Training Course Agenda

PDA 808.1 Characteristics of Pharmaceutical Elastomers in Parenteral Packaging Systems

DAY 1	
8:30	**Welcome and Introductions**
8:45	Introduction to Container Closure Systems • Vials, PFS, Cartridges with a focus on elastomeric and aluminum components
9:00	Introduction to Pharmaceutical Elastomers • Selection criteria and key considerations • Physical and chemical properties • Applications, variations, and functionalities • E/L profiles
10:00	**Coffee/Tea Break**
10:15	Pharmaceutical Elastomer Manufacturing Process • Manufacturing technologies • Understanding critical manufacturing parameters
11:00	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
12:00	**Lunch**
13:00	Common Challenges with Pharmaceutical Packaging
14:00	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
14:30	**Coffee/Tea Break**
14:45	Elastomeric Testing (cont.)
15:00	Regulatory Requirements Applicable to Elastomeric Closures
15:30	Case Studies and Best Practices • Panel Discussion • Q&A and Summary
16:00	**End of Training Course**