



# Training Course Agenda

PDA 515 The Impact of CGMPs on Biomanufacturing Facility Design and Operation

## DAY 1

**8:30**      **Welcome and Introductions**

9:00      The Product-Process-Facility relationship

**10:30**      **Break**

10:45      The Regulatory Attributes Driving Facility Design

- Process Definition, CQAs, CPPs
- Risk Management
- Contamination Control Strategy

11:15      Operational Impact

- Open vs. Closed Operations
- Process Closure
- Segregation Strategy

**12:00**      **Lunch**

13:00      GMP Layout Approaches

- The Impact of Closure
- Flows
- Area Classifications
- Transitions
- Air Lock Strategy
- Containment

**14:30**      **Break**

14:45      Manufacturing Support

- HVAC for Biological
- HVAC as a Component of CCS
- Waste Management
- Cold Chain Management

**16:00**      **End of Training Course**