



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**