UNIVERSITÀ DEGLI STUDI DI PAVIA

UNIVERSITÀ DI PAVIA

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

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

Associazione Farmaceutici Industria

Master in Tecnologie Farmaceutiche e Attività Regolatorie
Università di Pavia

WORKSHOP

22nd November, 2019

EUROPEAN, UNITED STATES AND JAPANESE PHARMACOPOEIAS: OVERVIEW, USES AND RELATED ACTIVITIES A GUIDE TOWARDS A CORRECT USE

Aula Magna – Collegio A. Volta
University of Pavia (Italy)

Scientific Program

8.30-9.00 Registration of participants
9.00-9.10 Introduction by Masters' coordinators: Maurizia Dossena, Carla M. Caramella
9.10-9.20 Welcome by Aschimfarma's President

First session: European Pharmacopoeia
Speaker: Cristian Sampaolesi (EDQM); Moderator: Giovanni Boccardi (AFI), Piero Iamartino (AFI)
9.20-10.00 Overview on Council of Europe, EDQM: history and framework of the European Pharmacopoeia. The structure of the Pharmaeurope
10.00-10.20 How is a monograph born, from the development proposal to the adoption and publication in EP.
10.20-11.00 Interactive section and demonstration on how to use and navigate the Ph Eur

COFFEE BREAK

Second session: US Pharmacopoeia
Speaker: Alex Fiechter, Consultant; Moderator: Marina Figini (PCA)
11.20-12.00 About USP: history, policy and rules
12.00-12.20 Pharmacopoeial Forum: a correct use of the tool
12.20-13.00 Interactive section (triggered by the moderators) and demonstration on how to use the USP

LUNCH

Third session: Japanese Pharmacopoeia
Speaker: Masami Kanzaki- CBC division Life Science; Moderator: Damiana Gentili (Procos)
14.20-14.40 JP History, policy and rules
14.40-15.00 JP Harmonization with other Pharmacopeias: process & expectations
15.00-15.20 JP in JDMF: PMDA expectations

Forth session: Certificate of Suitability
Speakers: Cristian Sampaolesi (EDQM); Antonella Volpe (Industriale Chimica); Marina Figini (PCA)
Moderators: Alessandro Regola (AFI), Giovanni Boccardi (AFI)
15.20-15.40 Certificate of Suitability: history, use and correct use. How and when to apply for a CEP - Sampaolesi
15.40-16.00 CEP: the industry perspective, perceived advantages and difficulties encountered - Volpe
16.00-16.20 Common deficiencies during the assessment of CEP dossiers, how to obviate - Sampaolesi
16.20-16.40 Beyond the CEP: the control strategy to assure quality of manufacturing - Figini
16.40-17.00 Q&A
17.00 Closure and remarks