CENTER FOR RESEARCH ON COMPLEX GENERICS

Scientific and Regulatory Considerations for Assessment of Immunogenicity Risk for Generic Peptide and Oligonucleotide Drug Products

Welcome Remarks

Anna Schwendeman, 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

Peptide Immunogenicity - Challenges with Development of Complex Generics

- **Need for regulatory science, research, tools and assays to employ and bridge non-clinical assessments with clinical studies early in the drug development process**
- **Challenges with non-clinical platforms to assess immunogenicity:**
  - Lack of regulatory guidance on in vitro method validation requirements for immunogenicity (sample dilution, masking effects, number of donors, type of IIRMI, sample dilution, false positive/false negatives, inherent variability, standardized assay controls)
  - Need for standardization statistical methods for immunogenicity assessments
  - How to assess immunogenicity when synthetic peptide is produced by recombinant process or administered orally and how to set the limits relative to peptide doses
  - Setting minimum assay sensitivity standards, variability and stressed samples
  - Need for direct correlation between in vitro and in vivo immunogenicity outcome using existing data

14 Educational Workshops & Training Completed

27,400+ Registered

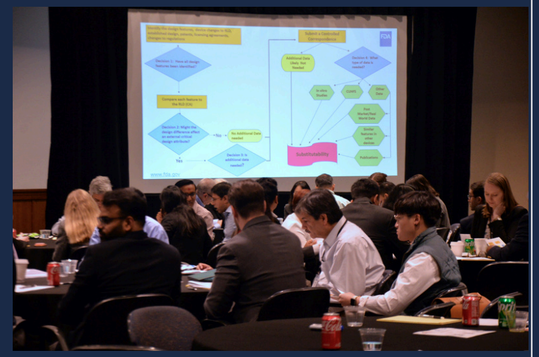
UPCOMING 2024 IN-PERSON（& VIRTUAL）WORKSHOPS & TRAINING

NOVEMBER 6 -7

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

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

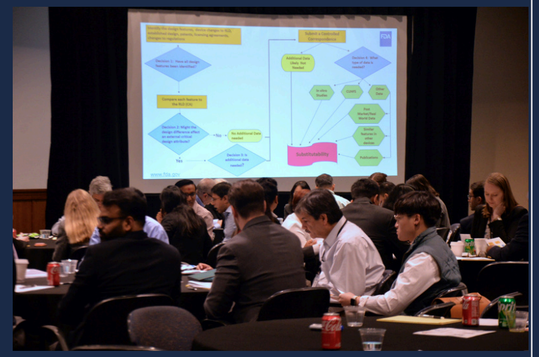
Mastering Particle Size Analysis: A Step-By-Step Illustration of Techniques and Best Practices

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
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.

center-for-research-on-complex-generics

@complexgenerics

Huge Thank You!!

To our Planning Committee Members for this workshop

FDA

- Dr. Eric Pang, Team Lead (acting), DTP I/ORS/OGD/CDER/FDA
- Dr. Cameron Smith, Supervisory Chemist, DPQA IV/OPQA I/OPQ/FDA
- Dr. Daniela Verthelyi, Chief, Laboratory of Immunology, DPQR IV/OPQR/OPQ/FDA
- Dr. Deyi Zhang, Senior Chemist, DTP I/ORS/OGD/FDA
- Dr. Sam Raney, Associate Director for Science, ORS, OGD

Industry

- Andrew Graves, Director - Immunogenicity Assessment, Teva Pharmaceuticals
- Dr Jeremy Fry, Director of Sales, ProImmune, Inc.
- Dr. Noel Smith, Director, Head of Immunology, Early Development Services, Lonza Biologics

Thank You for Your Participation!

FDA Opening Remarks

by
Iilun Murphy, MD

Director, OGD, FDA

Introduction: Immunogenicity of Generic Products - History and Present

by
Eric Pang, PhD

Team Lead (acting), DTP I/ORS/OGD/CDER/FDA