



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



FEDERCHIMICA
ASCHIMFARMA
Associazione nazionale produttori generici attivi
e interessati per l'industria farmaceutica

Master in Preformulazione, Sviluppo Farmaceutico e
Controllo di Medicinali



Master in Tecnologie Farmaceutiche e Attività Regolatorie
Università di Pavia

WORKSHOP

21st OCTOBER, 2016

Modern analytical techniques in Pharmaceutical Industry

Moderne tecniche analitiche nell'Industria Farmaceutica

A tool to support pharmaceutical quality and to ease regulatory process

Aula Magna - Collegio A. VOLTA

Via Ferrata, 17 - Pavia

Scientific Program

9.00-9.30 Registration

9.30-9.45 Welcome and introduction

1st session General aspects

9.45-10.10 **Eugenia Cogliandro (AIFA)** Analytical procedures under regulatory perspective: requirements to be considered in the assessment of the registration dossier

10.10-10.35 **Marina Figini (Aschimfarma/PCA)** Definition and analysis of critical parameters of an API to assure pharmaceutical quality

10.35-11.00 **Marino Nebuloni (Redox)** Analyses in outsourcing: from development to release of APIs

COFFEE BREAK

11.30 -11.55 **Silvana Bellini (EDQM)** Pharmacopea guidelines: new trend in modern analytical techniques

2nd session Spectroscopic analytical techniques

11.55-12.20 **Andrea Ruggiero (MHRA)** NMR Spectroscopy and the regulatory control

12.20-12.45 **Sara Branch (MHRA)** NMR in the view of European and US Pharmacopoeias

12.45-13.10 **Donata Bensi (LDO)** Heparin and Heparin-like substances: NMR as release analytical control

LUNCH

3rd session Separative and hyphenated analytical techniques

14.30-14.55 **Federica Bruno (AIFA)** Use of coupled chromatographic analytical techniques (HPLC/MS; GC/MS) in the registration of new medicinal products

14.55-15.20 **Ernesto M. Martinelli (Indena)** The powerful role of Chemometrics on analytical instrumental data in Quality Assessment of Herbal Extracts

15.20-15.45 **Annalisa Scali (Euticals)** Regulatory aspects of GS/MS HPLC/MS techniques as tools during the R&D study in an API development

4th session Miscellaneous

15.45-16.10 **Antonella Volpe (Industriale Chimica)** GMP and regulatory perspective inside development and validation of analytical techniques

16.10-16.35 **Marino Nebuloni (Redox)** Implementation of PAT in Pharmaceutical Industry

16.35-17.00 **Caterina Temporini (University of Pavia)** Application of HPLC-MS/MS to a fermentation product

17.00 Closure and remarks