



PDA IT chapter updates

“Aseptic filling: technological innovations and regulatory trends”

Pharmintech Bologna, 11th April 2019



Who we are...PDA in the world

- **PDA (Parenteral Drug Association)** is a pharmaceutical no-profit organization founded in 1946
- Leading **global provider of science**, technology, and regulatory information and committed to developing scientifically sound, practical technical information and expertise to advance pharmaceutical/biopharmaceutical manufacturing science and regulation with the final purpose of better serving patients
- PDA's governance is based on **regional chapters**: 14 chapters in USA and Canada, 5 chapters in EU (France, Ireland, Israel, Italy and UK), 1 chapter in LATAM and 6 chapters in APAC

«Our mission: connect people, science and regulation»



Who we are...PDA in Italy

- **PDA Italy Chapter** is strongly connected with the most important pharmaceutical companies based in Italy
- **PDA Italy Chapter** is committed, through its members and volunteers, to creating awareness and understanding of important issues facing community and industry

We are open to
welcome to join us
Further details on our
website: www.pda.org



WE WANT YOU!

participants are
desk and on our

Our Business Model

- **Different events format**
- Strong cooperation with **Italian Pharma Industries**
- Strong cooperation with **Machines, Services and Materials Suppliers** operating in the **Pharmaceutical Business**
- Possibility of **Sponsorship**





Our Structure

**Steering
Committee**

**Past Presidents
Membership Developer
Communication
Chapter Liaison and External Associations
Coordinator of Younger Professionals
Events Organizers
Subject Matter Experts**

**Executive
Committee**

**President
Vice-President
Treasurer
Secretary**

What's next?

PDA IT Chapter 2019 plans and events



PDA IT Chapter 2019 Goals





2019 events

- 11th April 2019 Conference, *Pharmintech Bologna*
“Aseptic filling: technological innovations and regulatory trends”
- June 2019 Congress, *Milan*
“Join conference with ISPE on Biotech”, *Milan*
- 18th September 2019 Technical training, *hosted by Corden Caponago*
**“Endotoxin and Pyrogen risk management in Pharmaceutical Industry:
advanced training”**



2019 events

➤ 9th October 2019 Conference, *Milan*

“Focus on the latest technological developments about Container Closure Integrity, Visual Inspection and worldwide regulatory directions”

➤ November 2019 Congress and Site Visit, *Rome*

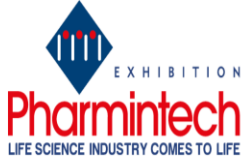
“ Single Use and Innovation Technologies to face new Regulatory Challenges”

➤ December 2019 Conference, *Florence*

“Annex 1: from guidance to practice”



Aseptic filling: agenda



10-12 APRILE, 2019
BOLOGNA, ITALY



Aseptic Filling: innovazioni tecnologiche e trend regolatori

GIOVEDÌ 11 APRILE 2019 POMERIGGIO (SALA PLENARIA PAD. 21)

PDA IT chapter and workshop introduction

Angela Molaschi, PDA IT Chapter President, NTC

Design and implementation of CIP&SIP systems applied to isolated filling machines

Andrea Zanotto, IMA

Quality by Design and innovation technology applied to a New RABS line

Patrizia Muscas, Eli Lilly

Aseptic Isolated Filling Line, QRM Approach and Case Study: the Comecer&IBI project

Simone Penazzi, Comecer and Luca Pezzano, IBI

Aseptic manufacturing through integrated solutions: advanced assembling zero defect lines

Alessandro Zannini, Stevanato

Q&A and round table



Thank you!