UNIVERSITA' DEGLI STUDI DI PAVIA

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

Italian Biocatalysis Center

Master in Tecnologie Farmaceutiche e Attività Regolatorie
Università di Pavia

FEDERCHIMICA
ASCHIMFARMA

WORKSHOP

Quality and Regulatory: New Frontiers in API Manufacture

Pavia, 26th September 2014, 9:00 a.m.

Aula Jucci, Dipartimento di Biologia e Biotecnologie "Lazzaro Spallanzani"
Via Ferrata, 9 - Palazzo Botta 2 - Pavia

The University of Pavia (Master on Regulatory Sciences) with the support of Italian Biocatalysis Center and Aschimfarma, organises a Workshop focused on the quality and regulatory aspects for API production.

Scientific Program

9:00-10:00 Registration/Welcome

10:00-10:45 Marco Terreni (University of Pavia - Italian Biocatalysis Center)
From synthesis to bio-transformation: control and management of the quality of APIs

10:45-11:30 Helene Bruguera (EDQM - Council of Europe)
Definition of API starting Materials

Coffee break

12:00-12:45 Marina Figini (P.C.A. S.p.A. - Quality and Regulatory Working Group - Aschimfarma)
Biological substances:tracebility and safety

12:45-13:30 Carlotti Fulvio (GNOSIS - Italian Biocatalysis Center)
Comparative analysis between the possible regulatory approaches to GMP compliance

Lunch

14:30-15:15 Enrico Perfler, (EUDAX - Italian Biocatalysis Center)
Borderline medical devices and combined products

15:15-16:00 Isabella Marta (AIFA)
Implementation of directive 2011/62: what's changed in API's production & import in Europe

16:00-16:45 Annalisa Scali (Euticals – Regulatory Affairs Dept.)
How GDP guidelines impact on APIs manufacturers

16:45-17:00 Closure and remarks