



Master Biennale di II livello in
Discipline Regolatorie "G. Benzi"



Master in Tecnologie Farmaceutiche e Attività Regolatorie
Università di Pavia

WORKSHOP

10th November, 2017

Data Integrity: reliability, quality and competitiveness factors of API manufacturers

Data Integrity: fattore di affidabilità, qualità e competitività del produttore di API

Aula Magna - Collegio VOLTA

Via Ferrara, 17 – Pavia

Opening remarks: **Mario Melazzini** – AIFA General Director

- 8.30-9.00** Registration of participants
- 9.00-9.10** Presentation of the workshop – **Maurizia Dossena, Carla Caramella (Master coordinators)**
- 9.10-10.10** Introduction to the theme: Data Integrity a logical outcome of Good Documentation rules
Marisa Delbò (AIFA)
Marina Figini (Aschimfarma)
Alessandro Regola (AFI)

Session 1 Data Integrity Definitions and Tools

- 10.10-10.35** ALCOA and data integrity: past and future - **Marina Figini (Aschimfarma/PCA)**
- 10.35-11.00** Site Data Integrity Road Map: towards a goal – **Luca Cenacchi (Industriale Chimica)**
- 11.00-11.25** Paper, paperless and hybrid systems - **Anna Tarzia (AIFA)**

COFFEE BREAK

Session 2 Compliance with data integrity principles

- 11.55-12:20** Risk assessment approach to data integrity – **Donato Migliarino (Gnosis)**
- 12:20-12:45** Inspections to API manufacturers on data integrity by Authorities - **Marisa Delbò (AIFA)**

LUNCH

- 14.30-14.55** Remediation Plan: risk mitigation – **Lorenzo Valletta (Bracco Imaging)**
- 14.55-15.20** Data integrity: policy, SOPs, check-lists – **Rita Brusa (IMS)**

Session 3 Practical aspects and case studies

- 15.20-15.45** Data Integrity in the supply chain – **Donata Bensi (LDO)**
- 15.45-16.10** Laboratory assessment: case history - **Damiana Gentili, Tiziano Ruffilli, Chiara Bovio (Procos)**
- 16.10-17.00** Data Integrity: added value in a global approach - **Paolo Guardamagna, Teresa De Quarti (Bidachem)**

- 17.00** Closure and remarks