2019 PDA EXTRACTABLES AND LEACHABLES TRAINING COURSE

September 30, 2019 | Sheraton Grand Incheon Hotel | Seoul, Koera

Trainers (subject to change)

Piet Christiaens, PhD, Scientific Director, *Nelson Labs Europe*

Pieter Van Wouwe, E&L Study Director – Disposable & SU systems and LVP's, *Nelson Labs Europe*

AGENDA

Monday, September 30, 2019

8:00 – 17:30 | Registration Open

9:00 – 12:00

Refreshment break from 10:30 – 10:45

Introduction on Extractables and Leachables & Helicopter view on Regulations

- What is the importance of a good E/L-qualification
- Historical cases of leachables, impacting the quality or the safety of a drug product
- Global regulatory requirements (FDA, EMA, etc.) for primary packaging

Understanding the Composition of Polymers Used in the Manufacture of Pharmaceutical Containers and Closures

- Understanding the composition of polymers
- Making the distinction between compounds that are intentionally added to a material/polymer and not intentionally added substances

Analytical Techniques to Perform Extractables and 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:

How to Perform a Safety Evaluation: Risk Assessment on Extractables and Leachables

- Toxicology 101
- EMA guideline on genotoxic impurities
- ICH M7 (DNA reactive Impurities) and it's suggested staged approach.
- The Safety Concern Threshold (SCT) and the Analytical Evaluation Threshold (AET) concept of PQRI (OINDP and PDP/ODP) Examples

12:00 – 13:00 | Networking Luncheon

13:00 – 17:00

How to Set-up Extractable and Leachable Studies

- Designing extraction studies that are compliant with USP <1663>
- Selecting the right conditions for extraction
- How to select the right compounds to monitor in a leachable study?
- Designing a leachable study compliant with USP <1664>

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 and BPOG recommendations, and how they can be implemented in the study design
- Performing e/l studies on filters: potential approaches

E/L Testing for a Small Volume Parenterals (Liquid and LYO applications)

- Glass vials and syringes: the issues with glass metals leaching, tungsten, glue residues and silicone oil
- The issue with rubbers: the stopper, the plunger, the needle shield, or the tip cap: different approaches needed?
- The impact of secondary packaging: option or necessity?
- Setting up extractable and leachable studies for a vial containment system (vial and stopper)
- Primary packaging for the lyophilized drug product – modus of interaction with the DP