

Workshop on Microbiological Quality Level (MQL)

hosted by ASTM E55 and the Kilmer Collaboration Teams

May 7th, 2024

ASTM Committee Week - Philadelphia, PA

TUESDAY - MAY 7th, 2024

8:30 - 8:50	Defining MQL	Welcome and Introductions	John Logar
8:50 - 9:15		Microbiological Quality - What is is and why we need it	John Logar / Steve Langille
9:15 - 9:30		ANSI Aseptic Processing Standard - Overview	Amanda McFarland
9:30 - 9:45		ASTM WK89812 - Guide for Establishment of a Microbiological Quality Level for Pharmaceutical and Biopharmaceutical Products and Processes	John Logar
BREAK			
10:15 - 10:35	Application of a MQL	MQL in Lieu of Sterility Testing: Leveraging experience from NASA	John Logar
10:35 - 10:55		Case Study: Establishing a MQL for a Process	TBD
10:55 - 11:15		Case Study: Establishing a MQL for a Process	TBD

11:15 - 11:30		MQL: Refining the Definition and Scope		Group
LUNCH				
1:30 - 1:45	Defining Critical Attributes	Establishing a MQL: Defining and Measuring Critical Attributes		John Logar
1:45 - 2:45		Break Out Session A: Product	Break Out Session B: Process/Equipment	Group
BREAK				
3:15 - 4:00	Measuring Critical Attributes	Break Out Session A: Product	Break Out Session B: Process/Equipment	Group
4:00 - 4:15	Report Out	Product Attributes Report Out		Session A Lead
4:15 - 4:30		Process / Equipment Report Out		Session B Lead
4:30 - 5:00	Workshop Close Out - Task Group Formation and Next Steps			John Logar
GROUP DINNER (For Those Interested)				