

Training Course Agenda

PDA EU00188 Characteristics of Pharmaceutical Elastomers and Aluminum Seals in Parenteral Packaging Systems

Day 1 – Tuesday, 19 March 2024		
9:00	Welcome, Introduction, and Collecting Participants' Expectations	
9:15	Introduction to Container Closure Systems <ul style="list-style-type: none"> Vials, Pre-filled Syringes, and Cartridges with a focus on elastomeric and aluminum components 	
9:45	Introduction to Pharmaceutical Elastomers <ul style="list-style-type: none"> Selection criteria and key considerations Physical and chemical properties Applications, variations, and functionalities Extractables & Leachables profiles 	
10:45	Coffee Break	
11:00	Pharmaceutical Elastomer Manufacturing Process <ul style="list-style-type: none"> Manufacturing technologies Understanding critical manufacturing parameters 	
12:00	Lunch Break	
13:00	Processing of Elastomeric Components <ul style="list-style-type: none"> Fundamentals of RFS (Ready-for-sterilization) and RTU (Ready-to-use) components Importance of siliconization and selection criteria Basics of camera inspection Sterilization choices and elastomer packaging selection 	
13:45	Combiseal <ul style="list-style-type: none"> Manufacturing technologies and processes Applications and functionalities 	
14:30	Plant Tour: Visit Datwyler's FirstLine Elastomer Manufacturing	
16:15	Coffee Break	
16:30	Aluminum Seals <ul style="list-style-type: none"> Manufacturing technologies and processes Key considerations, quality parameters, testing methods 	

17:15	End of Training Day 1
17:30 – 20:00	Dinner

Day 2 – Wednesday, 20 March 2024	
9:00	Different Coating Technologies and Their Unique Benefits
10:00	Elastomeric Testing <ul style="list-style-type: none"> • Understanding the 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
11:00	Coffee Break
11:15	Exercise: Defect classification (All participants will see and be able to recognize some possible defects in Datwyler's products)
12:00	Lunch Break
13:00	Regulatory requirements applicable to Elastomeric Closures and Aluminum Seals <ul style="list-style-type: none"> • Pharmacopeial requirements • PFAS (per-and polyfluoroalkyl substances): current situation, potential solution and consequences • Recent changes/updates in USP <381> and Ph. Eur. 3.2.9 • FDA requirements & post approval changes for container closures system / components • Recent EU regulations on primary packaging
14:00	Case Studies and Best Practices
15:00	Q&A and Summary
16:00	End of Course