FREE LIVE SEMINAR

Speakers & Program details

"How to overcome common obstacles on your road to a successful Medical Device submission"

Wednesday, May 4, 2022
1:45 – 4:30 P M CEST

MedtecLIVE
Connecting the medical technology supply chain

Conference room C6.1

Nelson Labs®
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INTRODUCTION

"How to overcome common obstacles on your road to a successful Medical Device submission"

The proper function and safety of a medical device is paramount. No device should present a safety risk to either the patient or user. Potential safety risks can come from many sources including the materials used in manufacturing the device or from a breach in its sterility.

During this seminar we will help you understand and overcome the following common obstacles:

- What to do if you experience a cytotoxicity failure
- How to investigate routine Ethylene Oxide sterilization failures
- Understanding your raw materials utilizing Chemical Characterization following ISO 10993-18

May 4, 1:45 PM-CEST

Lise Vanderkelen, PhD
Department Head Microbiology, in-vitro toxicology and healthcare reprocessing-Nelson Labs

Lise Vanderkelen received her Ph.D. from the Faculty of Bioscience Engineering at the University of Leuven (Belgium) in 2012. She started at Nelson Labs Europe in 2013 as Study Director Extractables & Leachables, focusing on parenteral applications and later for chemical characterization of medical devices.

In 2016, she became Department Head Pharma Services at Nelson Labs Europe. The main focus of this team is identifying organic impurities in drug products as well as in-use stability for drug-device combinations.

Since 2020, she is responsible for all microbiological including toxicological testing and healthcare reprocessing validations at Nelson Labs Leuven. Lise actively speaks about extractables and leachables, impurities, drugdevice interactions, biocompatibility and healthcare reprocessing and is an active member of several International Organization for Standardization (ISO) committees related to healthcare reprocessing.

Overcoming a Cytotoxicity Failure

Every medical device needs to have proven biocompatibility to protect users from potential biological risks arising from its intended use. In particular, cytotoxicity must be evaluated for every medical device, regardless of its classification. Cytotoxicity testing is often conducted using an in vitro cell culture method because of its high sensitivity and low cost. However, in vitro cytotoxicity testing is very sensitive and can result in failures. A normal reaction to a failing cytotoxicity test result is often a feeling of panic. This is understandable as it may seem like the submission of the device is in jeopardy and that the product will not be approved for commercialization. This presentation will provide a step-by-step guide regarding how to investigate and assess in vitro cytotoxicity failures to determine appropriate solutions.

May 4, 2:30 PM-CEST

Gregory Grams

Sterilization Technical Director-Sterigenics

Gregory Grams is a **Sterilization Technical Director** with Sotera Health Expert Advisory Services. He is responsible for the development of new cycles, customer validation, and R&D projects. He is a leader in validation, development, and cycle design and improvements in sterilization. Gregory is an active trainer who enjoys sharing his knowledge with others through formal seminars at trade shows, as well as informal customer training. He has been published in *Medical Design & Outsourcing and Med Device Online* and holds a patent EP 638909A1: "Process for preparing sterile Brinzolamide" (European patent application, 18/09/2013, F. Porstmann, J. Ondracek, K-T, Van Van, G. Grams).

He holds a master's degree in Industrial Chemistry from the High School de Liège (Belgium) and a Business Administration Certification from Cambridge (UK).

Routine BI Positive Failure Investigations

Ethylene oxide sterilization is a well-established sterilization technology, utilized to sterilize approximately 50% of all medical devices in the United

States annually. Despite, comprehensive, complex, and extensive validations, some failures may occur during routine processing. It is important to conduct a complete investigation to understand and potentially correct the root causes to keep the failure risk under control. It is also important to develop a mitigation and resolution plan to prevent major financial, commercial impact, or product shortages. This presentation will help you learn how to conduct a thorough investigation and implement a plan for moving forward.

May 4, 3:45 PM-CEST

Dries Cardoen, PhD

Study Director, Senior E&L Expert- Nelson Labs

Dries Cardoen received his Ph.D. from the Faculty of Biology at the University of Leuven (Belgium) in 2011. After his academic career as a post-doctoral researcher, he started at Nelson Labs Europe in 2013 as Study Director in the Extractables & Leachables Department. He is currently responsible for the group of study directors that is specialized in E&L testing of inhalation drug products and topical and transdermal drug products.

Chemical Characterization According to ISO10993-18

Manufacturers are often advised to perform an extractables study after completing a biological evaluation of their medical devices. This doesn't need to be a concern as the procedure is very well described in ISO10993-18. The standard includes guidance regarding how the extractions need to be performed, how the analytical chemistry should be completed, and how the results should be reported. Unfortunately, it is not always as straightforward as it seems. The universe of devices, materials, production processes, and applications is so diverse that a single, unified approach does not always fit each device. In such cases, it is important to build an alternative testing strategy, in which you move away from the standard testing. This presentation will show you how to work through a successful extractables and leachables program.