Virtual Agenda (Draft)  
(as of September 18, 2020)

DAY ONE: Tuesday, September 22, 2020

9:00 – 9:05 a.m. Day One Welcome

9:05 – 9:45 a.m. The Application of Osmolality to Drug Administration  
Marc Stranz, Pharm.D., Chief Clinical Officer, BioMatrix SpRx

9:45 – 9:55 a.m. Discussion and Q&A with Marc Stranz

9:55 – 10:00 a.m. Break

10:00 – 10:40 a.m. Considerations for Formulation Development to Improve Patient Experience  
Ashish Garg, Ph.D., Senior Consultant Engineer, Eli Lilly and Company

10:40 – 10:50 a.m. Discussion and Q&A with Ashish Garg

10:50 – 10:55 a.m. Break

10:55 – 11:35 a.m. Osmolality, Osmolarity and Tonicity – Understanding the Measurements  
Kristeena Wright, Ph.D., Application Scientist, Advanced Instruments, LLC

11:35 – 11:45 a.m. Discussion and Q&A with Kristeena Wright

11:45 a.m. – 12:45 p.m. Lunch Break

12:45 – 1:25 p.m. Vapor Pressure Osmometers: Comparison Between Models, Calibration Challenges, Quantitation Limits and Robustness  
Wen-Li Chung, M.S., QC Scientist/Validation Manager, Genentech

1:25 – 1:35 p.m. Discussion and Q&A with Wen-Li Chung

1:35 – 1:40 p.m. Break

1:40 – 2:20 p.m. Freezing Point Based versus Vapor Pressure Based Osmometers on High Concentration Protein Formulations: Instrument Selection Matters  
Erinc Sahin, Ph.D., Principal Scientist, Drug Product Science & Technology, Bristol-Myers Squibb
USP Virtual Workshop
Osmolarity/Osmolality and Tonicity as Critical Quality Parameters
September 22–23, 2020

2:20 – 2:30 p.m. Discussion and Q&A with Erinc Sahin
2:30 – 2:35 p.m. Break
2:35 – 3:15 p.m. Impact of Test Volume/Osmometer Models on Accuracy and Robustness for the Analysis of Biotherapeutics – Method Selection and Suitability Verification
Ann Wajs, Ph.D., Pharmaceutical Development Scientist, Genentech
Wen-Li Chung, M.S., QC Scientist/Validation Manager, Genentech
3:20 – 3:30 p.m. Discussion and Q&A with Wen-Li Chung
3:30 p.m. Day One Concludes

DAY TWO: Wednesday, September 23, 2020

9:00 – 9:05 a.m. Day Two Welcome
9:05 – 9:45 a.m. Osmolality as Important Component of a Multi-Attribute Continuous Product Characterisation Platform for Increased Process Control Monitoring
Noemi Dorival-Garcia, Ph.D., Research Fellow, National Institute for Bioprocessing Research and Training, Ireland
9:45 – 9:55 a.m. Discussion and Q&A with Noemi Dorival-Garcia
9:55 – 10:00 a.m. Break
10:00 – 10:40 a.m. Osmolarity Measurements in Highly Potent Drug Products
Meg Brunell, M.S., Senior Scientist, Merck
10:40 – 10:50 a.m. Discussion and Q&A with Elizabeth Pierson
10:50 – 10:55 a.m. Break
10:55 – 11:35 a.m. Osmolality – Considerations for Parenteral Biotech Drug Products
Dieter Roethlisberger, Ph.D., Head DP Technical Project Leaders, Lonza AG, Switzerland
11:35 – 11:45 a.m. Discussion and Q&A with Dieter Roethlisberger
11:45 a.m. – 12:45 p.m. Lunch Break
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<th>Time</th>
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<tr>
<td>12:45 – 1:25 p.m.</td>
<td>Osmolarity &amp; Tonicity – Considerations for Topical Ophthalmic Products</td>
<td>Chetan Pujara, Ph.D., Vice President, Pharmaceutical Sciences, Abbvie</td>
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<td>1:25 – 1:35 p.m.</td>
<td>Discussion and Q&amp;A with Chetan Pujara</td>
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<td>1:35 – 1:40 p.m.</td>
<td>Break</td>
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<td>1:40 – 2:20 p.m.</td>
<td>Osmolality and the new USP &lt;922&gt; Water Activity General Chapter</td>
<td>Michael Lally, Application &amp; Validation Specialist, Lighthouse Instruments</td>
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<td>2:20 – 2:30 p.m.</td>
<td>Discussion and Q&amp;A with Michael Lally</td>
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<td>2:30 – 2:35 p.m.</td>
<td>Break</td>
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<td>2:35 – 3:15 p.m.</td>
<td>Multi-attribute Raman Spectroscopy (MARS) as a New Technology for Osmolality Measurement</td>
<td>Bingchuan Wei, Ph.D., Genentech Research Early Development Scientist, Genentech</td>
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<td>3:15 – 3:25 p.m.</td>
<td>Discussion and Q&amp;A with Bingchuan Wei</td>
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<td>3:25 p.m.</td>
<td>Workshop Concludes</td>
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