

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 Lori Pfahler, MS Merck

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), Lori Pfahler (Merck)

Scribes: Poonam Delvadia (FDA), Amy Barker (Lilly)



BO SESSION C: WHAT IS THE PROPER “INFERENCE SPACE” FOR SIMILARITY STUDIES? ADDRESSING THIS IS KEY TO EXPERIMENTAL DESIGN

Moderators: Meiyu Shen (FDA), Yanbing Zheng (AbbVie)

Scribes: Xin Bu (BMS), Ivelisse Colon-Rivera (Vertex)

BO SESSION D: WHAT ARE THE ADVANTAGES AND DISADVANTAGES OF CURRENTLY AVAILABLE “STATISTICAL” APPROACHES FOR DISSOLUTION?

Moderators: Yi Tsong (FDA), Kim E. Vukovinsky (Pfizer)

Scribes: Huizi “Amy” Zhang (GSK), James Reynolds (AbbVie), Karin Rosenblatt (AbbVie)

BREAK (MODERATORS AND SCRIBES TO CONVENE)

SUMMARY OF BREAKOUT SESSIONS

Lead Moderators

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 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: Evangelos Kotzagiorgis (EMA), Sandra Suarez (FDA)

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), Okpo Eradiri (FDA)

BO SESSION C: HOW TO DESIGN A ROBUST DISSOLUTION STATISTICAL APPROACH (DECISION TREE) – PART 1

Moderators: Yanbing Zheng (AbbVie), Yi Tsong (FDA), Xin Bu (BMS)

Scribes: Om Ananda (FDA), Ivelisse Colon-Rivera (Vertex)

BO SESSION D: HOW TO DESIGN A ROBUST DISSOLUTION STATISTICAL APPROACH (DECISION TREE) – PART 2

Moderators: Poonam Delvadia (FDA), David Lavrich (Merck), Huizi “Amy” Zhang (GSK)

Scribes: Dave LeBlond (CMCStats), Michael Cohen (Pfizer)

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