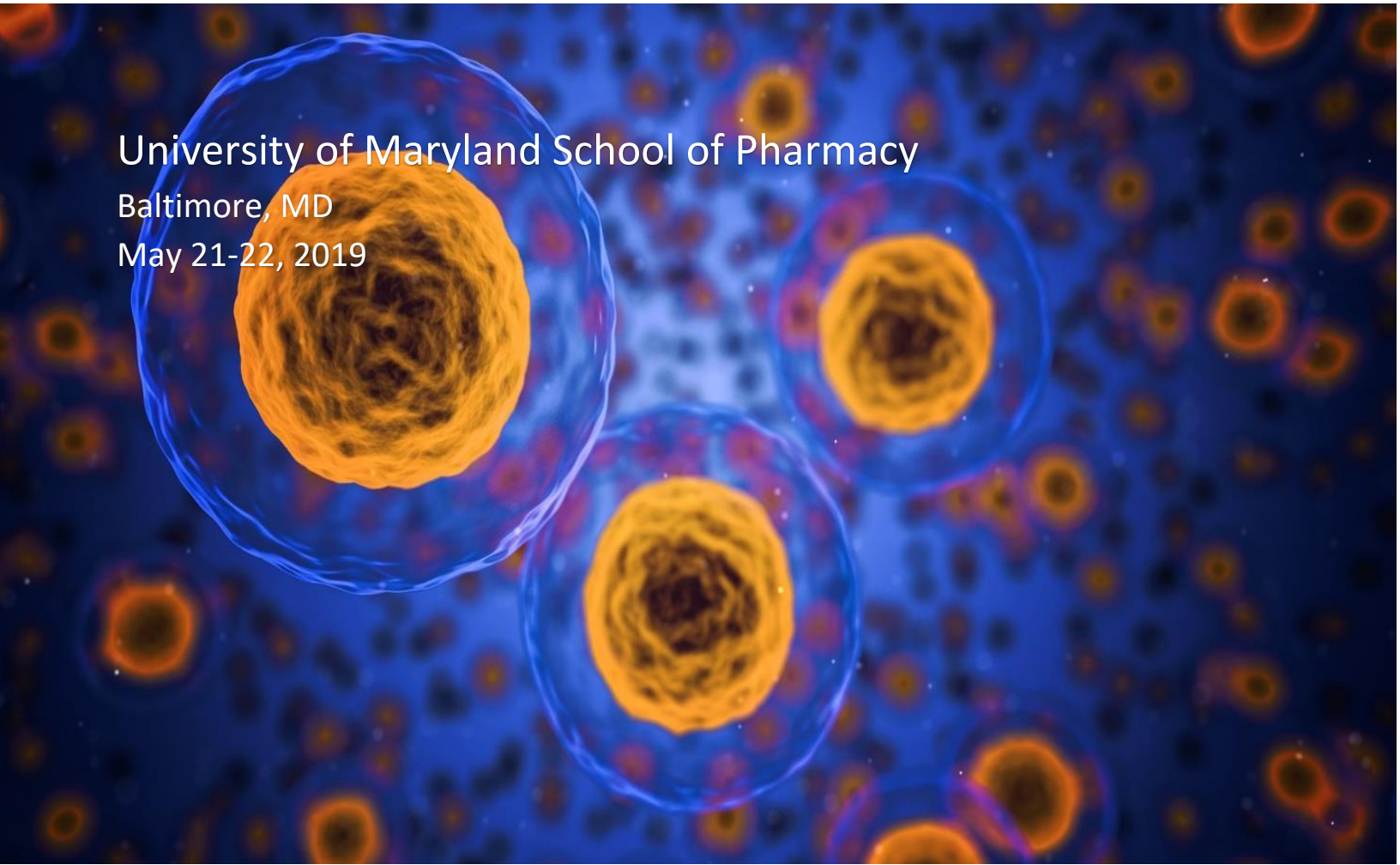
The University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) Presents:

In Vitro Dissolution Profiles Similarity Assessment in Support of Drug Product Quality: What, How, and When

www.pharmacy.umaryland.edu/dissolution-similarity



University of Maryland School of Pharmacy

Baltimore, MD

May 21-22, 2019

Conference Agenda

Tuesday, May 21, 2019

Moderators:

- Dorys Diaz (Pfizer)
- David LeBlond (CMCStats)

Agenda:

Time	Activity
8:30-8:35 a.m.	**Welcome and Logistics** **James Polli, PhD** University of Maryland School of Pharmacy
8:35-8:50 a.m.	**Introduction and Objectives of the Workshop** **Sandra Suarez, PhD** U.S. Food and Drug Administration
8:50-9:20 a.m.	**Keynote: The Value of Similarity Testing in Drug Product Development** **Roger Nosal, PhD** Pfizer
9:20-9:50 a.m.	**F2 Similarity Testing, Performance and Limitations** **Yi Tsong, PhD** U.S. Food and Drug Administration
9:50-10:20 a.m.	**Bootstrap Approach for Similarity Testing, Performance and Limitations** **Leslie Van Alstine, MS** Pfizer
10:20-10:30 a.m.	**Break**
10:30-11:00 a.m.	**Multivariate Statistical Distance Test (MSD) Performance and Limitations** **Thomas Hoffelder** Boehringer-Ingelheim

11:00-11:30 a.m.	**Bayesian Approach for Similarity Testing, Performance and Limitations** **Dave LeBlond, PhD** CMCStats
11:30 a.m. - Noon	**Weibull Model Approach for Similarity Testing, Performance and Limitations** **Stan Altan, PhD** Johnson & Johnson
Noon – 12:45 p.m.	**Lunch**
12:45-1:15 p.m.	**Rational Statistical Analysis Practice in Dissolution Profile Comparison: FDA Perspective** **Haritha Mandula, PhD** U.S. Food and Drug Administration
1:15-1:45 p.m.	**Rational Statistical Analysis Practice in Dissolution Profile Comparison for Product Quality Assessment of Similarity through Real Case Studies: Industry Perspective** **Yanbing Zheng, PhD** AbbVie
1:45-2:00 p.m.	**Introduction and Expectations of Breakout Sessions (BOs)** **Dave LeBlond, PhD** CMCStats **BO Sessions, Background Topic**: Advantages and Disadvantages of Available Statistical Approaches to Dissolution Profile Comparisons for Similarity Testing
2:00-2:15 p.m.	**Break and Transition to BOs**
2:15-4:15 p.m.	**Breakout Sessions (Choose One to Attend)** **BO Session A: Definition/Discussion of Similarity Terminology – How Should "Similarity" Be Most Usefully Defined?** **Moderators:** Dave LeBlond (CMCStats), Thomas Hoffelder (Boehringer-Ingelheim) **Scribes:** Haritha Mandula (FDA), Limin Zhang (BMS) **BO Session B: Best Practices for Performing Dissolution Similarity for Regulatory Applications** **Moderators:** Elena Rantou (FDA), Krista Witkowski (Merck) **Scribes:** Poonam Delvadia (FDA), Karin Rosenblatt (AbbVie)

	BO Session C: What is the Proper "Inference Space" for Similarity Studies? Addressing This is Key to Experimental Design **Moderators:** Meiyu Shen (FDA), James Reynolds (AbbVie) **Scribes:** David Lavrich (Merck), Ivelisse Colon-Rivera (Vertex)
	BO Session D: What Are the Advantages and Disadvantages of Currently Available "Statistical" Approaches for Dissolution? **Moderators:** Xiaoyu Cai (FDA), Kim E. Vukovinsky (Pfizer) **Scribes:** Amy (Huizi) Zhang (GSK), Zachary Bergeron (Agios)
4:15-4:45 p.m.	**Break (Moderators and Scribes to Convene)**
4:45-5:30 p.m.	**Summary of Breakout Sessions** **Lead Moderators**
5:30-6:15 p.m.	**OC Members/Moderators/Scribes**

Wednesday, May 22, 2019

Moderators:

- Andreas Abend (Merck)
- Poonam Delvadia (FDA)
- Sandra Suarez (FDA)

Agenda:

Time	Activity
	Introduction
8:30-8:35 a.m.	**Welcome and Logistics** **Poonam Delvadia, PhD** U.S. Food and Drug Administration
8:35-9:10 a.m.	**FDA's Current Practice and Challenges in the Evaluation of Dissolution Profile Comparisons in Support of Minor/Moderate Product Quality Changes: Case Studies** **Om Anand, PhD** U.S. Food and Drug Administration

9:10-9:40 a.m.	**EMA's Current Practice and Challenges in the Evaluation of Dissolution Profile Comparisons in Support of Minor/Moderate Product Quality Changes: Case Studies** **Evangelos Kotzagiorgis, MSc** European Medicines Agency
9:40-10:10 a.m.	**Dissolution Similarity Applications in New Drug Product Development – Issues and Challenges: Case Studies** **Limin Zhang, MS** Bristol-Myers Squibb
10:10-10:40 a.m.	**ANVISA's Current Practice and Challenges in the Evaluation of Dissolution Profile Comparisons in Support of Minor/Moderate Product Quality Changes: Case Studies** **Victor Gomez Pereira, PhD** Anvisa
10:40-11:00 a.m.	**Break**
11:00-11:30 a.m.	**Health Canada's Current Practice and Challenges in the Evaluation of Dissolution Profile Comparisons in Support of Minor/Moderate Product Quality Changes: Case Studies** **Susan Lum, PhD** Health Canada
11:30 a.m. - Noon	**FDA's Current Challenges in the Use of Dissolution Similarity Testing for Demonstration of BE: Case Studies** **Zhen Zhang, PhD** U.S. Food and Drug Administration
Noon - 12:30 p.m.	**Dissolution Similarity Applications in Generic Industry – Issues and Challenges: Case Studies** **Emilija Fredro-Kumbaradzi, PhD** Apotex
12:30-12:45 p.m.	**Introduction and Expectation of BO Sessions** **Andreas Abend, PhD** Merck **BO Sessions, Background Topic:** Dissolution Similarity Assessment, Requirements, and Global Expectations
12:45-1:30 p.m.	**Lunch**

1:30-3:30 p.m.	**BREAKOUT SESSIONS (CHOOSE ONE TO ATTEND)** **BO SESSION A: THE VALUE OF SIMILARITY TESTING IN LIGHT OF CLINICALLY RELEVANT SPECIFICATIONS AND SAFE SPACE** **Moderators:** Sandra Suarez (FDA), Gregory Rullo (AZ) **Scribes:** Elisabeth Kovacs, Andreas Abend (Merck) **BO SESSION B: DISSOLUTION SIMILARITY ASSESSMENT, REQUIREMENTS, AND GLOBAL EXPECTATIONS** **Moderators**: Johannes Kraemer (Disso-Science), Susan Lum (Health Canada) **Scribes**: Amy Barker (Lilly), Kelly Kitchens (FDA), Xin Bu (BMS) **BO SESSION C: HOW TO DESIGN A ROBUST STATISTICAL APPROACH (E.G., DECISION TREE) FOR THE ASSESSMENT OF DISSOLUTION PROFILE COMPARISONS – PART 1** **Moderators:** Yanbing Zheng (AbbVie), Meiyu Shen (FDA) **Scribes:** Om Ananda (FDA), Ivelisse Colon-Rivera (Vertex) **BO SESSION D: HOW TO DESIGN A ROBUST APPROACH (E.G., DECISION TREE) BEYOND STATISTICAL CONSIDERATIONS FOR THE ASSESSMENT OF DISSOLUTION PROFILE COMPARISON – PART 2** **Moderators**: Poonam Delvadia (FDA), David Lavrich (Merck), Amy (Huizi) Zhang (GSK) **Scribes**: Dave LeBlond (CMCStats), Michael Cohen (Pfizer), Gao Yi (AbbVie)
3:30-4:00 p.m.	**BREAK (MODERATORS/SCRIBES TO CONVENE)**
4:00-4:45 p.m.	**SUMMARY OF BREAKOUT SESSIONS** **Lead Moderators**
4:55-5:15 p.m.	**CONCLUSION AND FUTURE DIRECTIONS** **Dorys Diaz, MBA** Pfizer