SEMINAR DAY

ENSURING PRODUCT QUALITY ACROSS THE PHARMACEUTICAL LIFECYCLE

ANALYTICAL, MICROBIOLOGICAL AND REGULATORY PERSPECTIVES

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DOM HOTEL LIMBURG
GERMANY

ORGANISATON AND CONTACTS

EUROFINS BIOPHARMA PRODUCT TESTING GERMANY

E-MAIL:
PHARMATESTING@BPT.EUROFINSEU.COM

SPEAKERS

MODERN CLEANING VALIDATION: TOC-BASED RISK APPROACH AND REGULATORY ALIGNMENT

Daniel Kellner-Steinmetz, Veolia

This presentation examines the evolution of analytical methods and regulatory guidance for cleaning validation (CV), highlighting the shift towards risk-based programs, influenced by documents like the revised EU GMP Annex 1. The core discussion focuses on utilizing non-specific methods, specifically Total Organic Carbon (TOC) and Conductivity, as preferred tools for monitoring residual contamination, including APIs, excipients, and cleaning agents. The content details the toxicological approach and provides practical guidance on converting traditional product limits into TOC limits. Furthermore, it outlines a comprehensive, step-by-step process for implementing and validating TOC technology. Finally, the presentation explores the deployment of TOC in Off-Line, At-Line, and On-Line configurations, demonstrating how automation and effective data analysis enhance process understanding, lower risk, reduce costs, and increase manufacturing efficiency.

IN VITRO DRUG RELEASE TESTING: THEORY TO PRAXIS, A KEY TO OVERCOME DISSOLUTION CHALLENGES

Freddi Philippart, Eurofins BPT Germany

We will cover the following key points: Brief introduction to the theory of in vitro dissolution, Overview of the apparatus, Typical problems that can occur during in vitro dissolution and possible solutions In vitro drug release testing or dissolution plays a crucial role in the pharmaceutical R&D and quality control. In development, the identification of the most relevant dosage form as well as the most suitable formulation and manufacturing parameters require in vitro drug release testing. These studies are also necessary in quality control for stability studies, for batch release or for the evaluation of the bioavailability and the establishment of the bioequivalence. But what is the theory behind in vitro dissolution and how is it performed nowadays in praxis? What are the most common challenges and which solutions are currently available?

STANDARDS AND PRACTICAL INSIGHTS ON THE TRANSFER OF PHARMACEUTICAL ANALYTICAL METHODS UNDER GMP

Kristina Grötzinger, Eurofins BPT Germany

From the decision to qualify a new receiving laboratory for your validated method until completion it requires well-performed organization. This presentation will cover the global standards and the complete process of analytical method transfer.Most important points are diligent planning, decent communication, and gapless documentation. We provide an overview of general procedures of method transfers and practical application examples. Issues to anticipate and possible solutions will be discussed on practical examples like differences in laboratory environment and instrumentation.

SPEAKERS

NEXT-GENERATION ENDOTOXIN TESTING: LAL AND RCR EQUIVALENCE ON A MICROFLUIDIC PLATFORM

Daniel Kellner-Steinmetz, Veolia

This presentation demonstrates the comparability of traditional LAL and recombinant chromogenic reagents (rCR) for detecting bacterial endotoxins in water and non water samples. Testing on a microfluidics platform achieved a 90% reduction in reagents while maintaining compliance with USP <85> and EP 2.6.14, JP 4.01, and FDA requirements.

Data Set #1 tested several pharmaceutical products with both LAL and rCR reagents. Results showed strong comparability with all positive product control recoveries within 50-200% specification and coefficients of variation below 15%.

Data Set #2, a collaboration with Eli Lilly, evaluated multiple products using multiple LAL vendors and rCR reagents, demonstrating consistent performance across reagent types with comparable naturally occurring endotoxin results.
Key findings indicate excellent comparability between commercially available LAL and rCR reagents, reduced time to result, valid precision metrics, and capability for adoption multiple endotoxin detection applications across pharmaceutical manufacturing, biopharma, medical device manufacturers, and contract testing laboratories globally.

ADCS - BIOLOGICAL MISSILES AND THEIR DEMANDING QUALITY CONTROL

Felix Harion, Eurofins BPT Germany

Antibody drug Conjugates have been studied and developed for more than half a century. But what makes them so interesting for cancer therapies? How do they function and how do we assess their functionality by quality control? These complex platforms at the intersection between small and large molecule require an extended testing portfolio compared to monoclonal antibodies ultimately ensuring patient safety.

STORAGE AND STABILITY STUDIES – STABILITY-INDICATING METHOD DEVELOPMENT

Kristina Grötzinger, Eurofins BPT Germany

This talk will cover the development of analytical methods for stability studies. More information will follow soon.