

University of Maryland
Center for Excellence in Regulatory Science
and Innovation (M-CERSI)



**Methods to Assess Similarity in Dissolution Profiles in Support
of Drug Product Quality: What, How, and When**



Thank you

- Apotex



UNIVERSITY of MARYLAND



Upcoming Workshops

- Methods to Assess Similarity in Dissolution Profiles in Support of Drug Product Quality: What, How, and When
 - May 21 and 22 2019 at Baltimore
 - www.pharmacy.umaryland.edu/dissolution-similarity
- Pediatric formulation development: Challenges of today and strategies for tomorrow
 - June 18 and 19 2019 at Baltimore
 - www.pharmacy.umaryland.edu/pediatric-formulations
- Topical Drug Development– Evolution of Science and Regulatory Policy
 - July 29 and 30 2019 at Baltimore
 - www.pharmacy.umaryland.edu/topical



Questions about Oral Solid Dosage Forms

- Given in vitro dissolution data, do you have confidence in proposing an approach to assess whether two product profiles are similar or not?
- Regardless of your definition of “IVIVC analysis”, do you agree that effort to perform “IVIVC analysis” is currently optional?
- Do you think that effort to perform “IVIVC analysis” should be mandatory?

