



63 SIMPOSIO AFI
RIMINI 5·6·7
GIUGNO 2024



Associazione Farmaceutici Industria
Società Scientifica

DIGITAL WORKSHOP

PACKAGE INTEGRITY: INDUSTRY STANDARDS AND MEASUREMENT PRINCIPLES



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16 MAGGIO 2024 - ORE 14:30/16:30

The presentation explores the complex world of pharmaceutical manufacturing standards and regulations, with a specific focus on the integrity testing of containers for sterile medicinal products. It discusses the evolution of Annex 1 guidelines, highlighting the importance of container closure integrity testing, especially for containers closed through fusion methods. The emphasis is on the shift to more stringent testing requirements, stressing the need to assess, manage, and monitor parameters that impact seal integrity during operations.

Additionally, the presentation dives into the intricacies of primary barrier packaging standards established by ASTM, underscoring the role of package design and development in guaranteeing the integrity of pharmaceutical products. It touches on various testing methods used, from vacuum decay to vacuum deflection, each essential in upholding the quality and safety of parenteral bags, vials, ampoules, and blister packs.

Essentially, the presentation acts as a detailed guide to the precise procedures involved in container closure integrity testing, merging aspects of GMP regulations, ASTM standards, USP1207, and Annex guidelines to maintain the highest standards of quality and safety in the production of sterile medicinal products.

MODERATOR - SPEAKERS

Marco Adami - AFI

Philip Cooper - Chairperson of the ASTM F240 Package Integrity Sub-Committee

Stefano Menghini - Sales Manager - Emme 3

Eibhlin Owen - Area Sales Manager - Sepha



AGENDA

- Moderator:** Marco Adami - AFI
- 14:30-14:45** **EMME 3 – Introduction**
Stefano Menghini - Sales Manager - Emme 3
- 14:45-15:00** **SEPHA – Introduction**
Eibhlin Owen - Area Sales Manager - Sepha
- 15:00-15:30** **CCIT – Navigating Evolving Industry standards & Measurement Principles**
Philip Cooper - Chairperson of the ASTM F2.40 Package Integrity Sub-Committee
- 15:30-16:00** **Blister Package Integrity – Ensuring Quality & Compliance**
Philip Cooper - Head of Technology & New Product Development - Sepha
- 16:00 – 16:30** **Q&A**

SEPHA

SEPHA, part of TASI group, was founded in 1980 and has established a global reputation for innovation and development of specialised, high quality equipment for use in the manufacture of pharmaceutical blister packs, medical device and healthcare products. Our products enable customers to create high quality blister packs, to accurately detect leaks and weak seals in packaging, and to recover high value products from blister packs.

<https://sepha.com/>

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Participation is free of charge upon registration to be made by the day before the webinar.

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