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International Society for Pharmaceutical Engineering

ISPE EUROPE ANNUAL CONFERENCE
MADRID, 30 DE MARZO/1 DE ABRIL

This year the International Society for Pharmaceutical Engineering ISPE will make its Annual Conference in Madrid.
The ISPE is the global industry leader in connecting pharmaceutical knowledge to deliver manufacturing and supply chain innovation, operational excellence and regulatory insights to enhance industry efforts to develop, manufacture and reliably deliver quality medicines to patients.
The ISPE triggers to provide solutions to complex pharmaceutical industry challenges through manufacturing innovation, member and workforce development, technical, regulatory, and compliance collaboration. In this role, ISPE is committed to the advancement of the educational and technical efficiency of its members through forums for the exchange of ideas and practical experience.
The theme for the 2020 ISPE Europe Annual Conference will be the "The Roadmap to Success" with key note speakers, four robust tracks and attractive plant tours.

What are the main topics in the key notes of the Annual Conference?
On Monday, the "Executive Forum" will focus on how new product types such as biologics and personalised medicine will increase pressure to develop innovative solutions for factory building and engineering solutions. In addition, the BREXIT brings certain challenges to pharma operations in Europe.

The Executive Forum will highlight these limitations with 6 keynote sessions. The keynotes will explore how companies address accelerated disruption in science and technology, the political environment for the pharma Industry in Europe and the environmental aspects of manufacturing.

Our programme features top speakers from the FDA, European Federation of Pharmaceutical Industries and Associations (EFPIA), Mo-

derna Therapeutics, Menarini Group, Jacobs and the World Health Organisation (WHO).

On Tuesday, top keynote speakers from big pharma manufacturers Eli Lilly, Novartis, Merck KGA, and Genethon will give insight into their approaches to innovation and how to form a successful next decade for their operations. The Spanish Agency of Medicines and Medical Devices (AEMPS) will talk about the regulatory developments in Spain. Joined by the European Medicines Agency (EMA) that will shed light on the current regulatory developments in Europe.

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What will be addressed in the 4 Tracks of the Annual Conference?

The tracks will focus on:

- Track 1: Facilities of the Future. Continuous manufacturing for oral solids and biotech; aseptic processing new improvements and technical innovations.
- Track 2: Pharma 4.0TM. What is the way to implement the new operating model with industry cases, application of maturity models, digitisation, self-learning devices, plug and produce and a holistic control strategy.
- Track 3: Quality and Regulatory. Validation, Annex 1, Annex 2, ICH Q13 and the FDA's continuous manufacturing draft guidance, Annex 17 real time release testing and continuous verification. What can industry do in order to avoid drug shortages?
- Track 4: New Trends in CQV and Impact on Project Delivery. Small molecules, API, biopharmaceutical operations, key controls for being more exible, more agile, more adaptive to changing product portfolio.

How are Regulators involved in the ISPE Annual Conference?

In addition to the key notes from EMA, FDA and AEMPS and presentations in the quality&compliance Track 3, for the first time, the 2020 ISPE Europe Annual Conference will introduce a regulatory panel as a plenary session. The panel will represent Regulators from EMA, FDA, United Kingdom, Ireland, Spain, Germany, Italy, Switzerland, Russia, WHO, PIC/S and EDQM. The panel will be divided into three groups:

1. Global inspection and compliance, chances to harmonise, to apply more mutual recognition and to reduce burden of inspections.

Moderator: Andy Hopkins, Abbvie, former MHRA.

2. Global harmonisation of regulation, pharmacopoeias and Technical Standards e.g. for aseptic processing, for mass serialisation, and others.

Moderator: Ron Ogilvie, Pfizer.

3. New quality management approaches for existing principles, triggered by new product types, digitisation, Industry 4.0, new processes and new regulations.

Moderator: Rico Schulze, Regulator from Sachsen/Germany.

What are additional opportunities for attendees?

Eli Lilly and Normon in Madrid will open their doors and organize guided plant tours for small groups of interested visitors right after the conference.

Another opportunity is to join ISPE Training as back to back to the conference on April 2 – 3, 2020 in Madrid. The offered topics are:

- A Risk-based Approach to GxP Process Control Systems: Applying the GAMP Good Practice Guide: A Risk-Based Approach to GxP process Control Systems (2nd Edition).
- Basic Principles of Computerized Systems Compliance using GAMP 5, Including Revised Annex 11 and Part 11 - Updated!
- GMP for the Pharmaceutical Industry.
- Applying the Biopharmaceutical Manufacturing Facilities Baseline Guide Principles Updated!
- Aseptic Processing and Annex.

Dr Zimmer, why has ISPE selected to go to Madrid this year?

Spain is a classic country for pharmaceutical production with many pharmaceutical manufacturing companies. Many medium-sized and family owned companies are among them. All major international pharmaceutical companies have operations in Spain. ISPE has a Spanish affiliate with many colleagues from production, engineering, quality management and other functions as members. Hosting an annual conference respects the work of our colleagues in the country and helps to promote ISPE's achievements in the country.

In addition to the conference, more than 100 exhibitors will showcase their innovative products and services that will help companies meet the challenges of the future and build a "pharma 4.0" environment!

We are looking forward to active participation of international as well as Spanish conference visitors.