



FEDERCHIMICA
ASCHIMFARMA
Associazione nazionale produttori principi attivi
e intermedi per l'industria farmaceutica



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



UNIVERSITÀ DI PAVIA
Dipartimento di
Scienze del Farmaco

Pharmacopoeias: overview, uses and related activities

A guide towards a correct use

University of Pavia (Italy)

17th November 2023 Aula Magna – Collegio A. Volta

Welcome and introduction

09:00 Registration of participants

09:30 Introduction by Masters' coordinators - **M. Dossena, M. C. Bonferoni, E. Calleri, S. Rossi, G. Sandri**

09:40 Welcome by Aschimfarma's President - **P. Russolo**

First session: The European Pharmacopeia - Moderators: **M. C. Bonferoni** and **G. Sandri**, University of Pavia

09:45 **Introduction to the Pharmacopoeias**

E. Cogliandro, AIFA / Ph. Eur. Commission Vice-Chair and F. Nappi, Istituto Superiore Sanità

10:05 **Ph Eur and other pharmacopoeias - The ICH harmonization process of compendial texts**

E. Cogliandro, AIFA / Ph. Eur. Commission Vice-Chair

10:25 **The control of medicines in EU: the role of the OMCLs**

F. Nappi, Istituto Superiore Sanità

10:45 Coffee Break

Second session: Other Pharmacopoeias - Moderators: **L. Torchio**, Aschimfarma and **P. Iamartino**, AFI

11:15 **From pharmacopoeias to industrial analytical control**

C. Tadorelli, Curia

11:35 **Chapter 5.26 implementation of analytical methods and comparison with Ph. USP**

E. Imbriani, Angelini

12:05 **An important general chapter: 2.2.46 and harmonized text**

G. Boccardi, AFI and M. Maiocchi, CPS Analitica

12:35 **Q&A Session**

13:00 Lunch

Third session: Certificate of Suitability - Moderators: **C. Caramella**, University of Pavia and **P. Iamartino**, AFI

14:20 **Presentation of EDQM activities in relation to Ph Eur.**

A. Melloni, EDQM

14:40 **CEP procedure -Toward CEP 2.0**

A. Melloni, EDQM

15:20 **CEP: challenges & opportunities deriving from the EDQM procedure**

A. Volpe, InsudPharma / Chemo

Fourth session: Miscellaneous aspects - Moderators: **G. Boccardi**, AFI and **L. Torchio**, Aschimfarma

16:00 **Herbal Drugs and Herbal Drug Extracts according to European Pharmacopoeia**

E. M. Martinelli, Indena

16:40 **Products of biological origin and pharmacopoeias and aspects of viral origin**

L. Valenti and J. Buzi, ICE

17:00 **Q&A Session**