**Partners in Quality Excellence**  
A PCPC GMP Workshop

April 23, 2020  
The Westin Galleria Dallas  
13340 Dallas Pkwy  
Dallas, TX

7:30 - 8:30  **CONTINENTAL BREAKFAST**

**MORNING SESSION:**

8:30 – 8:45  Welcome and Opening Comments  
8:45 – 9:30  FDA Update, Ms. Monica Maxwell, Director, Division of Pharmaceutical Quality Operations II, Dallas District  
9:30 – 9:45  Break/Transition  
9:45 – 10:45  Concurrent Breakout Session 1  
10:45 – 11:00  Break/Transition  
11:00 – 12:00  Concurrent Breakout Session 2

12:00 – 1:00  **LUNCH**

**AFTERNOON SESSION:**

1:00 – 2:00  Concurrent Breakout Session 3  
2:00 – 2:15  Break/Transition  
2:15 – 3:15  Concurrent Breakout Session 4  
3:15 – 3:30  Break/Transition  
3:30 – 4:00  Breakout Session Key Takeaways  
4:00 – 4:45  Industry – Regulatory Discussion Panel  
4:45 – 5:00  Personal Takeaways and Closing

5:00 – 6:00  **NETWORKING MIXER**

**Breakout Session Topics**

1. OOS and Complaint Investigations  
2. Validation and Process Capability  
3. Quality Control Unit - Quality Maturity and Supply Chain Governance  
4. Inspections and Data Integrity