Training Course Agenda

Title: 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 Coffee/Tea Break

11:00 Pharmaceutical Elastomer Manufacturing Process
   • Manufacturing technologies
   • Understanding critical manufacturing parameters

12:00 Lunch

13:00 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

14:00 Plant Tour: Visit Datwyler’s First Line Elastomer Manufacturing

16:00 Coffee/Tea Break

16:15 Aluminum Seals
   • Manufacturing technologies and processes
   • Key considerations, quality parameters, testing methods

17:00 End of Day 1

DAY 2

9:00 Common Challenges with Pharmaceutical Packaging

10:00 Coffee/Tea Break

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

12:00 Lunch

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

14:00 Case Studies and Best Practices
   • Panel Discussion

15:00 Q&A and Summary

16:00 End of Training Course