Nelson Labs
A Sotera Health company

Large Volumes Parenteral Packaging Virtual Symposium 24 – 25 March

Day 1

Timings (CET)	Subject	Speaker	Company
13:30	Introduction	Georg Roessling, Senior Consultant	Former Senior Vice President PDA Europe
13:40	Nelson Labs Presentation		

Session 1: Introduction to LVPs and LVP packaging			
13:50	An Introduction to Large Volume Parenterals (LVPs) as a Pharmaceutical Dosage Form and an E&L Challenge	Dennis Jenke PhD, Principal Consultant	Nelson Labs
14:20	The development of a large volume parenteral packaging system: Things to keep in mind	Philippe Chanson, Associate Director, Head of Materials Platform	B. Braun
14:50	Q&A		
15:00	Break		

Session 2: Building an LVP from resins to commercial product			
15:15	LVP polyolefin solutions addressing different packaging and regulatory requirements	Anja Gottschalk, Application Development Engineer Healthcare	Borealis
15.45	The production, process and qualification of film: A film manufacturer perspective	Dr. Bianca Schweiger and Christian Kunz Head of Sales	PolyCine
16.15	The design, manufacturing and qualification of a large volume parenteral packaging system	Dominique Saint-Ellier, QA/RA Director	Technoflex
16.45	Break		
17:00	Blow-Fill-Seal technology in large volume parenteral packaging	Michael Spallek PhD, Director Research & Development	Rommelag
17:30	The design and qualification process for a LVP packaging system from a user perspective, Case study nitrosamines	Rawaa Ammar PhD, Senior Research Associate III / Extractables & Leachables Lead	Baxter
18:00	Notified Body Perspective on CE-marked Medical Devices versus Article 117 MDR combination products	i. A. Dr. Katharina Weidmann, Expert Biocompatibility and Dr Christiana Hofmann, Teamlead Non-Active Medical Devices	TÜV Süd
18:30	Final round of Q&A – wrap-up Day 1		
18:45	End		

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Day 2

Timings (CET)	Subject	Speaker	Company
13:50	Introduction	Georg Roessling, Senior Consultant	Former Senior Vice President PDA Europe

Session 4: Safety Qualification of LVPs, E&L			
14:00	Sharing experiences of historical submissions and regulatory feedback	Mike Hodgson, Senior Manager of Extractables & Leachables team	Baxter
14:30	Use of Auxiliary Information to Support the Development and Qualification of Flexible LVP Packaging	Dennis Jenke PhD, Principal Consultant	Nelson Labs
15:00	Testing of the packaging: Extractable study design and challenges	Karen Pieters, Senior E&L Expert	Nelson Labs Europe
15:30	Break		
15:45	The value of simulation studies for LVP packaging systems	Dennis Jenke PhD, Principal Consultant	Nelson Labs
16:15	Testing of the drug product, stored in a large volume parenteral packaging system: Leachable study design and challenges	Pieter Van Wouwe PhD, Senior E&L Expert	Nelson Labs Europe
16:45	The need for high-end analytical technology to support the need for higher level of identifications in large volume parenteral packaging qualifications	Ward d'Autry PhD Senior E&L Expert	Nelson Labs Europe

Session 5: Additional Considerations			
17:15	Break		
17:30	The challenges in tox assessments for large volume parenteral packaging system applications *(no data available, request for tox studies on compounds…)*	Koen van Deun PhD, Toxicologist	External Toxicologist
18:00	Common themes and challenges in LVP qualifications and submissions: Time for an "Interest Group"?	Piet Christiaens PhD, Scientific Director	Nelson Labs Europe
18:15	Final round of Q&A		
18:30	End		

*These time indications are **subject to change**; a **detailed program** will be released soon.