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:

<table>
<thead>
<tr>
<th>Time</th>
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<tr>
<td>8:30-8:35 a.m.</td>
<td>Welcome and Logistics&lt;br&gt;James Polli, PhD&lt;br&gt;University of Maryland School of Pharmacy</td>
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<td>8:35-8:50 a.m.</td>
<td>Introduction and Objectives of the Workshop&lt;br&gt;Sandra Suarez, PhD&lt;br&gt;U.S. Food and Drug Administration</td>
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<td>8:50-9:20 a.m.</td>
<td>Keynote: The Value of Similarity Testing in Drug Product Development&lt;br&gt;Roger Nosal, PhD&lt;br&gt;Pfizer</td>
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<td>9:20-9:50 a.m.</td>
<td>F2 Similarity Testing, Performance and Limitations&lt;br&gt;Yi Tsong, PhD&lt;br&gt;U.S. Food and Drug Administration</td>
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<td>9:50-10:20 a.m.</td>
<td>Bootstrap Approach for Similarity Testing, Performance and Limitations&lt;br&gt;Leslie Van Alstine, MS&lt;br&gt;Pfizer</td>
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<td>10:20-10:30 a.m.</td>
<td>Break</td>
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<td>10:30-11:00 a.m.</td>
<td>Multivariate Statistical Distance Test (MSD) Performance and Limitations&lt;br&gt;Thomas Hoffelder&lt;br&gt;Boehringer-Ingelheim</td>
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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 “INFERENECE 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.
4:45-5:30 p.m.
5:30-6:15 p.m.

WEDNESDAY, MAY 22, 2019

MODERATORS:

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

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<td>INTRODUCTION</td>
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| 8:35-9:10 a.m. | WELCOME AND LOGISTICS
Poonam Delvadia, PhD  
U.S. Food and Drug Administration |
|               | 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 |
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<tr>
<td>9:10-9:40 a.m.</td>
<td>EMA’s Current Practice and Challenges in the Evaluation of Dissolution Profile Comparisons in Support of Minor/Moderate Product Quality Changes: Case Studies</td>
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<td>Evangelos Kotzagiorgis, MSc</td>
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<td>European Medicines Agency</td>
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<td>9:40-10:10 a.m.</td>
<td>Dissolution Similarity Applications in New Drug Product Development – Issues and Challenges: Case Studies</td>
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<td>Limin Zhang, MS</td>
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<td>Bristol-Myers Squibb</td>
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<td>10:10-10:40 a.m.</td>
<td>Anvisa’s Current Practice and Challenges in the Evaluation of Dissolution Profile Comparisons in Support of Minor/Moderate Product Quality Changes: Case Studies</td>
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<td>Victor Gomez Pereira, PhD</td>
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<td>Anvisa</td>
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<td>10:40-11:00 a.m.</td>
<td>Break</td>
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<td>11:00-11:30 a.m.</td>
<td>Health Canada’s Current Practice and Challenges in the Evaluation of Dissolution Profile Comparisons in Support of Minor/Moderate Product Quality Changes: Case Studies</td>
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<td>Susan Lum, PhD</td>
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<td>Health Canada</td>
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<td>11:30 a.m. - Noon</td>
<td>FDA’s Current Challenges in the Use of Dissolution Similarity Testing for Demonstration of BE: Case Studies</td>
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<td>Zhen Zhang, PhD</td>
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<td>U.S. Food and Drug Administration</td>
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<td>Noon - 12:30 p.m.</td>
<td>Dissolution Similarity Applications in Generic Industry – Issues and Challenges: Case Studies</td>
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<td>Emilija Fredro-Kumbaradzi, PhD</td>
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<td>12:30-12:45 p.m.</td>
<td>Introduction and Expectation of BO Sessions</td>
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<td>Andreas Abend, PhD</td>
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<td>Merck</td>
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<td>12:45-1:30 p.m.</td>
<td>Lunch</td>
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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