



Training Course Agenda

PDA 514 Filtration Processes in the Pharmaceutical and Biopharmaceutical Industry

DAY 1

8:30 Welcome and Introductions

Membrane Materials and Retention Mechanisms

- Differences in Manufacturing
- Differences in Polymers
- Adsorptive Properties of Different Polymers
- Sieve vs Adsorptive Retention
- Influences on Rententivity

10:00 Coffee/Tea Break

- 10:30 Filter Handling and Care
- Documentation
- Steaming
- Troubleshooting

12:00 Lunch

- 13:00 Air Filtration
 - Regulations
 - Applications
 - Separation Mechanisms
 - Sizing

14:30 Coffee/Tea Break

- 15:00 Air Filtration
 - Application Considerations
 - Troubleshooting

16:00 Q&A

16:30 End of Day 1



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PDA 514 Filtration Processes in the Pharmaceutical and Biopharmaceutical Industry

DAY 2

Liquid Filtration Prefiltration

8:30

- Prefilter Construction and Materials
- Necessity of Prefilters
- Difference between Pre- and Final Filter
- Troubleshooting

10:00

Coffee/Tea Break

Liquid Filtration Final Filter

10:30

- Final Filter Construction and Materials
- Retention Mechanisms
- Important Aspects to Consider
- 0.2/0.1 Filtration
- Applications
- Troubleshooting

12:00

Lunch

Validation of Filters

13:00

- Filter Qualifications
- FDA Requirements/Guidance
- Viability/Bacteria Challenge Testing
- Chemical Compatibility
- Adsorption
- Extractable/Leachable
- Particulates

14:30

Coffee/Tea Break

Validation of Filters

15:00

- Contracting Validation
- Work Scope/Flow
- BCT Methods and Options
- BCT Performance

16:00

Q&A

16:30

End of Day 2



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DAY 3

Filter Evaluation, Choices and Sizing

8:30

- Filterability Trials
- 47 mm vs Pleating Devices
- Flow vs Throughput Testing

9:30

Coffee/Tea Break

10:00

Practical Work – Unspecific Adsorption
Filterability Test Set-up Description/Discussion

12:00

Lunch

13:00

Practical Work – Filterability

15:00

Coffee/Tea Break

15:30

Analysis of Results
Result Presentations
Lessons Learned

16:30

End of Day 3

DAY 4

Integrity Testing (Liquid Filters)

8:00

- Destructive/Non-Destructive Test
- Principle of Bubble Point Test
- Principle of Diffusive Flow Test
- Principle of Pressure Drop Test

9:00

Coffee/Tea Break

9:15

Practical Work – Integrity Testing

- Manual Diffusion Test
- Manual Bubble Point Test
- Automated Diffusive Flow/Bubble Point
- Troubleshooting

11:30

Integrity Testing (Air Filters)

- Testing of Hydrophobic Filters
- Feature & Benefits of the Tests

12:00

Lunch

13:00

Practical Work – Integrity Testing

- Water Intrusion Test

14:00

Trouble Shooting Exercise

15:00

Final Discussions and Questions

15:30

End of Training Course