



UNIVERSITY of MARYLAND



U.S. FOOD & DRUG  
ADMINISTRATION



CENTER FOR RESEARCH ON  
**COMPLEX**  
**GENERICS**

FDA-CRCG Webinar on Excipients and Formulation  
Assessments of Complex Generic Products: Best Practices and  
Lessons Learned

James Polli: Welcome and Opening Remarks

[www.complexgenerics.org](http://www.complexgenerics.org)

# Today's Webinar on Excipients and Formulation Assessment of Complex Generic Products

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## ▶ Purpose

- To provide an overview of the regulatory framework, scientific concepts, product-specific challenges, and best practices related to development of complex generic drug products that are either required or recommended to have the same formulation as their respective RLDs
- ▶ Slides and recordings of this webinar will be available in three weeks, and registrants will be emailed when available
- ▶ Agenda and speaker biographies available at [complexgenerics.org](http://complexgenerics.org)



# Center for Research on Complex Generics (CRCG)

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- ▶ To increase access to safe and effective generic drugs through enhanced infrastructure/communication, education, and research collaboration across industry, academia and the FDA
- ▶ Learn more about the Center (and signup for listserve) at:  
[www.complexgenerics.org](http://www.complexgenerics.org)



# 2023 Workshops

- ▶ In-person (& online) at The Universities at Shady Grove (USG; <https://shadygrove.umd.edu>), Rockville, MD
- ▶ DDCP 101 – Identifying, Developing, and Evaluating Generic Drug Device Combination Products (DDCP) (training)
  - Mar 16, 2023
- ▶ Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products – Considerations and Alternatives
  - Apr 20-21, 2023
- ▶ Mitigation Strategies for Nitrosamine Drug Substance Related Impurities: Quality and Bioequivalence Considerations for Generics
  - Jun 15, 2023
- ▶ Advances in PBPK Modeling and its Regulatory Utility for Oral Drug Product Development
  - Oct 12, 2023
- ▶ Comparative User Interface Assessment for Drug-Device Combination Products: Updates and Challenges in Demonstrating Generic Substitutability
  - Nov 2-3, 2023
- ▶ Characterization of Complex Excipients/Formulations
  - Dec 7-8, 2023



# Thank you

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- ▶ Thank you for your participation
- ▶ Please ask questions via Chat
- ▶ Slides and recordings of this workshop will be available in three weeks, and registrants will be emailed when available

