



Training Course Agenda

PDA 544.1 Validation of Lyophilization

DAY 1

8:30 Welcome and Introductions

9:00 Overview of Validation

10:30 Break

10:45 Equipment Used in Lyophilization

12:00 Lunch

13:00 Lyophilization Process Considerations

14:30 Break

14:45 Qualification vs Validation and Regulatory Perspective

16:00 End of Day 1

DAY 2

8:30 Recap Day 1

9:00 Equipment and Analytical Specifications

10:30 Break

10:45 Analytical Procedures

12:00 Lunch

13:00 Process Validation

14:30 Break

14:45 Special Topics and Case Studies

16:00 End of Training Course