CONFERENCE SCHEDULE

Day 1: 2nd September 2020

11:00 – 11:30 (CEST)	**Registration & Networking**
11:30 – 11:40 (CEST)	**Opening Remarks by Informa Markets In India**
11:40 – 12:10 (CEST)	**Regulations, Standards, PQRI Guidelines for Effective E&L Assessment:** • Regulatory requirements of EMA and US-FDA • PQRI recommendations and ICH guidelines: Safety thresholds and permitted daily exposure • Updates on latest amendments and revisions USP <1663> and USP <1665>, <665> **- Diane Paskiet, Director, Scientific Affairs, West Pharmaceutical Services & Chair of Product Quality Research Institute (PQRI) at Development Technical Committee (DTC)**
12:10 – 12:20 (CEST)	**Q&A Session**
12:20 – 12:30 (CEST)	**Break**
12:30 – 12:50 (CEST)	**E&L Safety Assessment with ICHQ3E Update:** • Overview of Pfizer E&L safety assessment process • Development of harmonised regulatory guidance ICHQ3E • Areas of uncertainty and scientific efforts underway to support development of best practices **- Patricia Parris, Global Risk Assessment Services Toxicologist, Pfizer**
12:50 – 01:00 (CEST)	**Q&A Session**
01:00 – 01:10 (CEST)	**Break**
01:10 – 01:30 (CEST)	**Importance of Extractable and Leachable Study in Packaging Development and Patient Safety:** • Impact of primary and secondary packaging on E&L Study • Criteria for selecting analytical method from various methods and risk validation process guidelines • Future of packaging development and measures for reducing skill gap
01:30 – 01:40 (CEST)	**Q&A Session**
01:40 – 02:10 (CEST)	**Networking Break**

02:10 – 02:30 (CEST)	**How to Write a Toxicological Risk Assessment to Support Extractables and/or Leachables Profiles: A Step-by-Step Process:** • Guidelines for setting up of chemical safety risk assessment of E&L testing developed for different phases of drug development • Impurities and E&L test data evaluation for better quality assessment • Primary considerations for setting acceptance limits of Maximum Daily Intakes (MDI) and Threshold of Toxicological Concern (TTC) • Essential process required for qualified toxicology reports • Safety and risk assessment mandates for pharma product launch **- Dr. Elizabeth Martin, Project Toxicologist at AstraZeneca**
02:30 – 02:40 (CEST)	**Q&A Session**
02:40 – 02:50 (CEST)	**Break**
02:50 – 03:20 (CEST)	**Risk Assessment of Extractables and Leachables in Different Phases of Development:** • Understanding the various drug development pathways • E&L assessment in development of a new chemical entity • E&L assessment in development of medical devices • Strategies to include E&L assessment in life cycle management of drug product **- Dr. Dr. Clemens Guenther, Director, Senior Expert Nonclinical Safety at Bayer AG**
03:20 – 03:30 (CEST)	**Q&A Session**
03:30 – 04:00 (CEST)	**Networking Break**
04:00 – 04:45 (CEST)	**Panel Discussion** **Risk Based Approaches to Extractable and Leachable Study Design:** • Factors affecting dose from risk of leachables • A structured approach to assessment of leachable risk • Linking risk to extractable or leachable studies • How extractable and /or leachable studies reduce project risk **- Dr. Clemens Guenther, Director, Senior Expert Nonclinical Safety at Bayer AG** **- Dr. Elizabeth Martin, Project Toxicologist at AstraZeneca** **- Patricia Parris, Global Risk Assessment Services Toxicologist, Pfizer**
04:45 – 05:00 (CEST)	**Q&A Session**
End of Conference Day 1	

Day 2: 3rd September 2020

11:00 – 11:30 (CEST)	**Registration & Networking**
11:30 – 11:35 (CEST)	**Opening Remarks by Informa Markets In India**
11:35 – 12:05 (CEST)	**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 **- Steve Zdravkovic, Senior Research Scientist at PPD**
12:05 – 12:15 (CEST)	**Q&A Session**
12:15 – 12:25 (CEST)	**Break**
12:25 – 01:05 (CEST)	**Extractables & Leachables Studies for Medical Devices:** • How to develop a biological safety evaluation strategy for devices that considers a chemical characterization/risk assessment approach for E&L compounds? • How to use the ISO standards to conduct a biological safety evaluation of device-related E&L compounds? • New directions for the medical devices toxicological risk assessment for E&L compounds **- Dr. Ron Brown, Former FDA & Toxicologist at Risk Science Consortium**
01:05 – 01:15 (CEST)	**Q&A Session**
01:15 – 01:45 (CEST)	**Networking Break**
01:45 – 02:05 (CEST)	**A Modular Approach Towards Generation of Leachable Data to Support Regulatory Filings:** • Ways for setting up a leachable study • Identifying challenges with known and unknown extractable data for identifying potential leachable compounds • Risk assessment strategy with identification of better method development and validation process • Discovering targeted & non-targeted leachable screening and stop limits • Crafting stability plan for leachable studies **- Dr. Anja Cerstiaens, Director E&L Services, Nelson Labs Europe**

02:05 – 02:15 (CEST)	**Q&A Session**
02:15 – 02:25 (CEST)	**Break**
02:25 – 02:45 (CEST)	**Best Practices for Deriving Health Based Exposure Limits for E&L Compounds:** • The session would focus on emerging issues and how to avoid common errors in deriving these values. **- Dr. Ron Brown, Former FDA & Toxicologist at Risk Science Consortium**
02:45 – 02:55 (CEST)	**Q&A Session**
02:55 – 03:05 (CEST)	**Break**
03:05 – 03:35 (CEST)	**Application of USP 665 Data to Support Qualification of Single Use Systems:** This talk will focus on an overall application of USP <665> starting from risk assessment to qualification of disposable manufacturing systems based on USP<665> data set. All the key principles with examples where these principles need to be satisfied before one can apply the USP<665> data for disposable manufacturing system qualification will be discussed and illustrated. Lastly, different qualification approaches will also be presented to provide broader understanding. **- Ken Wong, Deputy Director at Sanofi Pasteur**
03:35 – 03:45 (CEST)	**Q&A Session**
03:45 – 03:55 (CEST)	**Break**
03:55 – 04:25 (CEST)	**Future trends to Control Risks from Extractables & Leachables:** • Examples of how knowledge management is important to extractables and leachables from a risk assessment point of view • Sample preparation for extractable or leachable study and advances in detection and identification via mass spectroscopy. • Testing for extractables and leachables in biologics & vaccines **- Dr. Jason Creasey, Managing Director at Maven E&L Ltd**
04:25 – 04:35 (CEST)	**Q&A Session**
End of Conference	