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Extractable & Leachables Training Course

March 17 – Morning sessions		
Time	**Topic**	**Speaker**
9.00	Introduction and Attendee Expectations	
9.15	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	Koen Smets, PhD. **Nelson Labs**
10.15	Polymers & Glass • Understanding the Materials, Used in the Manufacture of Pharmaceutical Containers & Closures • Types of polymers – 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	Sona Kovackova, PhD. **Nelson Labs**
11.15	BREAK	
11.30	Polymers, Material Knowledge	
12.30	The Mechanism of Leaching – Polymer Migration • 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	Sona Kovackova, PhD. **Nelson Labs**
13.00	LUNCH BREAK	

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March 17 – Afternoon sessions		
Time	**Topic**	**Speaker**
13.45	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	Koen Smets, PhD. **Nelson Labs**
14.30	AET Concept	Pieter Van Wouwe, PhD. **Nelson Labs**
14.45	How to Set-up Extractables study • Selecting the right conditions for extraction	Pieter Van Wouwe, PhD. **Nelson Labs**
15.45	Q&A	
16.00	BREAK	
16.15	Gas Sterilization • Delivering the desired contamination risk reduction for a drug delivery device while ensuring product Integrity	Annick Gillet, PhD. **Sterigenics**
18.15	End Day 1	

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March 18 – Morning sessions		
Time	**Topic**	**Speaker**
9.00	Re-Cap Day 1	
9.15	How to Set-up Leachables Studies • How to select the right compounds to monitor in a leachable study • Designing a leachable study	Pieter Van Wouwe, PhD. **Nelson Labs**
10.00	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	Koen Smets, PhD. **Nelson Labs**
11.15	COFFEE BREAK	
11.30	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?	Sona Kovackova, PhD. **Nelson Labs**
12.30	LUNCH BREAK	

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March 18 – Afternoon sessions		
Time	**Topic**	**Speaker**
13.15	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	Koen Smets, PhD. **Nelson Labs**
14.15	Combination Products • 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?	Pieter Van Wouwe, PhD. **Nelson Labs**
15.15	BREAK	
15.30	Q&A	
16.00	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	Kevin Breesch **Nelson Labs**
17.00	End	