Land O’ Lakes 62nd Annual Pharmaceutical Analysis Conference

Monday, August 1, 2022

6:30 PM – 8:00 PM  Opening Plenary and Reception
Oros Executive Dining Room

6:45 PM – 7:00 PM  Introduction and Welcome
Tina Morris, Ph.D., AAPS

7:00 PM – 7:45 PM  Global Impact of Business Challenges of Scientific Research in a Pandemic: Lessons Learned for the Future
Shane Needham, Ph.D., Veloxity Labs

Tuesday, August 2, 2022

9:00 AM – 12:30 PM  Morning Plenary: New Technologies & Techniques: Supporting Accelerated/Efficient Development

9:00 AM – 9:05 AM  Introduction and Welcome
Stefanie Rentfrow, Perrigo
2022 Scientific Programming Committee Chair

9:05 AM – 9:40 AM  Future of Managing and Using Data
Toni Manzano, Ph.D.

9:40 AM – 9:50 AM  Discussion Session

9:50 AM – 10:25 AM  Digital CMC Knowledge and Lifecycle Management Using FAIR Data Frameworks
Yash Sabharwal, Ph.D., QbDVision

10:25 AM – 10:35 AM  Discussion Session

10:35 AM – 10:55 AM  Morning Break

10:55 AM – 11:30 AM  Predicting Pharmaceutical Product Performance through Modeling, Machine Learning and Statistics
Timothy Rhodes, Ph.D., Merck

Updated 7/28/2022
<table>
<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>11:30 AM – 11:45 AM</td>
<td>Discussion Session</td>
</tr>
<tr>
<td>11:45 AM – 12:15 PM</td>
<td><strong>Application of Risk-based Predictive Stability in Drug Product Development</strong></td>
</tr>
<tr>
<td></td>
<td>Timothy Schuchardt, Ph.D., Perrigo</td>
</tr>
<tr>
<td>12:15 PM – 12:25 PM</td>
<td>Discussion Session</td>
</tr>
<tr>
<td>12:25 PM – 12:30 PM</td>
<td><strong>Closing Remarks</strong></td>
</tr>
<tr>
<td></td>
<td>Stefanie Rentfrow, Perrigo</td>
</tr>
<tr>
<td><strong>12:30 PM – 1:30 PM</strong></td>
<td>Lunch</td>
</tr>
<tr>
<td><strong>1:30 PM – 3:00 PM</strong></td>
<td><strong>Afternoon Plenary: Global Impact of Business Challenges of Scientific Research in a Pandemic: Lessons Learned for the Future</strong></td>
</tr>
<tr>
<td>1:30 PM – 1:35 PM</td>
<td><strong>Introduction and Welcome</strong></td>
</tr>
<tr>
<td></td>
<td>Shane Needham, Ph.D., Veloxity Labs</td>
</tr>
<tr>
<td>1:35 PM – 1:55 PM</td>
<td><strong>Current Environment for Human Capital and Workforce Trends by Region</strong></td>
</tr>
<tr>
<td></td>
<td>Jason Neat, Ph.D., Eurofins</td>
</tr>
<tr>
<td>1:55 PM – 2:15 PM</td>
<td><strong>Lessons Learned About Supply Chain Constraints During COVID and Future Considerations</strong></td>
</tr>
<tr>
<td></td>
<td>Chuck York, Ph.D., Promega</td>
</tr>
<tr>
<td>2:15 PM – 2:35 PM</td>
<td><strong>Professional Development Options in the Future</strong></td>
</tr>
<tr>
<td></td>
<td>Tina Morris, Ph.D., AAPS</td>
</tr>
<tr>
<td>2:35 PM – 3:00 PM</td>
<td>Panel Discussion</td>
</tr>
<tr>
<td><strong>3:00 PM – 3:30 PM</strong></td>
<td><strong>Afternoon Break</strong></td>
</tr>
<tr>
<td><strong>3:30 PM – 4:30 PM</strong></td>
<td><strong>Rapid Fire Session 1</strong></td>
</tr>
<tr>
<td>3:30 PM – 3:45 PM</td>
<td><strong>Development of Automated Solid State Screening Workflows and Analytics to Support Efficient Developability Assessment in Preclinical Development</strong></td>
</tr>
<tr>
<td></td>
<td>Christopher Stewart, MS, Abbvie</td>
</tr>
</tbody>
</table>
3:45 PM – 4:00 PM  
**Efficiency Gains Through Moisture Specific Analysis**  
Trivikram Rawat, Ph.D., Perrigo

4:00 PM – 4:15 PM  
**Pharmaceutical Applications of Inverse Gas Chromatography for the Evaluation of Surface Properties**  
Minhthi Bui, M.Sc., Genentech

4:15 PM – 4:30 PM  
**Remote Regulatory Assessment by FDA Office of Study Integrity and Surveillance**  
Tahseen Mirza, Ph.D., FDA

6:00 PM – 8:00 PM  
**Evening Reception**  
Location: The Rigby Pub  
119 E Main St, Madison, WI 53703  
Sponsored by Cambrex

**Wednesday, August 3, 2022**

9:00 AM – 12:30 PM  
**New Therapeutic Modalities and Techniques**

9:00 AM – 9:05 AM  
**Introduction and Welcome**  
Fumin Li, PPD Laboratories

9:05 AM – 9:40 AM  
**Formulation, Characterization and Impact of Long-acting Implants and Injectables**  
Adrian Goodey, Ph.D., Merck

9:40 AM – 9:50 AM  
Discussion Session

9:50 AM – 10:25 AM  
**Lipid Nanoparticle Platform Formulation Development: From Feasibility to Scalability**  
Karthik Nagapudi, Ph.D., Genentech

10:25 AM – 10:35 AM  
Discussion Session

10:35 AM – 10:55 AM  
**Morning Break**

10:55 AM – 11:30 AM  
**Emerging Technologies with 3D Printing: Product and Process Understanding**  
Mansoor Khan, Ph.D., RPH, Texas A&M University

11:30 AM – 11:45 AM  
Discussion Session

11:45 AM – 12:15 PM  
**The Future Is Now: mRNA Analytics for the COVID-19 Vaccine**  
David Ripley, Ph.D., Pfizer

12:15 PM – 12:25 PM  
Discussion Session
12:25 PM – 12:30 PM  Closing Remarks  
Fumin Li, PPD Laboratories

12:30 PM – 1:30 PM  Lunch

1:30 PM – 3:00 PM  Afternoon Plenary: Control Strategies

1:30 PM – 1:35 PM  Introduction and Welcome  
Sachin Lohani, Ph.D., Merck

1:35 PM – 2:05 PM  Challenges with Attempts to Implement Globally Accepted Specifications  
Julie Adamson, Ph.D., Takeda

2:05 PM – 2:15 PM  Discussion Session

2:15 PM – 2:45 PM  Control Strategies for a Continuously Manufactured Drug Product  
David Wilsdon, Ph.D., Pfizer

2:45 PM – 2:55 PM  Discussion Session

2:55 PM – 3:00 PM  Closing Remarks  
Sachin Lohani, Ph.D., Merck

3:00 PM – 3:30 PM  Afternoon Break

3:30 PM – 4:15 PM  Rapid Fire Session 2

3:30 PM – 3:45 PM  Techniques and Considerations for Trace Analysis of N-nitrosamine Impurities in Complex Pharmaceutical Matrices  
Zachary Vanderpool, BS, Perrigo

3:45 PM – 4:00 PM  Evaluating and Controlling Crystallization Risk in Immediate-release Tablets Containing Amorphous API Dispersion  
Nathan Contrella, Ph.D., Merck & Co., Inc.

4:00 PM – 4:15 PM  Do Macrocyclic Peptide Drugs Interact with Biorelevant Colloids in the Gastrointestinal Environment?  
Tahnee Dening, Ph.D., Genetech
### Thursday, August 4, 2022

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>8:00 AM – 10:30 AM</strong></td>
<td><strong>Morning Plenary: Timely Regulatory Topics</strong></td>
</tr>
<tr>
<td>8:00 AM – 8:05 AM</td>
<td><strong>Introduction and Welcome</strong> Timothy Graul, Ph.D., Pfizer</td>
</tr>
<tr>
<td>8:05 AM – 8:40 AM</td>
<td><strong>Revised and New Guidance Under Consultation - Q2 (Validation of Analytical Procedures) / Q14 (Analytical Procedure Development)</strong> Mary Beth Pelletier, Ph.D., BioGen</td>
</tr>
<tr>
<td>8:40 AM – 8:50 AM</td>
<td>Discussion Session</td>
</tr>
<tr>
<td>8:50 AM – 9:25 AM</td>
<td><strong>New Guidance Under Consultation- Q13 (Continuous Manufacturing of Drug Substances and Drug Products)</strong> Mohan Ganapthy, Ph.D., Merck</td>
</tr>
<tr>
<td>9:25 AM – 9:35 AM</td>
<td>Discussion Session</td>
</tr>
<tr>
<td>10:10 AM – 10:20 AM</td>
<td>Discussion Session</td>
</tr>
<tr>
<td>10:20 AM – 10:30 AM</td>
<td><strong>Closing Remarks</strong> Timothy Graul, Ph.D., Pfizer 2023 Scientific Programming Committee Chair</td>
</tr>
</tbody>
</table>