



Training Course Agenda

PDA 808 Characteristics of Pharmaceutical Elastomers and Aluminum Seals in Parenteral Packaging Systems

DAY 1

9:00 Welcome and Introductions

9:15 Introduction to Container Closure Systems
Vials, PFS, Cartridges with a focus on elastomeric and aluminum components

9:45 Introduction to Pharmaceutical Elastomers

- Selection criteria and key considerations
- Physical and chemical properties
- Applications, variations, and functionalities
- E/L profiles

10:45 Break

11:00 Aluminum Seals

- Manufacturing technologies and processes
- Key considerations, quality parameters, testing methods

11:30 Activity

12:00 Lunch

13:00 Pharmaceutical Elastomer Manufacturing Process

- Manufacturing technologies
- Understanding critical manufacturing parameters

14:00 Processing of Elastomeric Components

- Fundamentals of RFS and RTU components
- Importance of siliconization and selection criteria
- Basics of camera inspection
- Sterilization choices and elastomer packaging selection

15:00 Break

15:15 Plant Tour: Visit Datwyler's FirstLine® Manufacturing Facility

17:00 End of Day 1



Training Course Agenda

PDA 808 Characteristics of Pharmaceutical Elastomers and Aluminum Seals in Parenteral Packaging Systems

DAY 2

9:00 Different Coating Technologies and Their Unique Benefits

10:00 **Break**

Elastomeric Testing

- 10:15
- Understanding origin of defects
 - Defect classification (discussion of PDA TR76 report)
 - Commonly applied analytical methods
 - Test methods discussion (CCI, silicone, moisture retention, chemical identification)
 - Quality/Analytical lab tour: Describe testing methodologies with practical examples

11:00 Activity

12:00 **Lunch**

13:00 Regulatory Requirements Applicable to Elastomeric Closures and Aluminum Seals

14:00 Case Studies and Best Practices

15:00 Q&A and Summary

16:00 **End of Training Course**