UNIVERSITÀ DEGLI STUDI DI PAVIA

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

Master in Tecnologie Farmaceutiche e Attività Regolatorie
Università di Pavia

WORKSHOP

23rd November, 2018

ASMF: GMP perspective and regulatory compliance from starting materials to API

ASMF: aspetti GMP e criticità regolatorie dallo starting material alla sostanza attiva

Aula Magna – Collegio A. Volta
Via Adolfo Ferrata, 19 – Pavia (PV)
University of Pavia (Italy)

Scientific Program

8.30-9.15	**Registration of participants**
9.15-9.30	**Introduction by Masters' coordinators**
9.30-9.40	**Welcome by Aschimfarma's President**
9.40-10.00	***Quality standards and guidances: overview related to the main Regulatory Authorities*** **- Luisa Torchio (Corden Pharma)**
10.00-10.20	***Starting material and API starting material: justification for the positioning in a multi-step process*** **- Cristian Sampaolesi (EDQM)**
10.20-10.40	***Compliance to D.Lgs219/2006: use and import of API starting material*** **– Marisa Delbò (AIFA) – in attesa di conferma**
10.40-11.00	***Traceability, supply chain and QP declaration: which impact for the drug product*** **- Alessandro Regola (AFI)**
	COFFEE BREAK
11.30-11:50	***Related substances: how to characterise and control the impurity profile of an API*** **– Cristian Sampaolesi (EDQM)**
11.50-12.10	***Solid state: why the increasing interest for the solid state of APIs?*** **– Marino Nebuloni (Redox)**
12.10-12.30	***Genotoxic impurities: impact on quality of APIs*** **– Antonella Volpe (Industriale Chimica)**
12.30-12.50	**Question time**
	LUNCH
14.40-15.00	***Modern trends in quality and regulatory aspects of herbal Extracts*** **- Ernesto M. Martinelli and Roberto Pace (Indena)**
15.00-15.20	**Herbal drugs - Marisa Delbò (AIFA) – in attesa di conferma**
15.20-15.40	***Analytical procedures and validation: how to guarantee the robustness of data and compliance with regulations*** **- Giovanni Boccardi (AFI)**
15.40-16.00	***Stability data and attribution of retest/shelflife*** **- Damiana Gentili (Procos)**
16.00-16.20	***Submission of data: ASMF or CEP?*** **- Marina Figini (P.C.A.)**
16.20-16.40	***Electronic submission: use of e-CTD*** **– Simonetta Conti (Euticals – part of AMRI)**
16.40-17.00	**Closure and remarks**