PMT Conferentie voor Ziekenhuis en Bereidingsapotheken

Datum: 6 en 7 Juni 2023

Locatie: Van der Valk Breukelen

Room 1: Release Testing		Room 2: Tablet Testing	
09.00-09.30	Cleaning validation with TOC Speaker: Daniel Kellner-Steinmetz	**09.00-09.30**	Advantages of pharmaceutical testing standardization Speaker: Michel Magnier
09.30-09.50	Q&A Open discussion, coffee break	**09.30-09.50**	Q&A Open discussion, coffee break
09.50-10.20	Microfluidic automation for Endotoxin Testing & Resolving test interferences Speaker: Daniel Kellner-Steinmetz	**09.50-10.20**	Flowt-hrough cell dissolution: method for multiple dosage forms Speaker: Michel Magnier
10.20-10.45	Q&A Open discussion, coffee break	**10.20-10.45**	Q&A Open discussion, coffee break
10.45-11.15	Ultrasensitive High Throughput Flow Cytometry for rapid bioburden testing and risk reduction Speaker: Daniel Kellner-Steinmetz	**10.45-11.15**	Ultra compact tablet press Speaker: Ingro Krause
11.15-12.00	Discussion: GMP Annex 1	**11.15-11.45**	Demo PrivMed
12.00-13.00	Lunch-buffet	**12.00-13.00**	Lunch-buffet
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11.15-12.00	Discussion: GMP Annex 1	**15.15-15.45**	Demo PrivMed

Dit programma geld voor beide dagen. Deelname is gratis.
Opgave kan via peter.versluis@pmtbenelux.com graag vermelden welke dagdelen u wilt volgen.

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Topics:

Cleaning validation with TOC

Increase efficiency, process understanding, and confidence throughout the lifecycle of your cleaning validation or verification program. TOC analysis is a fast and simple analytical method for detecting low levels of organic compounds and allows for detection of degradants and contamination not possible via HPLC. Compared to specific methods such as HPLC, TOC offers simpler method development and allows you to test not only for product removal, but also removal of excipients, degradants, and cleaning agents.

Microfluidic Automation for Endotoxin Testing

Understanding the basics of Bacterial Endotoxin testing & resolving test interferences.
Centripetal microfluidic automation simplifies endotoxin testing by offering a solution that is easy to set up, use, and maintain. It enables labs to achieve the ease of use, ease of training, and high throughput. Using new technologies, fully compliant endotoxin assays can be set up in short time, less than 30 pipetting steps, with up to 21 samples and up to a 5-point standard curve. Being sustainable with just 1 mL of LAL.

Flow Cytometry for rapid bioburden

The easier and faster it is to quantify microbial contamination in water systems, raw materials, or finished products, the better your ability to make rapid decisions that impact safety and quality. In pharmaceutical and medical device manufacturing and purification processes, this is critical for patient safety, regulatory compliance, and process efficiencies. But for years, pharmaceutical waters have been released at risk due to waiting five days for bioburden results using growth-based methods. It’s time for faster, reliable methods to provide the information you need to minimize risks.

Advantages of pharmaceutical testing standardization

The evolution of pharmaceutical testing methodologies during the last fifty years has been driven by the ability to export results. To understand them, judge them and to challenge them - scientifically - in the interest of patients. Compendial instruments as dissolution testers were first experimental set-ups, varying from laboratory to laboratory and therefore comparisons of obtained results were prone to misinterpretation. The optimization of methodologies started when results from compendial instruments could be benchmarked. Qualification of instruments, Automation of systems and enforcement of Data Management policies have strengthened the industry productivity but have also brought along the same path major improvements in reproducibility and

Flow-through cell dissolution

"a compliant, reproducible and informative method for multiple dosage forms"
The Flow-through cell technique has started with a common problem: how to test poorly soluble compounds dissolution efficiently and from there has spread, with the help of universities and industry R&D departments, to mostly all dosage forms' drug release testing. The flexibility of the FTC method is due to the possibility of changing cells, selecting the one which addresses the inherent dosage form challenges. The configuration of the system also allows functionalities directly relevant to In-Vivo comparison as pH change or low dose products testing. From APIs to intermediates and final dosage forms the Flow-through cell dissolution can cover several characterization aspects. Used in R&D, QC or for re-formulation, on tablets and capsules or complex dosage forms, the flow-through cell dissolution is described in all pharmacopoeias and

Ultra compact tablet press

The ultra-compact tablet press for city or hospital pharmacies, for pharmacist production groups that jointly supply entire regions, and for food supplement manufacturers.
Adressing patient centric medication, as gender differences in pharmacological response, pediatric healthcare, chronic deseases etc.
Active ingredient containers with ready API blends (as e.g. from Fagron) are easily inserted, and the production parameters are stored on a chip so that no setting is necessary.
A built-in, high-precision weighing module monitors the dosage of the active ingredient for each individual tablet – a first in industrial tablet production, where weighting cannot be carried out individually in mass production, but instead is controlled via the much less precise pressing force value.

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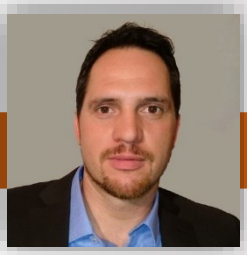
Speakers:

Michel Magnier (M.Sc.)

Michel Magnier is currently Global Dissolution Product Manager in SOTAX AG (CH). He has worked 30 years in scientific instrumentation after a MSc of Biochemistry in Paris XI, spending most of his international career in the pharmaceutical testing segment.



Daniel Kellner-Steinmetz (B.Sc)

Daniel Kellner-Steinmetz has been working in the pharmaceutical area since 2009 in different functions of quality and manufacturing. He is applications and regulatory specialist, conducting international trainings, webinars, and specialized seminars on applications in Pharma, Cosmetics and Medical Device Industry. Passionate about Pharma 4.0 and implementation of technologies to drive automation, rapid release methods and best practices in pharma labs.

Ingo Krause (Ing)

Ingo Krause is a chemical engineer and is working is the field of pharmaceutical machines (oral dosage forms) for 22 years. Since 2006 he has been developing concepts for innovative R&D tablet presses, including the legendary RoTab T, the RoTab Bilayer and, since 2015, the Futoruqe with full containment in the compression of hormone and production of oncological preparations.