



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 Ferrata, 17 – Pavia

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

- 8.30-9.00 Registration of participants
9.00-9.05 Presentation of the workshop – **Maurizia Dossena, Carla Caramella (Master coordinators)**
9.05-9.10 Welcome from **Gian Mario Baccalini** – President of Aschimfarma

CHAIRMEN: Piero Iamartino and Alessandro Regola

- 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

CHAIRMEN: Giovanni Boccardi and Marina Figini

- 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, Elisa Reduzzi (Bidachem), Massimiliano Zorzan (Novartis-Sandoz)**

- 17.00 Closure and remarks