

4th Annual Science of Stability Conference Agenda



Day 1

Monday, October 22, 2018

7:00 AM - 8:00 AM

Breakfast

Conference Check-In and Badge Pick Up

Sunrise Session

Lexington-Concord Meeting Room

8:00 AM - 8:45 AM

Kenneth Waterman, Ph.D. – President, FreeThink Technologies, Inc.

“Introduction to the Accelerated Stability Assessment Program (ASAP)”

8:45 AM – 9:00 AM

Coffee Break

Session I

ASAP and Its Applications

9:00 AM - 9:10 AM

Session Chair - Dr. Kenneth Waterman

Opening Remarks & Invitation to FreeThink Open House

9:10 AM - 9:50 AM

Freneil Jariwala, Ph.D. – Senior Scientist, P&G Healthcare, R&D

“Feeling the Crunch: Accelerated Stability in the Land of OTC Drugs/Dietary Supplements”

9:50 AM - 10:30 AM

Dawen Kou, Ph.D. – Senior Scientist, Genentech

“Application of Accelerated Stability Assessment Programs to Facilitate Market Formulation Development of a Small Molecule Drug Product”

10:30 AM - 10:40 AM

Morning Break

10:40 AM - 11:20 AM

Sabine Thielges, Ph.D. – Principal Scientist, Novartis

“ASAP for Parenteral Formulation Development – Solution and Lyophilisate”

11:20 AM - 12:00 PM

Helen Williams, Ph.D. – Associate Principal Scientist, AstraZeneca

“Validating ASAP Predictions with ICH-Compliant Stability Data and Implementing GMP ASAP Studies”

12:00 PM - 1:25 PM

Lunch

Exhibitor Tables Open and Poster Viewing in the Winthrop Room

[more]

Session II

Accelerated Stability beyond ASAPprime®

1:25 PM - 1:35 PM

Session Chair – Dr. Helen Williams

Afternoon Remarks

1:35 PM - 2:15 PM

Donald Clancy – Modeling Lead - Modeling Center of Excellence, GlaxoSmithKline

“Improving the Accuracy of Accelerated Stability Modeling”

2:15 PM – 2:55 PM

Meng John Zhao, Ph.D. – Research Advisor, Eli Lilly

“Some Product Stability Findings When There is Little or No Degradation in Accelerated Stability Tests”

2:55 PM - 3:10 PM

Afternoon Break

3:10 PM - 3:50 PM

Garry Scrivens, Ph.D. – Senior Principal Scientist, Pfizer

“Prediction of the Long-Term Dissolution Performance of an Immediate-Release Tablet Using Accelerated Stability Studies”

3:50 PM - 4:30 PM

Kenneth Waterman, Ph.D. – President, FreeThink Technologies, Inc.

“ASAPprime® Version 6 Algorithm-Based Data Analysis”

4:30 PM - 6:30 PM

FreeThink Sponsored Networking Event, Poster Session, and Exhibitor Expo – Winthrop Room

Day 2

Tuesday, October 23, 2018

7:00 AM - 9:00 AM

Breakfast

Exhibitor Tables Open and Poster Viewing in the Winthrop Room

Session III

Accelerated Stability and Global Regulatory

9:00 AM - 9:10 AM

Session Chair – Dr. Darren Reid

Opening Remarks

9:10 AM - 9:50 AM

Megan McMahon, Ph.D. – Associate Director, Global Regulatory CMC, Pfizer

“IQ Update: Lean Stability Perspectives Across Industry and Current Regulatory Feedback”

9:50 AM - 10:30 AM

Fenghe Qiu, Ph.D. – Senior Research Fellow, Boehringer Ingelheim Pharmaceuticals, Inc.

“Regulatory Update: IQ Risk-Based Predictive Stability Regulatory Sub-Team”

10:30 AM - 10:45 AM

Morning Break

Session IV

Degradation Chemistry

10:45 AM - 11:25 AM

Steven Baertschi, Ph.D. – Baertschi Consulting, LLC

“The Remarkably Complex Degradation Chemistry of Drug X: Solving a Stubborn Mass Balance Problem”

[more]

11:25 AM - 12:05 PM Shane Eisenbeis, Ph.D. – Associate Research Fellow, Pfizer
“Passivation of Carbohydrate-Containing Excipients via an Innovative Formulation Strategy: Proof of Concept”

12:05 PM - 1:25 PM **Lunch**
Exhibitor Tables Open and Poster Viewing in the Winthrop Meeting Room

1:25 PM - 1:35 PM Session Chair – Dr. Steven Baertschi
Afternoon Remarks

1:35 PM - 2:15 PM Kausik K. Nanda, Ph.D. – Associate Principal Scientist, Merck Research Laboratories
“Transition Metal Catalyzed Chemistry in Solid Oral Dosages”

2:15 PM – 2:55 PM Manvi Hasija – Scientist, Sanofi Pasteur
“Forced Degradation Studies: An Essential Tool for the Formulation Development of Vaccines”

2:55 PM - 3:10 PM **Afternoon Break**

3:10 PM - 3:50 PM Rachel Hemingway, Ph.D. – Senior Scientist, Lhasa Limited
“Zeneth Knowledge-Based System for the Prediction of Forced Degradation of Organic Compounds”

Session V

Stability Indicating Method Development

3:50 PM - 4:30 PM Michael Dong, Ph.D. – Principal Consultant, MWD Consulting
“Developing Stability Indicating Methods: Case Studies”

4:30 PM - 5:10 PM Christopher Riley, Ph.D. – President, Riley and Rabel Consulting
“Complex Solid-State Study: Challenging Analytical Case Study – An Analytical Quality by Design (AQbD) Approach”

5:10 PM – 5:50 PM Marc Caporini, Ph.D. – Scientist, Amgen
“Predicting Stability of Lyophilized Formulations from Molecular Mobility Measurements in Solid”

5:50 PM – 6:00 PM Dr. Kenneth Waterman
Closing Remarks