The Parenteral Drug Association Italy Chapter presents

2015 PDA Italy Chapter Forum:

Highlights from PDA Parenteral Packaging, PDA Aseptic Manufacturing and Update on PDA Annual Meeting, Regulations, Technologies and Applications by End Users in Sterile Products.

Thursday, 10 of September 2015
Hotel Londra - Firenze - Italy

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, have 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 2015 Parenteral Packaging & Aseptic Manufacturing Forum. In this one-day conference, you will be collect 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 available to date.

Do not miss this great opportunity to increase your knowledge and your company compliance status regarding Parenteral Packaging & Aseptic Manufacturing and all the implication on Environmental monitoring. Preliminary program:

09:00-09.45	**Attendees Registration**	
09.45-10.00	**Welcome and Introduction**	Gaetano Fiorentino – PDA Italy Chapter President QA Supervisor Inj. Mgr. ITALFARMACO
10.00-10.30	**Annex 1 : Key aspect and open issues**	**Giuseppe Ruggirello, CTP**
10.30-11.00	**Changes to GMP Annex 1 and cGMP force cleanroom re-classifications**	**Tony Harrison, Beckman Coulter Life Sciences -UK**
11.00-11.30	**Update and Revisions to USP <1207> Sterile Product Package Integrity Evaluation: Excerpts from Revision Expert Panel, PDA Europe Parenteral Conference 2014**	**Andrea Simonetti – PDA Expert Panel**
11.30-12.30	**A review of the Updated USP 1116: Implication on Environmental Monitoring and a case study**	**Claudio Denoya, PMS and USP expert USA**
12.30-13.30	**Lunch break**	
	Vendor section 13:30 – 14:30	
13.30 – 14.00	**Container closure integrity on liquid products : a synergy between high voltage and other vision inspection systems"**	**MATTEO COZZUOL, Brevetti C.E.A.**
14.00-14.30	**Techniques for leak test and particles inspection in plastic bags – a case study**	**Andrea Gallo, Convel srl**
14.30-15.00	**Industry Case Studies: Best Practice Approaches for Achieving Desired Quality of Parenteral Products: 100% Container Closure Integrity and Automatic Visual Inspection**	**Andrea Simonetti – Bonfiglioli Engineering Tasi Group**
15.00-15.30	**100% Container Closure Integrity Inspection Data for Lyophilized Product Vials: Lessons Learned**	**Derek Duncan - Lighthouse Instruments**
15.30-16.00	**Coffee break**	
16.00-1630	**Modern Concepts of Sterility Assurance for Aseptic Processes Aspects of Improved Environmental Monitoring Technologies**	**Gilberto Dalmaso, PMS**
16.30-17.15	**FDA's Major Observations in 2015 from 483's and Warning Letters for Pharmaceutical Manufacturers**	**D. Dills, Regulatory Affairs & Compliance Consultant - USA**
17.15-17.45	**Round Table Discussion and final consideration.**	

Chair of the Forum: **Mauro Giusti / Lilly**

Planning Committee
Lucia Ceresa – PMS
Gaetano Fiorentino – Italfarmaco
Massimo Golia – Pall Italia
Gabriele Peron – Stevanato Group
Walter De Matteo – IBSA
Stefano Macciò – CTP
Domenico Capestrani - CTP

GENERAL INFORMATION

Venue:
Hotel Londra Via Jacopo da Diacceto, 16/20
50123 Firenze
http://www.hotellondra.com/en

Registration Fees:
300€ PDA members
350€ PDA NON members
470€ new PDA members including the first year of membership - not renewal
700€ Sponsor + Table Top (2 pax)
900€ Vendor + Table Top (2 pax)

Fee is VAT free, in accordance with art. 4, quinto comma del DPR n° 633/72. A receipt will be issued, after the payment. (In quanto operazione esente dall'imposta, sarà emessa una ricevuta e 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 10 SETTEMBRE - Firenze**
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To register to the event visit
http://registration.congressiefiere.com/cmsweb/Login.asp?IDcommessa=C106/15&Lang=EN

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