

The Parenteral Drug Association Italy Chapter presents

2013 PDA Italy Chapter Forum

Visual Inspection and Leak Test: Updates on Regulations, Technologies and Applications by End Users in Sterile Products



Absence of particles and Container Closure Integrity are amongst the main aspects to consider in the manufacturing of sterile products.

In recent years, a number of recalls from the market, as well as critical observations during GMP inspections prompted pharmaceutical companies to find improved technical solutions and raise their quality standards. With the spirit of supporting the Pharmaceutical Industry in achieving the expected improvements, the PDA Italy Chapter is pleased to invite you to the 2013 Visual Inspection & Leak Test Forum. In this one-day conference, you will be provided with all the latest news and updates in the field.

Pharmaceutical companies operating in national and international markets will share with you interesting case studies on the subject and vendors will present the latest technology of automated Visual Inspection and Leak Testing available to date. Also, the perspective and expectations of regulatory agencies will be illustrated by one of the most acknowledged experts in the field.

Chair of the Forum: Mauro Giusti - Director - Eli Lilly Italia, Technical Svcs/Mfg. Science & Mfg Sourcing/Vendor Mnngt

10.00 - 10.30	Attendees Registration	
10.30 - 10.45	Welcome and Introduction	Walter De Matteo <i>PDA Italy Chapter President</i> <i>Microbiological Laboratory Mgr. IBSA</i>
10.45 - 11.15	Visual Inspection of Injectable Products: An Update on Recent Technical and Regulatory Trends	John Shabushnig - <i>Ph.D. Principal Consultant Insight Pharma Consulting, LLC</i>
11.15 - 11.45	New Steps in Automated Inspection Performances and Validation. A case study	Emanuele Cudiferro - <i>Service Manager Brevetti Cea</i>
11.45 - 12.30	Improvement in the inspection of ampoules tip in presence of liquid drops. A case study	Andrea Sardella - <i>Engineering R&D Manager, Optrel - Stevanato Group</i>
12.30 - 13.30	Lunch break	
13.30 - 14.15	The final quality concept for parenteral products - inspecting the complete production for container closure integrity, product quality, and foreign particles on one machine platform	Heino Prinz <i>R&D manager</i> <i>WILCO</i>
14.15 - 14.45	New approaches to detect floating, white particulated in Pre-filled syringes by means of automatic visual inspection machines	Massimo Mannini <i>Aseptic Operations Manager, Manufacturing Science & Technology, Novartis</i>
14.45 - 15.15	Cracks in prefilled glass syringes - avoid and detect	Nik Seidenader - <i>Consultant Seidenader Maschinenbau GmbH</i>
15.15 - 15.45	Coffee break	
15.45 - 16.15	A Proper Characterization of the Defect for Optimal Training of Personnel in Manual Visual Inspection	Eleonora Spanò - <i>Validation Specialist, IBSA</i> Davide Zacchia - <i>Sterile Production Supervisor, IBSA</i>
16.15 - 16.45	Non - destructive CCI testing strategies Development for various Parenteral Packaging Systems	Andrea Simonetti <i>Bonfiglioli Engineering</i>
16.45 - 17.15	Visual inspection of high volume biotechnology products in a computer manufacturing integrated environment: standard approach and case studies for specific exceptions	M. Rocchi <i>Eli Lilly</i>
17.15 - 18.00	Round Table Discussion	

Tuesday, 28th May 2013
Auditorium di Sant'Apollonia
Via San Gallo 25/a, Firenze - Italy

Do not miss this great opportunity to increase your knowledge and you company compliance status regarding Visual Inspections and Leak Testing!



Applications form: PDA IT FIRENZE 28 May 2013
(Please fill in block letters)

Last name: _____ First Name: _____

Job title: _____

Company: _____

Address: _____

Postal code: _____ City: _____

Phone: _____ Fax: _____

E-mail: _____

Venue

Auditorium di Sant'Apollonia, Via San Gallo 25/a,
(10 min walk from Firenze SMN Train Station)
Firenze – Italy.

Fees

130 € PDA members

160 € Non members

Fee is IVA free, in accord with art. 4, quinto comma DPR n° 633/72.

A receipt will be issued (Sarà emessa una ricevuta - non fattura - a fronte del pagamento effettuato).

Payment options:

Bank transfer to: PDA Italy Chapter, Loc. Salceto, 91- 53036 Poggibonsi (SI)

Bank address: Banca Monte dei Paschi di Siena, Agenzia di Poggibonsi,
Loc. Salceto, 95 - 53036 Poggibonsi (SI) – **Rif.:** PDA IT 28 maggio 2013 - Firenze

BIC: PASCITMMPOG

IBAN: IT55 T010 3071 9400 0000 2767 926

Send this application form to:

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+39 - 0577.98.07.62 (to Stefano Macciò)
- by e-mail: lucia_ceresa@europe.pall.com
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Planning Committee

Lucia Ceresa - *Pall Italia*
Giovanni Curotto - *Novartis*
Walter De Matteo - *IBSA*
Gaetano Fiorentino - *Italfarmaco*
Antonino Giannetto - *Consultant*
Mauro Giusti - *Eli Lilly*
Massimo Golia - *Pall Italia*
Gabriele Gori - *Novartis*
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Gabriele Peron - *Stevanato Group*
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