Training Course Agenda

PDA EU00007 Extractables and Leachables

CEST

Day 1, 20 April 2023	09:00 – 18:00
09:00	**Intro and Attendee Expectations**
09:15	**Introduction on Extractables & Leachables (E/L)** • What is the importance of a good E/L-qualification? • Historical cases of leachables, impacting the quality or the safety of a drug product • Regulatory requirements (FDA, EMA…) for primary packaging
10:30	**Coffee Break**
	Understanding the Materials, Used in the Manufacture of Pharmaceutical Containers & Closures • Types of polymers and their physicochemical properties: examples in medical/pharmaceutical use • Understanding the composition of polymers: Intentionally added & Non-Intentionally added Compounds: Their function and origin • The issues with glass in parenteral applications
	The Mechanism of Leaching • What are the physicochemical parameters to be considered when trying to understand polymer migration • How do leachables move through a polymer, the diffusion model • Special cases in migration
12:00	**Lunch Break**
13:00	**How to Set-up Extractables & Leachables Studies for Pharmaceutical Container Closure Systems** • Selecting the right conditions for extraction • How to select the right compounds to monitor in a leachable study • Designing a leachable study
14:45	**Coffee Break**
15:00	**Analytical Techniques to Perform Extractables & Leachables Research** • The importance of sample preparation: the corner stone in E/L research • What are the target compounds for material research • How does a classification of these compounds assist in finding the right analytical technique • From basic “screening” methodologies to state-of-the-art equipment
15:45	**How to Perform a Safety Evaluation – Risk Assessment on Extractables & Leachables** • Toxicology 101 • EMA Guideline on Genotoxic Impurities • ICH M7 (DNA reactive Impurities) and its suggested staged approach • The Threshold Concept of PQRI (OINDP and PDP/ODP) • Examples
17:00	***End of Training Course Day 1***

Day 2, 1 June 2022	09:00 – 16:30
09:00	**Recap Day 1**
	E/L Testing for a Small Volume Parenteral Container Closure systems • Glass Syringes: the issues with tungsten, glue residues and silicone oil and glass metals leaching • The Issue with rubbers: the plunger, the needle shield or the tip cap: different approaches needed? • The impact of secondary packaging – option or necessity? • Setting up extractable & leachable studies for a pre-filled Syringe • Biological Drug Products versus Small Molecule Drug Products. • Primary packaging for the lyophilized drug product – modus of interaction with the DP • Critical aspects when designing leachable studies for lyophilized DP • Reactivity Of Leachables: concern for Lyophized drug Products • Integration of the administration procedure (e.g. IV-set, pump system) in leachables evaluation
10:30	**Coffee Break**
	E/L Testing for Disposable and Single-Use Systems in Bioproduction • How to classify the risk of different single-use systems in the bioproduction process? • Understanding BPSA & BPOG recommendations, and how they can be implemented in the study design • Performing E/L studies on filters: potential approaches
	Large Volume Parenterals • The challenge in E/L testing for LVP's • Primary packaging for LVP's – critical materials and components • Secondary packaging for LVP: critical points to consider
12:00	**Lunch Break**
13:00	**Qualification of Injection Devices used for Parenteral Administrations** • Short introduction into Medical Device Regulations (ISO 10993 series) • Difference in Approaches for Medical Devices, compared to Pharmaceutical Packaging • Considerations for Combination Products: how to proceed?
14:30	**Coffee Break**

	Updates of E/L- Regulations, Standards and Recommendations
	• Pharma Packaging:
	  ○ Final PQRI recommendations of the Parenteral Drug Product (DPD) Chemistry group
	  ○ USP <661> & USP<665> chapters: where are we, where could it go to?
	• (Bio)Pharmaceutical Manufacturing
	  ○ The BPOG protocol

16:15	**Q&A**
16:30	***End of Training Course***
The training course will include two coffee breaks and one lunch break	