KEY POINTS

The following key points are discussed:

• Container-closure integrity is a critical property of a pharmaceutical product. This attribute is especially important for sterile products. The US Food and Drug Administration guidance has categorized container-closure risks for common pharmaceutical products including degree of concern associated with route of administration (highest-low) and likelihood of packaging component-dosage form interaction (high-low). Sterile product container closure systems are described for most common sterile products including ampoules, sterile vials, and other systems. Multiple integrity test methods including microbial immersion test, microbial aerosol challenge, bubble test, and other methods are described.

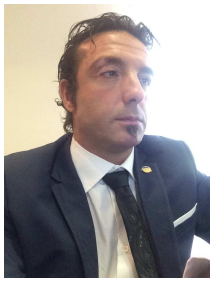
Validation considerations for integrity tests are discussed.

INTRODUCTION

One of the main purposes of a container closure system is to protect its contents from the surrounding environment. In the case of sterile products, this means maintaining the sterility of the product. The container-closure system may also need to protect the product from other potentially harmful agents such as light, moisture, and oxygen. This paper discusses container-closure integrity—maintaining the sterility of the product plus protecting the product from moisture and oxygen. It further discusses various test methods used to test for container-closure integrity.

The US Food and Drug Administration defines a container-closure system as the following:

"A container closure system refers to the sum of packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection to the drug product. A packaging system is equivalent to a container closure system"

	***Presented by**:* *Andrea Simonetti* *Director of Pharma* ***Bonfiglioli Engineering**a a **TASI GROUP** Company*	*Manage the global pharmaceutical initiative at TASI APTI group. Design and implement business initiatives and strategic development activities by leading and overseeing the activities of an international team. Create synergies with other companies and industry associations and foster positive business relationships with clients by supporting multilateral cooperation and generating added value. In 2010 started providing educational support to US Food and Drug Administration - Office of Pharmaceutical Science. Currently working with PDA "Technical Report 27 – Pharmaceutical Package Integrity" and Prefilled Syringes task force teams*
	***Prepared by**:* *Gaetano Fiorentino* *President PDA Italy*	*Many years of experience in the management of facilities and production of Parenterals. Great knowledge of vision systems management software and monitoring SCADA Expert in all process validation and new plant and machinery.Development and realization of machines prototypes in order to improve the quality and productivity. Continuous improvement of quality and economic production in the crops in being and existing plants. Management documentation and staff training. Continuously updated on new technologies and the feasibility study on the potential for their use in the pharmaceutical environment.*

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Container Closure Integrity & Visual Inspection

Regulations, Theory, Test Methods and Applications of CCI Innovations including Hands-On Activities

AGENDA

09:00. Welcome and Introduction

a) Presentation of participants

b) Scope of the training

c) Agenda for the day

10:00 Technology Overview: Non Destructive Test and Inspection Methods for Parenteral Containers

a) CCIT: Vacuum Decay, Pressure Decay, Lid Deflection, Force Decay

b) Visual Inspection: Detection of Critical, major and minor defects

c) Headspace Gas Analysis: Monitoring Oxygen + Moisture Level & Absolute Pressure in the headspace of sterile parenteral containers

11:00 Regulatory Requirements and Pharmacopeial Updates

a) EU, US, Other Countries

12:00. Technology Detail: Each Test and Inspection Method is Detailed

a) Principle of operation

b) Industry case studies

c) Challenge tests

d) Validation approach

e) Lessons learned

13:00 Lunch Break

14:00. Hands-On:

1. Laboratory:

a) How to set-up and run off-line test and inspection systems

b) Creation of positive controls and reference standards

c) Testing and process validation

d) Practical live demonstration

15:30 Lunch Break

16:00. Hands-On:

2. Production Area:

a) Analysis of a 100% in-line Headspace Gas Analysis equipment

2015 PDA Italy Conference, Workshop

Container Closure Integrity & Visual Inspection

10 December | Ferrara | Italy

2 WAYS TO REGISTER

1. **ONLINE: https://www.pda-it.org/CCI**
2. **EMAIL: elena.baccalaro@congressiefiere.com**
3. **EMAIL: dt-fiorentino@italfarmaco.com**
4.

Your Contact Person is
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9 For assistance contact: Gaetano Fiorentino, President PDA Italy

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