CENTER FOR RESEARCH ON COMPLEX GENERICS

Navigating the Transition to Low Global Warming Potential Propellants

Welcome and Opening Remarks

James Polli, PhD

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UNIVERSITY of MARYLAND BALTIMORE

UNIVERSITY OF MICHIGAN

FDA U.S. FOOD & DRUG ADMINISTRATION

Established in 2020, The Center for Research on Complex Generics (CRCG) is a collaboration between the University of Maryland, the University of Michigan, and the FDA.

About CRCG

Our Mission

Increase access to safe and effective generic drugs through enhanced infrastructure/communication, education, and research collaboration across industry, academia and the FDA.

We are dedicated to advancing programs that stimulate scientific dialogue, disseminate current insights, and generate new knowledge about complex generics in support of the FDA's mission to promote and protect the public health.

Primary Goals of the CRCG

INFRASTRUCTURE & COMMUNICATION

Establishing core program infrastructure and enhancing communications to advance complex generics development

EDUCATION & TRAINING

Providing education and training through workshops, webinars, hands-on demonstrations, and on-site visits

COLLABORATIVE RESEARCH

Conducting collaborative research and enabling pilot research projects and technological development

Ongoing Engagement to Advance Complex Generics Product Development

Periodic interviews with key complex generics players to understand challenges and opportunities in advancing complex generics product development

Future?

- Lessons from prior transition from chlorofluorocarbons (CFCs) to hydrofluoroalkane (HFAs) propellants
- Breztri (budesonide/glycopyrrolate/formoterol fumarate) inhalation aerosol
- HFO-1234ze

16 Educational Workshops & Training Completed

32,700+ Registered

2025 IN-PERSON (& VIRTUAL) WORKSHOPS & TRAINING

MARCH 27-28

Implementing FDA's IVPT Guidance Recommendations: A Step-By-Step Illustration

APRIL 29-30

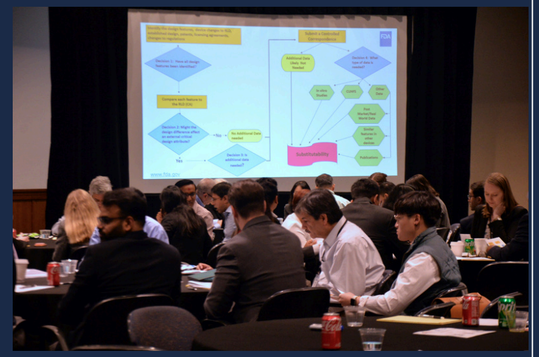
Mastering Particle Size Analysis: A Step-By-Step Illustration of Techniques and Best Practices

OCTOBER 15-16

Modeling and Artificial Intelligence in Generic Drugs: Regulatory Insights and Future Trends

NOVEMBER 19-20

Visionary Standards: Advancing Science and Regulation in Generic Ophthalmic Products



Research Projects

- Research and education needs for complex generics
- Towards best practice in novel bioequivalence studies of long-acting injectable products: A complete framework for model-integrated design with the MonolixSuite
- Accelerating generic drug development using an MIBE approach
- Evaluation of micelle/colloid diffusivity to better parameterized physiologically based pharmacokinetic models for oral drug absorption
- Reverse engineering, IVR and small-scale manufacturing of ONIVYDE™
- Reverse engineering of Invega Sustenna® (paliperidome palmitate suspension)
- Scientific challenges and opportunities in the development of complex generics
- Best practices and standards in nanotechnology
- Lack of effect of antioxidants on BCS Class III drug permeability
- Mitigation of nitrosamine formation in solid dosage form through formulation
- Toolkit to assess adhesion performance of topical & transdermal delivery systems in vitro

CRCG Team

Dr. James Polli
co-Director

Dr. Anna Schwendeman
co-Director

Dr. Vishalakshi Krishnan
Manager

Dana Hammell
Events Coordinator

Jennifer Dick
Administrative Assistant

CRCG Contact & Media Platforms

Email: info@complexgenerics.org

Website

Learn more about the Center & signup for listserv

www.complexgenerics.org

YouTube Channel

Recordings from CRCG events will be posted here. Subscribe for updates.

@complexgenerics

Social Media

Please follow CRCG for event related updates.

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@complexgenerics

Huge Thank You!!

To our Planning Committee Members for this workshop

FDA

- Dr. Bryan Newman, Lead Pharmacologist, DTP I, ORS, OGD
- Dr. Elizabeth Bielski, Senior Pharmacologist, DTP I, ORS, OGD
- Dr. Anubhav Kaviratna, Pharmacologist, DTP I, ORS, OGD
- Dr. Kimberly Raines, Associate Director of Science, OPPQ, OPQ
- Dr. Craig Bertha, Chemist (CMC), DPQA VIII, OPQA II, OPQ
- Dr. Haritha Mandula, Senior Pharmaceutical Quality Assessor, DPQA VI, OPQA I, OPQ
- Dr. Ross Walenga, Senior Chemical Engineer, DQMM, ORS, OGD
- Dr. Bing Li, Associate Director for Science, OB, OGD
- Dr. Robert Dorsam, Division Director, DPTR, OSCE, OGD
- Dr. Susan Levine, Supervisory Regulatory Counsel, DPD, OGDP, OGD
- Dr. Dhaval Gaglani, Supervisory Chemist, DPQA V, OPQA I, OPQ
- Dr. Mahesh Ramanadham, Deputy Director, OPPQ, OPQ
- Dr. Vibhakar Shah, Senior Policy Advisor, DIPC, OPPQ, OPQ
- Dr. Robert Lim, Deputy Division Director FO, DPACC, OII, OND
- Dr. Stacy Chin, Lead Physician, DPACC, OII, OND
- Dr. Sally Seymour, Supervisory Physician, DPACC, OII, OND
- Dr. Qi Zhang, Lead Pharmacologist, DTP II, ORS, OGD
- Dr. Markham Luke, Supervisory Physician, DTP I, ORS, OGD
- Dr. Sarah Ibrahim, Associate Director for Stakeholder and Global Engagement, OGD
- Dr. Sam Raney, Associate Director for Science, ORS, OGD

Huge Thank You!!

To our Planning Committee Members for this workshop

Industry

- Dr. Karolina Torneke, Associated Professor, Senior Clinical Assessor, Swedish Medical Products Agency, EMA
- Dr. Liang Zhao, Professor and Director, Center of Regulatory Science, School of Pharm. Univ. of California, San Francisco
- Alan Thompson, Director, Inhalation Regulatory Affairs, Teva Pharmaceuticals; IPAC-RS
- Giuseppe Randazzo, Vice President, Science and Regulatory Affairs, Association for Accessible Medicines
- Ann Purrington, Regulatory Affairs Director, Kindeva Drug Delivery; IPAC-RS
- Dr. Luke Simmons, Senior Manager, Pharmaceutical Development, Vectura Group plc.; IPAC-RS
- Julie Suman, Vice President Scientific Affairs, Aptar Pharma; IPAC-RS
- Dr. Jennifer Edeline, Senior Regulatory Affairs Manager, Aptar Pharma; IPAC-RS
- Dr. Rupi Pannu, Senior Director, Respiratory R&D Project Leader, Viatris; IPAC-RS
- Dr. Anabela Marcal, Head of Compliance and Inspections, European Medicines Agency (EMA)
- Sarin (Sagrario) Rey Torre, Product Lead, Therapies for Immune & Inflammatory Diseases, EMA
- Dede Godstrey, Project Coordinator, Faegre Drinker; IPAC-RS

Thank You for Your Participation!

FDA Opening Remarks
&
Workshop Day 1 Overview

by
Markham Luke, MD, PhD

Director, DTP I, ORS, OGD, FDA

Session 1 Moderator

Sally Seymour, MD

Director, DPACC, OII, OND, FDA