CENTER FOR RESEARCH ON COMPLEX GENERICS

Drug-Device Combination Products: Updates and Challenges with Demonstrating Generic Substitutability

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.

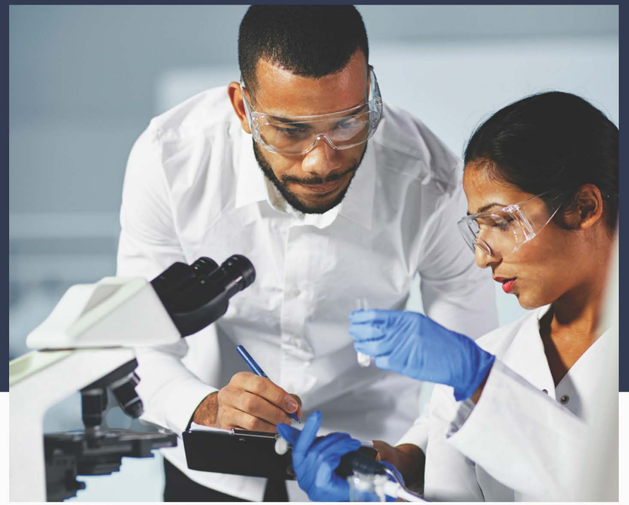
Primary Goals of the CRCG

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

750+ engagements with key complex generics players to understand challenges and opportunities in advancing complex generics product development

DDCPs: A Few Unique Challenges

- Need FDA's clarification on when it is critical for a generic to be identical to RLD and when human factors (HF) testing may be useful in overcoming any differences that may not impact the safety or usability of the product
- HF studies are:
  - Expensive
  - Never identical to the RLD due to intellectual property
  - Evaluated quantitatively rather than qualitatively yielding yield little meaningful information about safety and effectiveness
  - Difficult to successfully conduct while meeting regulatory requirements
  - Particularly burdensome for highly variable RLDs

DDCPs: Other Challenges

- Device differences possibly leading to small variations in the patient usage side have high barrier for approval
- FDA has been wary of adopting or accepting certain scientific methods that sponsors consider commonplace or routine
- Need for regulatory science and research regarding acceptable non-inferiority margins in comparative use human factors studies, including workshops, training, and focus groups

DDCPs: Intellectual property (IP) interferes with the progress of generic development

- Even if a generic elicits desirable functionality, if it does not meet all RLD specifications due to concerns over prior art, it impacts approval
- IP blocks companies from making acceptable “mimics” of the innovator. The uncertainty of new patent claims, makes it challenging to predict infringement, design human factor studies and begin scaling up manufacturing.
- Trade dress can prevent companies from using the same device shape, color and/or delivery design. For inhalation products, like albuterol, shape of the device is crucial for proper drug delivery and optimal dosing. For life-saving injectables such as EpiPen®, the color helps patients readily identify their medication in times of anaphylaxis.

12 Educational Workshops & Training Completed

24,400+ Registered

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

MAY 2 - 3

Considerations and Potential Regulatory Applications for a Model Master File

OCTOBER 7 - 8

Scientific and Regulatory Considerations for Assessment of Immunogenicity Risk for Generic Peptide and Oligonucleotide Drug Products: Present State and Future Directions

NOVEMBER 7

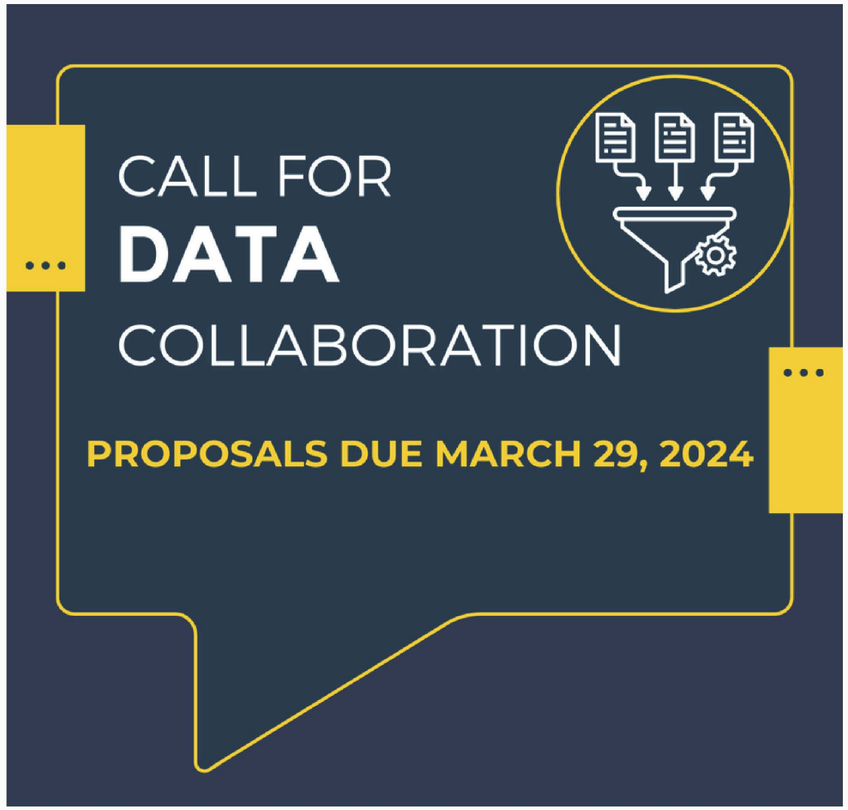
Updates on Approaches to Acceptable Intakes of Nitrosamine Drug Substance Related Impurities (NDSRIs) and Bioequivalence Assessment for Reformulated Drug Products

DECEMBER 4 - 5

Navigating the Transition to Low Global Warming Potential Propellants

CRCG Call for Data Contribution

Under grant (1U01FD007904)



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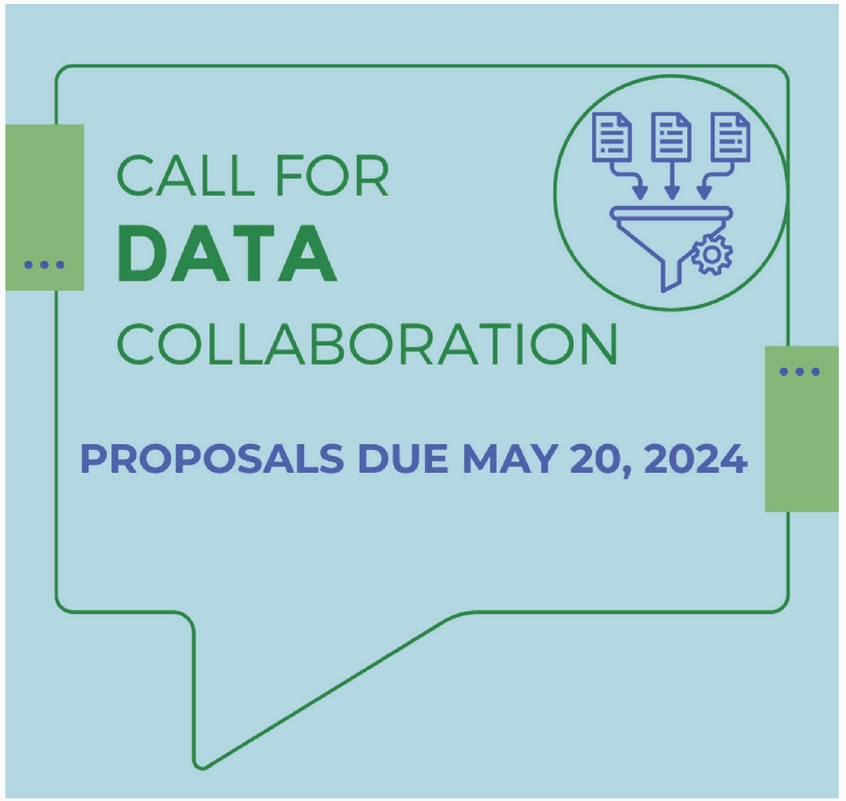
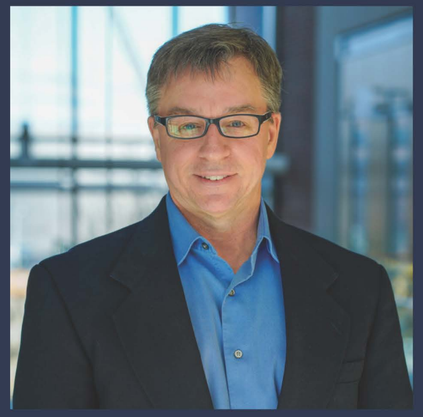


Simulations Plus

CRCG Team



Dr. James Polli
co-Director

Dr. Anna Schwendeman
co-Director

Dr. Vishalakshi Krishnan
Associate Director

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.

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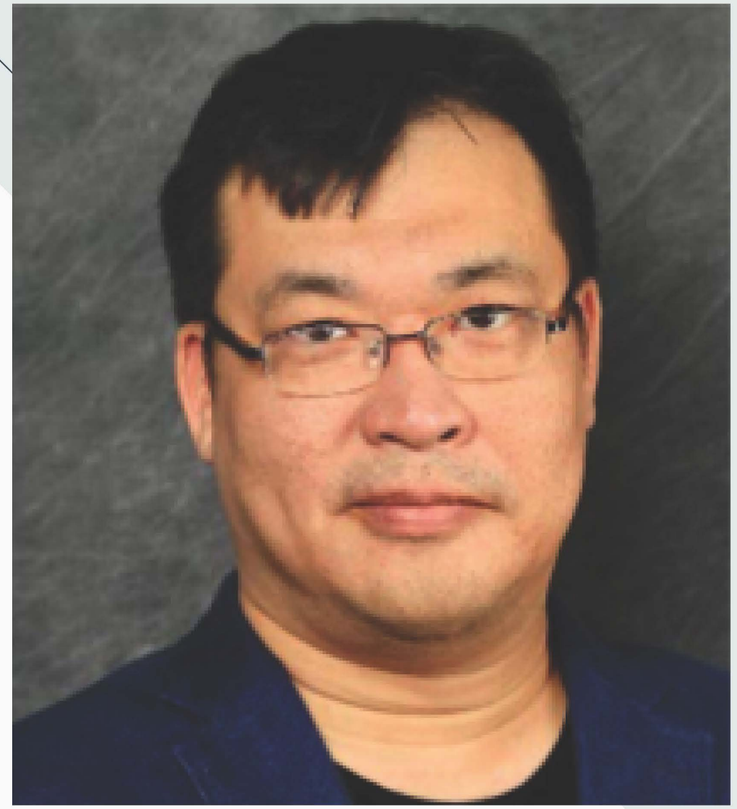
Thank You for Your Participation!

Opening Remarks

by
Dr. Markham Luke

Director, DTP I, ORS, OGD, FDA



Summary of 2023 DDCP 101 course and Day 1 Overview

Katharine B. Feibus, MD

Team Leader, Device Evaluation Team, DTP I,
ORS, OGD, FDA

Brandon Wood, BS

Director of Regulatory Affairs, Generic Steriles,
Teva Pharmaceuticals USA, Inc.