



# Training Course Agenda

575 – Technical Report No. 49: Points to Consider for Biotechnology Cleaning Validation

## 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



# Training Course Agenda

575 – Technical Report No. 49: Points to Consider for Biotechnology Cleaning Validation

## 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 Day 3**