

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 Anna Schwendeman, PhD	Co-Director, CRCG 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 A'ishah Ali, MD	Senior Physician, DPACC, OII, OND, FDA
11:10 AM – 12:00 PM	Q&A Session with Panel Moderator: Panelists:	Director, DPACC, OII, OND, FDA Senior Physician, DPACC, OII, OND, FDA CMC Reviewer, DPQA VII, OPQA II, OPQ, FDA Clinical Team Leader, DPACC, OII, OND, FDA Senior Clinical Pharmacologist, DIIP, OTS, FDA

Luke Hall-Jordan, MPH
Luqi Pei, PhD
Stephen Stein, MS
Hailing Zhang, PhD

Supervisory Environmental Policy Analyst, Phasedown Implement Branch, EPA
Master Pharmacologist, DPT II, OII, OND, FDA
Scientific Director, Inhalation Product Development, Kindeva Drug Delivery
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 Maturro, 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 Maturro, MS

R&D Global Technical Leader, CHIESI Farmaceutici

Ann Purrington, BS, RPh, RAC

Regulatory Affairs Director, Kindeva Drug Delivery

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, Viatrix

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

Anna Schwendeman, PhD

Co-Director, CRCG

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, OGD, 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, Viatriis

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 & Pharmacoconomics, 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, Viatriis

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

Moderator:
Panelists:

Q&A Session with Panel

Sarah Ibrahim, PhD Associate Director, Stakeholder and Global Engagement, OGD, FDA
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

Moderator:
Panelists:

Holistic Panel Discussion

Darby Kozak, PhD Deputy Director, OGD, FDA
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, Viatrix
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