



Agenda

Elements of GxP Training and Personnel Qualification Program Essentials Workshop
(PDA 201)

DAY 1

8:30 Welcome and Introductions

- 9:00 An Overview of Quality Systems
- How does Training fit in with other Quality Systems?

- 9:30 Training and Personnel Requirements from a Regulatory Perspective
- What do the regulations say about Training and Personnel Qualification?

10:30 Break

- 10:45 Translating Requirements to Program Elements
- Roles and Responsibilities
 - Onboarding
 - Identifying Training Needs
 - Building a Training Matrix

12:00 Lunch

- 13:00 Translating Requirements to Program Elements (cont.)
- Creating and Individual Training Plan
 - Delivery of Training
 - Training Documentation
 - Evaluating Training Effectiveness
 - Monitoring and Reporting

14:30 Break

- 15:00 Gauging Maturity and Implementing Accordingly
- How to identify phases of maturity and build a roadmap

- 15:30 Audits and Inspections
- Preparing to showcase your program and demonstrate control

16:00 End of Essentials Workshop