

USP Virtual Workshop

Osmolarity/Osmolality and Tonicity as Critical Quality Parameters

September 22–23, 2020



Virtual Agenda (Draft)

(as of September 18, 2020)

All times are in Eastern Daylight Time (EDT) – Washington, DC time zone

DAY ONE: Tuesday, September 22, 2020

9:00 – 9:05 a.m. EDT	Day One Welcome
9:05 – 9:45 a.m.	The Application of Osmolality to Drug Administration Marc Stranz, Pharm.D., <i>Chief Clinical Officer, BioMatrix SpRx</i>
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., <i>Senior Consultant Engineer, Eli Lilly and Company</i>
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., <i>Application Scientist, Advanced Instruments, LLC</i>
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., <i>QC Scientist/Validation Manager, Genentech</i>
1:25 – 1:35 p.m.	Discussion and Q&A with Wen-Li Chung
1:35 – 1:40 p.m.	Break

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- 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*
- 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 Woys, 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 Meg Brunell**
- 10:50 – 10:55 a.m.** **Break**

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- 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**
- 12:45 – 1:25 p.m.** **Osmolarity & Tonicity – Considerations for Topical Ophthalmic Products**
Chetan Pujara, Ph.D., *Vice President, Pharmaceutical Sciences, Abbvie*
- 1:25 – 1:35 p.m.** **Discussion and Q&A with Chetan Pujara**
- 1:35 – 1:40 p.m.** **Break**
- 1:40 – 2:20 p.m.** **Osmolality and the new USP <922> Water Activity General Chapter**
Michael Lally, *Application & Validation Specialist, Lighthouse Instruments*
- 2:20 – 2:30 p.m.** **Discussion and Q&A with Michael Lally**
- 2:30 – 2:35 p.m.** **Break**
- 2:35 – 3:15 p.m.** **Multi-attribute Raman Spectroscopy (MARS) as a New Technology for Osmolality Measurement**
Bingchuan Wei, Ph.D., *Genentech Research Early Development Scientist, Genentech*
- 3:15 – 3:25 p.m.** **Discussion and Q&A with Bingchuan Wei**
- 3:25 p.m.** **Workshop Concludes**