharma Co.
	Stephen Stein, MS	Scientific Director, Inhalation Product Development, Kindeva Drug Delivery
	Siva Vaithiyalingam, PhD	Senior Vice President/Head of US Regulatory Affairs, Cipla, Ltd
3:50 PM – 4:00 PM	***Closing Remarks (Day 2)***	
	Robert Lionberger, PhD	Director, ORS, OGD, FDA

Appendix of Abbreviations

ANDA	Abbreviated New Drug Application
Assoc.	Associate
BS or BSc	Bachelor of Science
BPharm	Bachelor of Pharmacy
Chem	Chemistry
CMC	Chemistry, Manufacturing and Controls
Co.	Company
CRCG	Center for Research on Complex Generics
Dept	Department
DIIP	Division of Inflammation and Immune Pharmacology
Dir	Director
DPACC	Division of Pulmonary Allergy and Critical Care
DPD	Division of Policy Development
DPhil	Doctor of Philosophy
DPQA VII	Division of Product Quality Assessment VII
DPQA XII	Division of Product Quality Assessment XII
DPT II	Division of Pharmacology/Toxicology for Immunology and Inflammation
Dr	Doctor
DTP I	Division of Therapeutic Performance I
DQMM	Division of Quantitative Methods and Modeling
DVM	Doctor of Veterinary Medicine
EPA	Environmental Protection Agency
EVP	Executive Vice President
FDA	Food and Drug Administration
FAAPS	Fellow of the American Association of Pharmaceutical Scientists
GSK	GlaxoSmithKline
IPD	Inhalation Product Development
LGWP	Low Global Warming Potential
LLC	Limited Liability Company
LTD	Limited
MBA	Master of Business Administration
MBBS	Bachelor of Medicine, Bachelor of Surgery in India
MChem	Master of Chemistry
MD	Doctor of Medicine
Med	Medicine
MHRA	Medicines and Healthcare products Regulatory Agency
MPH	Master of Public Health
MPharm	Master of Pharmacy
MRPharmS	Member of the Royal Pharmaceutical Society
MS or MSci	Master of Science
NDA	New Drug Application
OB	Office of Bioequivalence
OGD	Office of Generic Drugs
OGDP	Office of Generic Drug Policy
OII	Office of Immunology and Inflammation
OPQ	Office of Pharmaceutical Quality
OPQA I	Office of Pharmaceutical Quality I
OPQA II	Office of Pharmaceutical Quality Assessment II
ORS	Office of Research and Standards
OTS	Office of Translational Sciences
PGCert	Post Graduate Certification
PGDip Stat QI	Post Graduate Diploma in Statistics and Quality Improvement
PhD	Doctor of Philosophy
Prof	Professor
PT&D	Pharmaceutical Technology & Development
RAC	Regulatory Affairs Certification
R&D	Research and Development
Sr	Senior
VP	Vice President