

USP/IQ Consortium Roundtable: Subvisible Silicone Oil Droplets on Particle Analysis

Monday, October 7th, 2024, 8:00 am – 4:00 pm (Eastern Times, USA)

USP Headquarters, Rockville, MD

Moderators: Marszal, Ewa Ewa.Marszal@fda.hhs.gov and Linda Narhi lindaonarhi@gmail.com

8:00 a.m. – 10:00 a.m. Session I: Welcome, Introduction, USP, Immunogenicity & Regulatory	
8:10am – 8:40am	Introduction / Agenda: Desmond Hunt - DGH@usp.org
8:40am – 9:10 am	Silicon Oil Immunogenicity: Miguel Saggu - saggu.miguel@gene.com
9:10am – 9:40am	Silicon Oil Analytics: Ashwinkumar Bhirder - ashwinkumar.bhirde@fda.hhs.gov
9:40am – 10:00am	Q&A Panel I - Stan Kwok / Linda Narhi - Stanley.kwok1@astrazeneca.com lindaonarhi@gmail.com
10:00 a.m. – 10:15 a.m. Break (15min)	
10:15 a.m. – 11:45 a.m. Session II: Focus on Toxicology and Development Challenges	
10:15am – 10:45am	Toxicology – Monica Pombo - MPombo@its.jnj.com
10:45am – 11:15am	Challenges with SubVisible Particles for PFS products – Bin Zhang - Shalini.Minocha@alexion.com
11:15am – 11:45am	Q&A Panel II - Stan Kwok / Linda Narhi - Stanley.kwok1@astrazeneca.com lindaonarhi@gmail.com
11:45am – 1:00 p.m. Lunch	
1:00 p.m. – 2:30 p.m. Session III: Potential Breakouts: 1) Impact on Quality; 2) Clinical Implications; 3) Current State of Knowledge and Gaps; 4) Analytical	
2:30 p.m. – 2:45 p.m. Break and Social	
2:45 p.m. – 4:00 p.m. Session IV: Gathering for Next Steps: Finalizing Proceedings of Breakouts & Path Forward	