



Training Course Agenda

PDA 575 Validation of Biotechnology-Related Cleaning Processes

DAY 1

8:30 Welcome and Introductions

Cleaning Process Design and Development

- 9:00
- Cleaning Processes
 - Cleaning Process Parameters

10:30 Coffee/Tea Break

Cleaning Process Design and Development (cont.)

- 10:45
- Equipment Design Considerations
 - Coverage Testing

Lab Module 1: Coverage Testing

- 11:15
- Soil Evaluation
 - Coupon Studies
 - Process Parameter Determination
 - Design Space

12:00 Lunch

Lab Module 2: Cleaning Agent Selection

- 13:00
- Soil Evaluation
 - Coupon Studies
 - Process Parameter Determination
 - Design Space

14:30 Coffee/Tea Break

14:45 Acceptance Limits

15:30 Lab Module 3: Residual Limits

16:00 End of Day 1

DAY 2

8:30 Acceptance Limits (cont.)

9:00 Lab Module 4: Cycle Development (with Coupons)

9:30 Lab Module 5: Rinse Time

10:00 Coffee/Tea Break

10:15 Sampling Method Selection

12:00 Lunch

13:00 Sampling Method Selection (Swab Technique Review)

14:30 Coffee/Tea Break

14:45 Lab Module 7: Swab Recovery

16:00 End of Day 2



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DAY 3

8:30 Review Swab Recovery Data

9:00 Analytical Methods

10:15 Coffee/Tea Break

10:45 Cleaning Validation Protocols and Worst Cases

11:00 Lab Module 8: Soiled Tank

12:00 Lunch

13:00 Lab Module 9: Manual Cleaning

14:15 Coffee/Tea Break

14:45 Maintenance of Validated State, Special Considerations, Regulatory Issues

15:45 Wrap-Up and Evaluations

16:00 End of Training Course