

FREE PRE-CONFERENCE WORKSHOP: ASAP 101 USE AND IMPLEMENTATION  
MONDAY, OCTOBER 12, 2015

7:00 PM – 7:30 PM      ASAPprime® Review

Ken Waterman, FreeThink Technologies, Inc. Groton, CT USA

7:30 PM – 9:00 PM      Implementation of ASAP Workflows:

Application of ASAP in Early API and Formulation Development

Fenghe Qiu, Boehringer Ingelheim, Ridgefield, CT, USA

Drug Product Development

Sabine Thielges, Janssen Pharmaceuticals (J&J), Beerse, Belgium

Applications of Accelerated Stability Assessment Program (ASAP) in  
Pharmaceutical Development

Llurellyn Malcolm, Pfizer, Pearl River, New York, USA

Panel Discussion: Q&A

Ken Waterman, Fenghe Qiu, Sabine Thielges, Llurellyn Malcolm

SESSION I: FORCED DEGRADATION AND METHOD DEVELOPMENT  
TUESDAY, OCTOBER 13, 2015

- 8:00 AM – 9:00 AM      Registration and Breakfast  
Paragon, 24th Floor, Grand Pequot Tower
- 9:00 AM – 9:05 AM      Opening Remarks  
Ken Waterman, FreeThink Technologies, Inc., Groton, CT, USA
- 9:05 AM – 9:10 AM      Session Introduction  
Session Chair, Sabine Thielges, Janssen Pharmaceuticals (J&J), Beerse, Belgium
- 9:10 AM – 9:50 AM      *In Silico* Modeling of Degradation Chemistry  
Steve Baertschi, Baertschi Consulting, Indianapolis, IN, USA
- 9:50 AM – 11:00 AM      Developing Stability:  
Forced Degradation of Pharmaceuticals: What? Why? How?  
Tom Sharp, FreeThink Technologies, Inc., Groton, CT
- A Systematic Approach to Developing Stability Indicating Assay Methods  
Jennifer Lewis, FreeThink Technologies, Inc., Groton, CT, USA
- 11:00 AM – 11:15 AM      Break
- 11:15 AM – 11:55 AM      Stress Testing Degradation Pathways: Case Studies  
Peter Persich, Janssen Pharmaceuticals (J&J), Beerse, Belgium

SESSION II: THE SCIENCE OF ACCELERATION

TUESDAY, OCTOBER 13, 2015

- 11:55 AM – 12:55 PM    Lunch  
Paragon, 24th Floor, Grand Pequot Tower
- 12:55 PM – 1:35 PM    Oxidative Susceptibility Testing  
Steve Baertschi, Baertschi Consulting, Indianapolis, IN, USA
- 1:35PM – 2:15 PM      Modeling of Degradation Chemistry at AstraZeneca  
Anders Broo, Astra Zeneca, Sweden
- 2:15 PM – 2:55 PM    ASAP Fundamentals  
Garry Scrivens, Pfizer, Sandwich, UK
- 2:55 PM – 3:15 PM    Break and Refreshments  
Paragon, 24th Floor, Grand Pequot Tower
- 3:15 PM – 3:55 PM    Temperature and Humidity Impact and the Interactions Involved in Solids; Why ASAP does not add Extra Cross-Terms  
Ken Waterman, FreeThink Technologies, Inc., Groton, CT, USA
- 3:55 PM – 4:15 PM    Panel Discussion and Closing Remarks, Day 1  
Steve Baertschi, Tom Sharp, Jennifer Lewis, Peter Persich, Anders Broo, Garry Scrivens, Ken Waterman
- 4:15 PM – 5:30 PM    Wine and Cheese Social  
Paragon, 24th Floor, Grand Pequot Tower

SESSION II: THE SCIENCE OF ACCELERATION, CONTINUED

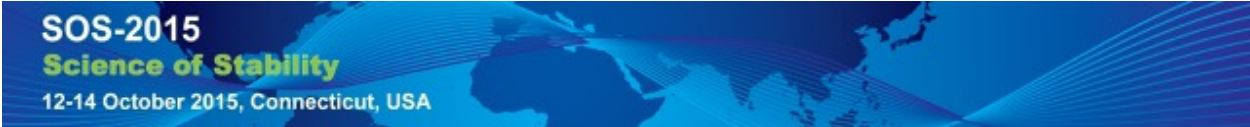
WEDNESDAY, OCTOBER 14, 2015

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| 8:00 AM – 9:00 AM | Registration and Breakfast<br>Paragon, 24th Floor, Grand Pequot Tower  |
| 9:00 AM – 9:05 AM | Opening Remarks<br>Steve Baertschi<br>Baertschi Consulting, Indianapolis, IN, USA  |
| 9:05 AM – 9:10 AM | Session Introduction<br>Session Chair, Steve Baertschi, Baertschi Consulting, Indianapolis, IN, USA  |
| 9:10 AM – 9:50 AM | ASAP Assumptions and the Impact on Predictions: Case Study on Controlling Mutagenic Degradation<br>Brian Pack, Eli Lilly and Company, Indianapolis, IN |

SESSION III: LEARNING FROM EXAMPLES

WEDNESDAY, OCTOBER 14, 2015

- 9:50 AM – 10:30 AM    Excipient Compatibility as Predicted by ASAP: A Case Study  
Jerusha Thompson, Upsher-Smith, Maple Grove, Minnesota
- 10:30 AM – 10:45 AM    Break
- 10:45 AM – 11:25 AM    Predicting Degradation Rate as a Function of Drug Load in Solid-State Drug Products  
Allison Dill, Lilly, Indianapolis, IN, USA
- 11:25 AM – 12:05 PM    Use of ASAP in Formulation Development: Case Studies  
Sabine Thielges, Janssen Pharmaceuticals (J&J), Beerse, Belgium
- 12:05 PM – 1:05 PM    Lunch  
Paragon, 24th Floor, Grand Pequot Tower
- 1:05 PM – 1:45 PM    Interesting Degradation Chemistry  
Patrick Jansen, Eli Lilly and Company, Indianapolis, IN, USA



SOS-2015

Science of Stability

12-14 October 2015, Connecticut, USA

SESSION IV: LET'S GET PHYSICAL

WEDNESDAY, OCTOBER 14, 2015

- 1:45 PM – 2:25 PM      Creating Tomorrow's Packaging Today: Technology and Collaboration-Based Approaches to Optimize Pharmaceutical Package Design  
Carlos Daniel Stagnaro & Steven Warakomski, Klöckner Pentaplast, Charlottesville, VA, USA
- 2:25 PM – 2:45 PM      Break and Refreshments  
Paragon, 24th Floor, Grand Pequot Tower
- 2:45 PM – 3:25 PM      Recent Advances in Functional Coatings for Immediate Release Dosage Forms  
Jason Teckoe, Colorcon, Harleysville, PA, USA
- 3:25 PM – 4:05 PM      Accelerated Stability for Proteins: A Peptide Case Study  
Ken Waterman, FreeThink Technologies, Inc., Groton, CT, USA
- 4:05 PM – 4:45 PM      Full System Moisture Management for Drug Preservation  
Valere Logel, Clariant, Belen, NM
- 4:45 PM – 5:00 PM      Panel Discussion and Closing Remarks, Day 2  
Brian Pack, Jerusha Thompson, Allison Dill, Sabine Thielges, Patrick Jansen, Daniel Stagnaro, Steven Warakomski, Jason Teckoe, Ken Waterman, Valere Logel