



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

12:15 Lunch

13:00 Pharmaceutical Elastomer Manufacturing Process

- Manufacturing technologies
- Understanding critical manufacturing parameters

13:45 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

14:45 Break

15:00 Regulatory Requirements Part I

- Pharmacopoeial requirements on elastomeric components
- Recent changes/updates in USP <381> and Ph. Eur. 3.2.9
- USP <382> testing
- FDA requirements & post approval changes for container closure systems/components

16:00 Plant Tour: Visit Datwyler's FirstLine® Manufacturing Facility

17:00 End of Day 1



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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

11:15 Activity

12:00 Lunch

Regulatory Requirements Part II

- 13:00
- PFAS regulations, current situation, consequences, future perspective, etc.
 - EU GMP Annex-1 revision – supplier’s perspective, contamination control strategy
 - EU Medical Device Regulation – PDA TR-73-2

14:00 Case Studies and Best Practices

14:45 Q&A and Summary

15:30 End of Training Course