CENTER FOR RESEARCH ON COMPLEX GENERICS

Updates on Approaches to Acceptable Intakes of Nitrosamine Drug Substance Related Impurities (NDSRIs) and Bioequivalence Assessment for Reformulated Drug Products

Welcome Remarks

James Polli, PhD

November 6, 2024

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

Prior FDA-CRCG Workshop on Nitrosamines

Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics

June 15, 2023

https://www.complexgenerics.org/education-training/

Recent FDA Guidance on Nitrosamines

Control of Nitrosamine Impurities in Human Drugs Guidance for Industry

September 2024

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/control-nitrosamine-impurities-human-drugs

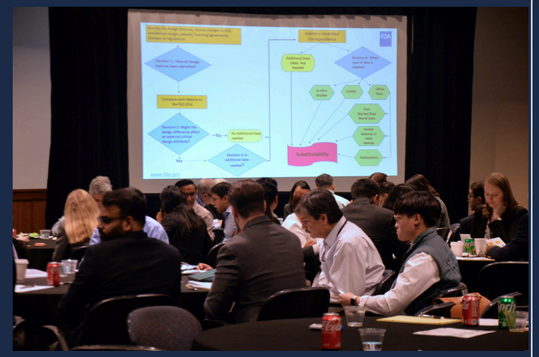
15 Educational Workshops & Training Completed

29,600+ Registered

UPCOMING 2024 IN-PERSON（& VIRTUAL）WORKSHOPS & TRAINING

DECEMBER 4 - 5

Navigating the Transition to Low Global Warming Potential Propellants



SAVE-THE-DATE

2025 In-Person (& Virtual) Workshops & Training

MARCH 27-28

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

APRIL 29-30

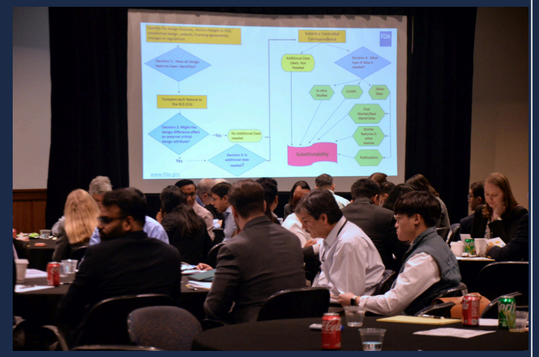
Mastering Particle Size Analysis: A Step-By-Step Illustration of Techniques and Best Practices

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
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Dr. Vishalakshi Krishnan
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Events Coordinator

Jennifer Dick
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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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Huge Thank You!!

To our Planning Committee Members for this workshop

FDA

- Dr. Khondoker Alam, Senior Staff Fellow, DQMM, ORS, OGD
- Dr. Qi Zhang, Lead Pharmacologist, DTP II, ORS, OGD
- Dr. Andre Raw, Associate Director for Science & Communication, OLDP, OPQ
- Dr. Baoqing Ma, CMC Reviewer, DPQA VII, OPQA II, OPQ
- Dr. Bhagwant Rege, Division Director, DB, ONDP, OPQ
- Dr. Bing Li, Associate Director of Science, OB, OGD
- Dr. Dan Berger, CMC Reviewer, DPQA II, OPQA I, OPQ
- Dr. Diaa Shakleya, Senior Research Scientist, (Pharmacologist) DPQRB, OTR, OPQ
- Dr. Dongmei Lu, Policy Lead, OPPQ/OPQ
- Dr. Jingyue (Jan) Yang, Senior Research Scientist, DPA, OTR, OPQ
- Dr. Govindaraj Kumaran, Chemist, DPQA XIX, OPQA III, OPQ
- Dr. Liang Zhao, Director, DQMM, ORS, OGD
- Dr. Matthew Vera, Supervisory Chemist, DPQA II, OPQA I, OPQ
- Dr. Robert (Bob) Dorsam, Division Director, DPTR, OSCE, OGD
- Dr. Rong Wang, Acting Associate, Director, DB I, OB, OGD
- Dr. Xin Fu, Pharmacologist, DPTR, OSCE, OGD
- Dr. Sam Raney, Associate Director for Science, ORS, OGD

Huge Thank You!!

To our Planning Committee Members for this workshop

Industry

- Dr. Brett Howard, Senior Director, US Regulatory Policy, US Pharmacopeia
- Dr. Kevin Cross, Vice President, Regulatory Science, Instem
- Dr Martin Ehlert, Vice President, Global API R&D, Apotex
- Nalin Karkra, General Manager, Sun Pharmaceuticals Industries Lt
- Dr. Tausif Ahmed, Head-Biopharm., Preclinical and Clinical Bioanal, Global Clinical Management (VP), Dr. Reddy's Laboratories Ltd

Thank You for Your Participation!

FDA Opening Remarks

by
Robert Lionberger, PhD

Director, ORS, OGD, FDA

Workshop Overview

by
Khondoker Alam, PhD

Senior Pharmacologist, DQMM, ORS, OGD, FDA