HELLAMCO®
ΕΠΙΣΤΗΜΟΝΙΚΟΣ ΕΞΟΠΛΙΣΜΟΣ

Virtual Seminar

# Pharma Week

1-3 Φεβρουαρίου 2022

Σύγχρονες μεθοδολογίες
και τελευταίες εξελίξεις
στην φαρμακευτική ανάλυση:

- Ελέγχου Ποιότητας (QC)
- Έρευνας & Ανάπτυξης (R&D)
- In Process Control (IPC)

# Programme

## Tuesday 1/2/2022

**13.15** Welcome - Introduction
**Mr. Michael Kontogiannis**/Managing Director Hellamco S.A.
**Mr. Chris Kontogiannis**/General Manager Hellamco S.A.

**13.30** Title: Data Integrity-Managing Change in Change Resistant Laboratories
Presenter: **Dr. Christoph Jansen**/Technical Key Account Manager

**14.15** Title: Method Migration
Presenter: **Mr. Rainer Rozenich**/Business Development Manager LC Systems

**14.45** Title: How to Approach a Method Conversion (HPLC to or from UHPLC)
Presenter: **Mr. Rainer Rozenich**/Business Development Manager LC Systems

**15.15** Title: USP IV a compendial method for Novel Dosage form method development in R&D
Presenter: **Mr. Michel Magnier**/Product Manager Dissolution USP 4

**16.00** Title: Understanding Powder Behaviour Using the FT4 Powder Rheometer®
and presenting in the R&D session
Presenter: **Dr. Jamie Clayton**/Operations Director

**16.30** Title: Empower LMS/Strategic Innovations
Presenter: **Mr. Peter Gruener**/Senior Account Manager Information Management

## Wednesday 2/02/2022

**13.15** Welcome - Introduction
**Mr. Michael Kontogiannis**/Managing Director Hellamco S.A.
**Mr. Chris Kontogiannis**/General Manager Hellamco S.A.

**13.30** Title: How to Introduce the Concepts of AQbD into a QC Laboratory
Presenter: **Mr. Rainer Rozenich**/Business Development Manager LC Systems

**14.00** Title: Automatization of Pipetting Routines
Presenter: **Mr. Rainer Rozenich**/Business Development Manager LC Systems

**14.30** Title: European Pharmacopoeia-How to ensure compliance with
the new Ph. Eur. General Chapter 2.1.7.?
Presenter: **Mrs. Simona Venzin**/ Head of Service Product Management
(and Ph. Eur. Campaign Manager)

**15.15** Title: Microwave sample preparation for the analysis of elemental impurities in pharmaceutical formulations and raw materials, following new USP 232 and 233, as well as older EUPharm methods.
Presenters: **Messers. Axel Schoener**/Director of Distributor Sales, EMEA and Southern Asia
**Maxim Diel**/ International Technical Specialist

**15.45** Title: The Role of XRF & XRD in Pharma Products
Presenter: **Dr. Robert Taylor**/Segment Marketing Manager

**16.15** Title: The importance of pycnometry and mercury porosimetry in characterising tableted medicines and pharmaceutical ribbons.
Presenter: **Dr. Luca Lucarelli**/Technical Analytical Consultant

**16.45** Title: Improving efficiency, throughput and Quality of QC batch Release Testing by fully automating dissolution and content uniformity testing
Presenters: **Messrs. Rene Faessler**/Product Manager Dissolution USP 1,2,5,6
**Duncan Tärran**/Product Specialist-ASP

## Thursday 3/02/2022

**13.15** Welcome - Introduction
**Mr. Michael Kontogiannis**/Managing Director Hellamco S.A.
**Mr. Chris Kontogiannis**/General Manager Hellamco S.A.

**13.30** Title: Characterising Pharmaceutical Products - The Malvern Panalytical Tool Box
Presenter: **Mr. Stuart Wakefield**/Regional Manager - Middle East & India

**14.00** Title: Complex Generics Characterisation
Presenter: **Mr. Stuart Wakefield**/Regional Manager - Middle East & India

**14.30** Title: Determination of BET Surface Area – Methods, Applications and Best Practice
Presenter: **Dr. Katharina Peikert**

**15.00** Title: Data Integrity from R&D, IPC/Production to QC
Presenter: **Mr. Ramsey Khinda**/Head of Sales & Marketing - Market Unit Europe

**15.45** Title: PAT – In process measurement of Milling and Granulation process in Pharmaceutical Industry
Presenter: **Mr. Stuart Wakefield**/Regional Manager - Middle East & India

**16.15** Title: Understanding Density Measurement Techniques for Improved Quality Control and Research and Development.
Presenter: **Dr. Jack Saad**/Applications Scientist Technical Training and Support Manager

**16.45** Title: WATERS Mass Spec Systems & Appls in Pharma
Presenter: **Mr. Dev Sriranganadane**/Regional Business Development Specialist

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Virtual Seminar

# Pharma Week

1-3 Φεβρουαρίου 2022

Σύγχρονες μεθοδολογίες και τελευταίες εξελίξεις στην φαρμακευτική ανάλυση:

- Ελέγχου Ποιότητας (QC)
- Έρευνας & Ανάπτυξης (R&D)
- In Process Control (IPC)

# ABSTRACTS

*(περιλήψεις παρουσιάσεων)*

## Tuesday 1/2/2022

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|---|---|---|
| **13.30** | **METTLER-TOLEDO**<br>Title: Data Integrity-Managing Change in Change Resistant Laboratories<br>Presenter: Dr. Christoph Jansen/Technical Key Account Manager | ABSTRACT:<br>"Never change a winning team", - with this motto, many laboratories do not dare to update their processes and procedures according to regulations, technical requirement changes, and software updates. They might not be informed about compliance risks, and opportunities for improvements with state of the art technologies and easier workflows might be missed. The pharmaceutical industry especially is often reluctant to change. This is understandable when you keep in mind the efforts needed in paperwork and re-validation.<br>Presentations about future trends in laboratories are booming, generating great interest in progressive development, which is in contrast to conservative practices in many laboratories.<br>With "fit for future" projects, the digital transformation is growing quickly in many labs today. For quality control labs, this is a consequence of regulatory pressure. For R&D labs, this is a question of business benefits and increasing efficiency, reducing cost while improving data quality.<br>At the end of 2020, US Pharmacopoeia published a Draft General Chapter 1220 with a new method lifecycle model for ISO 17025 and GMP processes. This includes method development as the most important step and recommends leaving enough design space for update flexibility. |
| **14.15** | **WATERS**<br>Title: Method Migration<br>Presenter: Rainer Rozenich | ABSTRACT<br>- **Purpose**:<br>**Keep the lab operational when instruments models become no longer available**<br>**Successfully implement legacy (pharmacopoeia) methods on modern equipment**<br>- Difference between transfer and migration<br>- Regulations EP + USP<br>- Benchmarking the System Volume<br>- Moving the method under consideration of the system volumes<br>- Verification of method performance<br>(critical pair resolution, theoretical plates, S/N, linearity check, overlay detector channels, etc)<br>Checking AP and lab SOP, do we need to run change control measures? |
| **14.45** | **WATERS**<br>Title: How to Approach a Method Conversion (HPLC to or from UHPLC)<br>Presenter: Rainer Rozenich | ABSTRACT<br>- **Purpose**:<br>**Lower costs, increase capacity**<br>**Faster time to result (for IPC)**<br>**Maximize equipment occupancy**<br>- Benefits of HPLC and UPLC methods and weak points<br>- How to convert the method+ rules outlined by EP and USP<br>- Validation of the method, tips and tricks, demonstrate comparability of the results, how to submit the method to regulatory bodies<br>- Challenging strongpoints (risks) |
| **15.15** | **SOTAX**<br>Title: USP IV a compendial method for Novel Dosage form method development in R&D<br>Presenter: Mr. Michel Magnier/Product Manager Dissolution USP 4 | ABSTRACT:<br>USP 4 flow-through cell is the most efficient In-Vitro technique being compendial and flexible enough to acknowledge novel dosage forms constraints. During formulation every dosage form brings its own challenges and developing a corresponding In-Vitro method is not easier. An In-Vitro method has to be discriminant whether it has to differentiate formulations, manufacturing batches or to align an innovator and a generic product. With its unique possibilities the Flow-Through Cell offers more possibilities at the start, in R&D and even allows to work on APIs and intermediates while testing the final formulation. Automated, software driven and easy to qualify, the USP 4 flow-through cell dissolution has also its place in QC for a robust scale-up. In this presentation, you will hear about the possibilities of the USP4 technique over different dosage forms examples. |
| **16.00** | **MICROMERITICS**<br>Title: "Understanding Powder Behaviour Using the FT4 Powder Rheometer®" and presenting in the R&D session<br>Presenter: Dr. Jamie Clayton/Operations Director | ABSTRACT<br>Powders are challenging materials, as evidenced by frequent problems during storage, processing and final product quality. Powders are assemblies of solids, liquids and gases which results in complex behaviour that provides their industrial value – they can aerate to behave like a fluid or can compact into a tablet – but also makes characterisation difficult.<br>Powder processing equipment present various stress and flow regimes making it possible for a powder to behave a certain way in one operation but differently in another. It is critical that powders are compatible with the process environment and the final application.<br>Many powder testers don't deliver relevant information as the tests don't represent the process. The presentation will demonstrate how the FT4 Powder Rheometer® can be used to generate relevant data by measuring dynamic, bulk and shear properties enabling a powder's response to different stress and flow regimes to be quantified. |
| **16.30** | **WATERS**<br>Title: Empower LMS/Strategic Innovations<br>Presenter: Peter Gruener | ***Not available*** |

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## *(περιλήψεις παρουσιάσεων)*

## Wednesday 2/02/2022

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| **13.30** | **WATERS**<br>Title: How to Introduce the Concepts of AQbD into a QC Laboratory<br>Presenter: Rainer Rozenich | ABSTRACT<br>- **Purpose:**<br>**reduce number of OOX results in the lab**<br>- Explaining AQbD and the USP 1220<br>- Fishbone diagrams<br>- Risk mitigation by automation<br>- Risk mitigation by using right chemistry products |
| **14.00** | **WATERS**<br>Title: Automatization of Pipetting Routines<br>Presenter: Rainer Rozenich | ABSTRACT<br>- **Purpose**<br>**reduce risk of human errors**<br>**win back analyst time for data processing**<br>- Pipetting techniques (positive, negative, direct replacement)<br>- Use of Andrew Alliance pipette Plus or Andrew Alliance Robot<br>- Use of ACQUITY Sample manger functions such as vial mixing in needle or auto dilution via purge solvent<br>- Technical implementation via technical comparability report, then out roll subsequentially via change control |
| **14.30** | **METTLER-TOLEDO**<br>Title: European Pharmacopoeia-How to ensure compliance with the new Ph. Eur. General Chapter 2.1.7.?<br>Presenter: Mrs. Simona Venzin/ Head of Service Product Management (and Ph. Eur. Campaign Manager) | ABSTRACT<br>Learn everything you need to know about the new Ph. Eur. General Chapter 2.1.7 "Balances for Analytical Purposes".<br>• The key elements of General Chapter 2.1.7 "Balances for Analytical Purposes"<br>• The similarities and differences between Ph. Eur. and USP requirements<br>• Why calibration is an essential task in a quality management system<br>• The specific performance checks required to assess the accuracy and precision of an instrument<br>• How GWP, a scientific standard, supports compliance with General Chapter 2.1.7 |
| **15.15** | **CEM**<br>Title: Microwave sample preparation for the analysis of elemental impurities in pharmaceutical formulations and raw materials, following new USP 232 and 233, as well as older EUPharm methods.<br>Presenters: Messers. Axel Schoener/Director of distributor sales, EMEA and Southern Asia & Maxim Diel/International Technical Specialist | ABSTRACT<br>Known limitations with USP Chapter <231> – Heavy Metals, which was written in 1905, have led to the development of new methods for the preparation and analysis of pharmaceutical samples. The proposed replacements, USP Chapters <232> and <233>, were first published in January of 2010. USP Chapter <233> discusses the sample preparation and analysis procedures for the determination of heavy metals in pharmaceutical raw materials and finished products. The chapter outlines four sample preparation techniques: Neat, Direct Aqueous Solution, Direct Organic Solution, and Indirect Solution. Most pharmaceutical raw materials and finished products will require the Indirect Solution technique, a closed vessel digestion in a concentrated acid solution that solubilizes the sample for analysis via an inductively coupled plasma optical emission spectrometer (ICP-OES) or an inductively coupled plasma mass spectrometer (ICP-MS). Microwave digestion instrumentation offers several advantages over other digestion techniques, such as hot plates and hot blocks, including rapid heating in sealed containers to provide greater control of volatile elements, more complete destruction of background organics, and lower acid consumption. Temperature and pressure control options available on microwave digestion systems allow for more reproducible digestion conditions, as well as rapid turnaround of digested samples. In addition, it allows for precise documentation of the preparation conditions of every sample . In addition to the new USP 232/233 methods, we will look at earlier microwave digestion methods outlined in EUPharm e.g. general chapter Heavy metals (2.4.8). 2.4.8 will eventually be replaced by 232/233. |
| **15.45** | **MALVERN-PANALYTICAL**<br>Title: The role of XRD and XRF in Pharma Products<br>Presenter: Dr. Robert Taylor/Segment Marketing Manager | ABSTRACT<br>The time pressures to develop and qualify new and generic drug products continues to present a major challenge. Technology lies at the heart of the solution and X-Ray Fluorescence and X-Ray Diffraction are two stalwarts of drug substance and product characterization that help towards this end.<br>Despite the common source of radiation used in these techniques; they both use X-rays, their applications are very diverse. This talk will discuss those differences and highlight the processes which they support. From solid-state screening in lead optimization to identification and quantification of impurities in products, the data captured represents a broad range of interest. This can help inform development decisions and meet regulatory requirements. |
| **16.15** | **MICROMERITICS**<br>Title: The importance of pycnometry and mercury porosimetry in characterising tableted medicines and pharmaceutical ribbons.<br>Presenter: Dr. Luca Lucarelli/Technical Analytical Consultant | ABSTRACT<br>The physical characterisation of pharmaceutical products and intermediates is key to fully understanding their performance. Porosity, surface area, particle size and density are all useful quantities that can be studied during the manufacturing process and for final product delivery and efficacy. The particle size of raw materials such as lubricants or disintegrating agents in combination with production parameters directly influence the porosity and exposed surface area of the final product. Bulk, envelope, and skeletal density in addition to porosity and pore size distribution can also be correlated to liquid permeability, giving important insights towards product optimization throughout the manufacturing process. The proper interpretation of mercury porosimetry data obtained on some organic materials will be discussed in this presentation. |
| **16.45** | **SOTAX**<br>Title: Improving efficiency, throughput and Quality of QC batch Release Testing by fully automating dissolution and content uniformity testing<br>Presenters: Messrs. Rene Faessler/Product Manager Dissolution USP 1,2,5,6 & Duncan Tärran/Product Specialist-ASP | ABSTRACT<br>- Improving efficiency, throughput and Quality of QC batch Release Testing by fully automating dissolution and content uniformity testing<br>Improving efficiency, throughput, and Quality of batch Release Testing.<br>Automate your complete dissolution process USP <711> from preparing dissolution media and filling vessels to system cleaning at the end of each test run.<br>The ATF Xtend™ automatically prepares the media needed for your dissolution tests, heats & degasses it by vacuum, and precisely fills in all vessels.<br>On completion of a test run, all vessels are emptied, and the entire system cleans itself with robust customizable washing routines to be ready for the next run.<br>This automated process ensures perfect reproducibility, efficiency, and traceability. The ATF system is driven by our q-doc® Software which fulfils all needs in terms of data management.<br>In this presentation, you will see how the ATF is working through all of these automated steps<br>- Improving efficiency, throughput, and Quality of batch Release Testing.<br>Automate your complete content uniformity tests USP <905>from sample weighing, to extraction, to filtration, dilution for your analytical finish. The TPW – Tablet Processing Workstation for efficiency, throughput, quality, reproducibility, and traceability. The TPW is driven by our TPSoft 10 ® which fulfils all needs in terms of data management and for Data Transfer to Empower 3 |

# ABSTRACTS
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## Thursday 3/02/2022

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| **13.30** | **MALVERN-PANALYTICAL**<br>Title: Characterising Pharmaceutical Products - The Malvern Panalytical Tool Box<br>Presenter: Mr. Stuart Wakefield/Regional Manager - Middle East & India | The challenges facing the pharmaceutical industry are significant. The risks of developing novel drug products are high, with successful market introduction of a new therapy taking over 10 years and costing an estimated $3 billion. Although the demand for new products is high, healthcare providers and regulators are also looking to manage costs by actively promoting the introduction of generic medicines. Balancing the reward of new product introductions against the commercial risks of market success has never been harder.<br>Malvern Panalytical provides a unique set of analysis tools which enable rapid, robust and confident decision-making at all stages of the development workflow. Our technologies can accelerate the pace of early development, ensuring confidence in the selection of druggable targets and candidate molecules. Understanding and ultimately controlling the critical quality attributes (CQAs) and critical process parameters (CPPs) associated with defining and optimizing drug product performance alongside the demands on data integrity/validation is key. This short presentation will look at the tools available to assist with these challenges using OSD products as an example. |
| **14.00** | **MALVERN-PANALYTICAL**<br>Title: Complex Generics Characterisation<br>Presenter: Mr. Stuart Wakefield/Regional Manager - Middle East & India | In the face of increasing pressure on health care access and costs, regulators such as the US FDA are actively seeking ways to enable the rapid development and launch of new generic medicines. Within this, there has been significant focus on complex products, such as OINDP (orally Inhaled & Nasal Drug Products) and topical creams, where the delivery method and site of action makes bioequivalence assessments difficult using traditional in vivo approaches. As a result, many off-patent complex drug products are not subject to generic competition. The US FDA has therefore committed to providing improved scientific and regulatory clarity with respect to complex generic drug approvals, leading to the publication of product-specific guidance documents which outline the requirements for assessing in vitro bioequivalence by considering physicochemical (Q3) equivalence.<br>This presentation webinar will consider the workflows associated with evaluation of physicochemical (Q3) bioequivalence with reference to the measurement solutions offered by Malvern Panalytical. Example case studies will be shared, including data on topical cream and nasal spray formulations. |
| **14.30** | **MICROMERITICS**<br>Title: Determination of BET Surface Area – Methods, Applications, and Best Practice<br>Presenter: Dr. Katharina Peikert | ABSTRACT<br>Surface area and porosity play major roles in the purification, processing, blending, tableting, and packaging of pharmaceutical products as well as their useful shelf life, dissolution rate, and bioavailability.<br>In this presentation we will talk about the challenges that come with the BET method and the best way of applying it. Using examples from the pharmaceutical sector we will discuss sample preparation and setting up the best analysis parameters as well as how to use the Micromeritics Software to make most out of the BET measurements. |
| **15.00** | **SOTAX**<br>Title: Data Integrity from R&D, IPC/Production to QC<br>Presenter: Mr. Ramsey Khinda/Head of Sales & Marketing - Market Unit Europe | ABSTRACT<br><br>Compliance to current regulatory requirements on Data Management is business critical. Q-doc data Management software allows companies to have the full confidence of meeting such regulatory pressures. Ensuring Data Management SW is set up also ensure that compliance and COST saving are met. Q-doc is unique in that it allows full instrument control and data management of the AT Xtend dissolution line and the physical testing devices covering R&D, QC/Stability, IPC/Productions. |
| **15.45** | **MALVERN-PANALYTICAL**<br>Title: PAT – In process measurement of Milling and Granulation process in Pharmaceutical Industry<br>Presenter: Mr. Stuart Wakefield/Regional Manager - Middle East & India | ABSTRACT<br>While traditional end-product testing provides a measure of whether or not the required quality has been achieved, the application of process analytical technologies (PAT) enables the active maintenance of a product's specifications within its design space. PAT tools provide the means to understand and monitor CPPs and, as continuous processing gains momentum in pharmaceutical manufacturing, these in- and online analysis tools are essential to its enablement.<br>Particle size distribution is a critical parameter throughout many pharmaceutical manufacturing processes. This presentation will look at the application of fully-automated real-time particle size measurement and how it enables the continuous monitoring and control of processes such as milling, spray drying and granulation from development through to commercial manufacture. An overview of the technologies along with application examples and implementation will be shown. |
| **16.15** | **MICROMERITICS**<br>Title: Understanding Density Measurement Techniques for Improved Quality Control and Research and Development.<br>Presenter: Mr. Jack Saad/Applications Scientist Technical Training and Support Manager | ABSTRACT<br>A critical attribute that contributes to the quality of a manufacturing process is the density of the powdered or solid material. Density gives information about the amount of material in a given volume which can offer a prediction of how the powdered material will pack. Density also gives information on the amount of hollow cavities and/or porosity that could be present in a solid material. When characterizing a material using density, it is important to know what type of density is being determined based on how the volume is defined. In this presentation, we explore and compare Skeletal Density, Bulk Density, Envelope Density, and T.A.P. Density for some common pharmaceutical applications. These densities are determined by gas displacement, solid displacement, and liquid displacement using modern analytical instruments. |
| **16.45** | **WATERS**<br>Title: WATERS Mass Spec Systems & Appls in Pharma<br>Presenter: Mr. Dev Sriranganadane/Regional Business Development Specialist | ***Not available*** |