

Workshop

Inspección y Revisión de Estériles

AGENDA

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| Barcelona Wednesday, 14 June 2017, at 9:00 a.m. Inibsa | Madrid Thursday, 15 June 2017, at 9:00 a.m. Pfizer |
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9:00 Reception

9:25 Welcome

Oriol Argemi, ISPE Spain Affiliate

9:30 *Particles & Fibers detection in CZ plastic cartridges and syringes filled with viscous product – A practical case*

Massimo Frasson, General Manager, Brevetti CEA

TOPIC KEY WORDS: CZ Plastic PFS, CZ plastic cartridges, particles & fibers detection, viscous product, automatic inspection.

Contaminates such as particles and fibers often represent a challenge in terms of detection, especially in case of high viscosity products. The application of plastic containers within the pharmaceutical production lines is constantly increasing, arising further new difficulties by the inspection world.

*Standard inspection techniques used to detect particles and fibers contained in glass containers cannot be applied on plastic containers.
Key topic is presenting a case study based on the direct experience of a major international pharmaceutical Company.*

The presentation will describe in details the right approach and possible solutions to reach successful inspection performances in CZ plastic cartridges and syringes filled with viscous product.

Auditors will have the chance of seeing real images and videos of the technique applied in this specific case.

Speakers will show and explain how the combination of special lights, algorithms and high resolution cameras can positively affect the inspection results.

10:15 *Inspection of milky and Viscous products in LVP*

Gaetano Baccinelli, Optrel

11:00 Coffee Break

Contacto

Para más información por favor contactar con conferenciasispe@ispe.org.es M: 683 112 430

11:20 *Container Closure Integrity Testing: Ensuring purity in parenterals*

Rupert Depner, Seidenader Maschinenbau, GmbH

We will highlight some aspects of CCI, a topic of growing interest.

What is CCI? Sterile product–package integrity (or container closure integrity) is the ability of a sterile product container–closure system to keep product contents in, while keeping detrimental environmental contaminants out. (USP 1207)

How can you test CCI? Solutions for liquid- and for lyo products.

12:05 *100% container closure integrity (CCI) testing using
headspace analysis or vacuum decay method*

Dr. Wolfram Schindler, Bosch Packaging Technology

Defect types and leak sizes

Physical fundamentals of the testing methods laser-based headspace analysis and vacuum decay

Selection of the right method according to the product requirements and properties

12:40 Workshop Wrap-Up

Oriol Argemi, ISPE Spain Affiliate

12:45 Plan visit: Inibsa in Barcelona. Pfizer Biotech in Madrid

14:00 Lunch/ Branch



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