7/14/2021

Partners in Quality Excellence

A Virtual GMP Workshop

July 20-21, 2021 | 12:45 p.m. - 4:00 p.m. Eastern Time

Tuesday, July 20	
12:45 p.m.	Welcome and Opening Remarks
1:00 p.m.	FDA Update, Diana Amador-Toro, FDA New Jersey District Director and ORA OPQO Pharma Division I Director
1:30 p.m.	Concurrent Breakout Session
2:30 p.m.	Concurrent Breakout Session
3:30 p.m.	Key Takeaways
4:00 p.m.	Meeting Close
Wednesday, July 21	
12:45 p.m.	Welcome and Opening Remarks
1:00 p.m.	Concurrent Breakout Session
2:00 p.m.	Concurrent Breakout Session
3:00 p.m.	Key Takeaways
3:30 p.m.	Discussion
4:00 p.m.	Meeting Close

Breakout Session Topics and Team Leaders*

1. **Record Requests/Remote Audits/New FDA Guidance (4003)**
   Stephen Mottola, FDA
   Steve Greer, GMP Consultant and Business Leader, ESi
   Kristina Parkanzky, Amway, Chief Compliance Officer - Quality Assurance

2. **Inspections/Data Integrity**
   Sena Dissmeyer, FDA, Consumer Safety Officer, Division I
   Tim Parrent, Mary Kay, Senior Manager Corporate Quality
   Nelson Webb, P&G, Director - Quality Assurance, External Engagement

3. **Investigations**
   Doug Kovacs, FDA
   Tim King, Henkel, Quality Manager Manufacturing and Supplier Quality
   Debi Chinsky, Colgate-Palmolive, Associate Director Global Quality

4. **Quality in the Supply Chain (including impurities, nitrosamines, methanol, etc.)**
   Barbara Wilimczyk-Macri, FDA
   Cathleen Owen, Q Laboratories, Director, Pharmaceutical and Personal Care Services
   Joe Pasapane, Seppic, Director Regulatory, Quality and External Affairs

*Participants will be placed in groups and rotate through each concurrent session. All participants attend each topic.