

Manufacturing Alcohol to Combat a Public Health Emergency:

Insights on Regulatory and Quality Requirements



Final Agenda

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

DAY ONE: Wednesday, January 27, 2021

Regulatory and Compendial information for manufacturing pharmaceutical grade alcohol

Event Facilitator: Robert Shimahara, Director, Strategy Customer Development-Americas | USP

- 9:00 a.m. – 9:05 a.m. **Welcome**
Speaker: Jacqueline D. Starkes, Senior Stakeholder Affairs Coordinator | USP
- 9:05 a.m. – 9:15 a.m. **Opening Remarks**
Speaker: Jennifer Devine, SVP, Documentary Standards & Compendial Policy | USP
- 9:15 a.m. – 9:20 a.m. **Goals and Objectives**
Speaker: Danita Broyles, Senior Market Development Manager | USP
- 9:20 a.m. – 9:40 a.m. **Antiseptic Hand Rubs in the COVID-19 Pandemic**
Speaker: Theresa M. Michele, Director, Office of Nonprescription Drugs | U.S. FDA
- 9:40 a.m. – 10:25 a.m. **Alcohol Requirements for Hand Sanitizer Production**
Speaker: Francis Godwin, MBA, Office Director, Office of Manufacturing Quality | U.S. FDA
- 10:25 a.m. – 10:45 a.m. **General Overview of USP**
Speaker: Robert Shimahara, Director, Strategy Customer Development-Americas | USP
- 10:45 a.m. – 11:00 a.m. **Break**
- Alcohol Industry Needs*
- 11:00 a.m. – 11:20 a.m. **Alcohol Distributor Perspectives**
Speaker: Conner Curran, CEO, Managing Director | Dexterous DMCC
- 11:20 a.m. – 11:40 a.m. **Fuel Ethanol Industry Perspectives**
Speaker: Kristin Moore, Principal Scientist | KMoore Consulting LLC

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11:40 a.m. – 12:50 p.m. **Open Floor – Question & Answer with the Panel**

Panelists:

- Conner Curran | Dexterous DMCC
- Francis Godwin | U.S. FDA
- Robert Lafaver | USP
- Theresa Michelle | U.S. FDA
- Kristin Moore | KMoore Consulting LLC
- Andy Powers | Newton Enterprises
- Robert Shimahara | USP

Panel Discussion Facilitator: Danita Broyles & Andy Powers

12:50 p.m. – 1:00 p.m. **Day One Summary and Closing Remarks**
Discussion Facilitator: Danita Broyles | USP

DAY TWO: Thursday, January 28, 2021

USP solutions and services to assist all who manufacture/use alcohol in the drug product supply chain

Facilitator: Peter Claise, Director, Product Management | USP

9:00 a.m. – 9:05 a.m. **Welcome**
Speaker: Jacqueline D. Starkes, Senior Stakeholder Affairs Coordinator | USP

9:05 a.m. – 9:15 a.m. **Welcome and Opening Remarks**
Speaker: Ronald T. Piervincenzi, Ph.D., Chief Executive Officer | USP

9:15 a.m. – 9:25 a.m. **Overview of Day One**
Speaker: Peter R. Claise, Director, Product Management | USP

9:25 a.m. – 9:55 a.m. **USP Alcohol Monograph/Reference Standards**
Speakers: Robert H. Lafaver, Technical Services Manager | USP

9:55 a.m. – 10:25 a.m. **FCC Alcohol Monograph/Reference Standards**
Speakers: Steve Gendel, Senior Director, Science - Foods | USP

10:25 a.m. – 10:35 a.m. **Break**

USP Open Forum | January 27 & 28, 2021

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10:35 a.m. – 11:20 a.m.

USP Ingredient Verification Program

Speaker: Danita Broyles, Senior Market Development Manager | USP

11:20 a.m. – 12:20 p.m.

Open Floor – Question & Answer with the Panel

Panelists:

- Andy Powers | Newton Enterprises
- Robert Shimahara | USP
- Steve Andruski | USP
- Danita Broyles | USP
- Robert H. Lafaver | USP
- Steve Gendel | USP

Discussion Facilitator: Peter R. Claise, Director, Product Management | USP

12:20 p.m. – 12:35 p.m.

Next Steps and Closing Remarks

Speaker: Danita Broyles, Senior Market Development Manager | USP