



Event Agenda

Filtration Processes in the Pharmaceutical and Biopharmaceutical Industry Training Course
(PDA 514)

DAY 1

8:30 **Welcome and Introductions**

9:00 Introduction to Filters and Terminology (FG)

Membrane Materials and Retention Mechanisms (FG)

- 9:30
- Differences in Manufacturing
 - Differences in Polymers
 - Adsorptive Properties of Different Polymers
 - Sieve vs Adsorptive Retention
 - Influences on Retentivity

10:15 **Break**

Liquid Filtration Prefiltration (AL)

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

10:30 Liquid Filtration Final Filter (AL)

- Final Filter Construction and Materials
- Retention Mechanisms
- Important Aspects to Consider
- Applications

12:00 **Lunch**

13:00 Lab - Membrane Adsorption

14:00 **Break**

Air Filtration (AL)

- 14:30
- Regulations
 - Separation Mechanisms
 - Sizing
 - Applications

16:00 Q&A

16:30 **End of Day 1**

DAY 2

Integrity Testing (Liquid Filters) (AL)

- 8:30
- 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

10:00 **Break**

Lab – Integrity Testing Liquid Filters

- 10:15
- Color Syringe Bubble Point Exercise/Form
 - Manual Diffusion Test
 - Manual Bubble Point Test
 - Automated Diffusive Flow/Bubble Point
 - Troubleshooting – Failure Mode Simulations



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12:00 **Lunch**

Integrity Testing (Gas Filters) (AL)

- 13:00
- Destructive/Non-Destructive Tests
 - Feature and Benefits of the Tests

13:30 **Break**

Lab – Integrity Testing of Gas Filters

- 14:00
- Water Intrusion Test
 - Failure Mode Simulations

16:00 Q&A

16:30 **End of Day 2**

DAY 3

Trouble Shooting Exercise

- 8:30
- Considerations for a Reliable Test (FG)
 - Reviewing Test Reports

10:00 **Break**

Filter Evaluation, Choices, and Sizing (FG)

- 10:30
- Filterability Trials
 - 47 mm vs Pleated Devices
 - Flow vs Throughput Testing

12:00 **Lunch**

13:00 Lab – Filterability

15:00 **Break**

Conclusion

- 15:30
- Analysis of Results
 - Result Presentations
 - Lessons Learned

16:30 **End of Day 3**

DAY 4

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**



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Filter Handling and Care (AL)

13:00

- Documentation
- Steaming
- Troubleshooting

14:00

Final Discussions and Questions

15:00

End of Event
