



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 (FG)

9:00

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

10:00 Break

10:30

Filter Handling and Care (FG)
Documentation
Steaming
Troubleshooting

12:00 Lunch

13:00

Liquid Filtration Prefiltration (AL)

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

14:30 Break

15:00

Liquid Filtration Final Filter (AL)

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

16:00

Q&A

16:30 End of Day 1



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DAY 2

Validation of Filters (FG)

8:30

- Filter Qualifications
- FDA Requirements/Guidance
- Viability/Bacterial Retention Test
- Chemical Compatibility
- Adsorption
- Extractable/Leachable
- Particulates

10:00

Break

Validation of Filters (FG)

10:30

- Bacterial Retention Test Methods and Options
- Bacterial Retention Test Performance

12:00

Lunch

Air Filtration (AL)

13:00

- Regulations
- Separation Mechanisms
- Sizing
- Applications

14:30

Break

Air Filtration (AL)

15:00

- Application Considerations

16:00

Q&A

16:30

End of Day 2



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DAY 3

Filter Evaluation, Choices and Sizing (FG)

8:30

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

9:30

Break

10:00

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

12:00

Lunch

13:00

Practical Work – Filterability

15:00

Break

15:30

Analysis of Results
Result Presentations
Lessons Learned

16:30

End of Day 3



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DAY 4

Integrity Testing (Liquid Filters) (AL)

8:00

- Destructive/Non-Destructive Test
- Principle of Bubble Point Test
- Principle of Diffusive Flow Test
- Principle of Pressure Drop Test
- Automatic Integrity Testing
- Product Specific Integrity Testing

9:00

Break

Practical Work – Integrity Testing

9:15

- Color Syringe bubble point exercise/form
- Manual Diffusion Test
- Manual Bubble Point Test
- Automated Diffusive Flow/Bubble Point
 - Troubleshooting – Failure Mode Simulations

Trouble Shooting Exercise

- Considerations for a Reliable Test (FG)
- Reviewing test reports

12:00

Lunch

Integrity Testing (Air Filters) (AL)

13:00 –

- Destructive/Non-Destructive Tests

13:30

- Feature & Benefits of the Tests

13:30 –

Practical Work – Integrity Testing

14:30

- Water Intrusion Test

14:30

Final Discussions and Questions

15:30

End of Training Course