

FEDERCHIMICA ASCHIMFARMA



Master in Tecnologie Farmaceutiche e Attività Regolatorie Università di Pavia





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

"cGMPs approach and regulatory overview applied to APIs focused on bio-products and semi-synthesis processes"

Pavia, 11th May 2012

Aula Grande, Dipartimento di Biologia e Biotecnologie "Lazzaro Spallanzani" Via Ferrara 9, Pavia

The Italian Biocatalysis Center, University of Pavia, with the support of Aschimfarma, organises a Workshop focusing on the following subjects:

- 1. Quality of APIs and fermentation products
- 2. EDQM and CEP
- 3. GMP and Inspection
- 4. Registration of biological products

Scientific Work Program

9:00-9:30	Participants' registration
9:30-9:40	Workshop Opening Dr. Maurizia DOSSENA, University of Pavia, Biology and Biotechnology Dept., Italy
9:40-10:00	<i>The role of Aschimfarma in Italian APIs' manufacturing scenario</i> Dr. Gian Mario BACCALINI, President of Aschimfarma, Milan, Italy
10:00-11:00	Quality of APIs and fermentation products Prof. Marco TERRENI ,University of Pavia, IBIOCAT President, EDQM Assessor for Certification procedure
11:00-11:20	Coffee break
11:20-11:50	<i>Quality problems for APIs used in essential medicines for developing</i> <i>countries: role of WHO and its pre-qualification program</i> Dr. Corinne POUGET, Former EDQM Head of Certification Unit, Consultant in Castres, France
11:50-12:30	<i>The EDQM Certification procedure and inspection program for API</i> <i>manufacturers</i> Dr. Helene BRUGUERA, Head of Certification Unit, EDQM, Strasburg, France
12:30-13:00	Process development and application of Q11 to semi-synthesis API processes Dr. Annalisa SCALI/Dr. Luisa TORCHIO, Regulatory Affairs Dept., EUTICALS Spa, Milano, Italy
13:00-14:00	Lunch
14:00-14:30	Registration of biological medicinal products in EU: a regulatory <i>perspective</i> Dr. Carla MARTINO, Scientific Administrator at European Medicines Agency, London, England
14:30-15:15	GMP and Quality Risk Management Process for multi product on fermentation and microfiltration equipment. Case study from class B1 products Dr. Fulvio CARLOTTI, Quality Assurance Director, GNOSIS Spa, Desio, Italy
15:15-16:00	APIs production, regulatory aspects and auditing activity Dr. Isabella MARTA, Head of API Inspection Unit, AIFA, Roma, Italy
16:00-16:30	Round Table
16:30-16:45	Closure of workshop
Chairmans: Dr. Maurizia DOSSENA, University of Pavia, Biology and Biotechnology Dept.	

Dr. Marina FIGINI, Quality and Regulatory Working Group, Aschimfarma

How to get

By train:

From "Milano Centrale" Station to Pavia Station by train. Then in the square in front of train station catch bus number 3 (direction "S. Lanfranco-Colombarone") or number 7 (direction "Maugeri"). Get off at Via Ferrata 9.

By car:

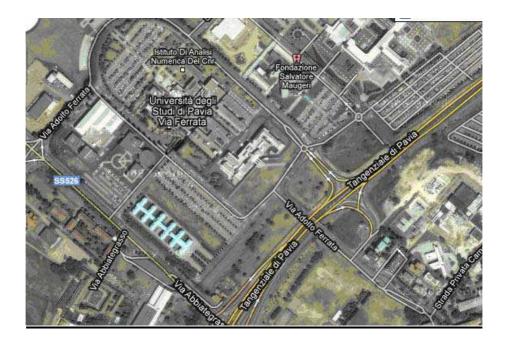
Highway A7 Milan-Genoa (exit Bereguardo / Pavia North): When indicated Bereguardo exit, take the highway connection Bereguardo-Pavia and then the west freeway, North Pavia direction, exit to "Universities", turn right twice and go straight for about 100m

Highway A21 Torino-Piacenza (Casteggio exit):

When indicated Casteggio-Casatisma exit, follow indications to Pavia, arrived in the town of San Martino Siccomario take the ring road of Pavia and follow the indication as given above for "A7".

Arriving to Pavia from various directions, follow the indications to Hospital Policlinico San Matteo and University Colleges. See the map.

<u>Map</u>



Registration fees: 150 Euro

Registration form:

http://www.italianbiocatalysis.eu/admin/files/Iscrizione%20REGULATORY%202012.doc

Please download the registration form and return it by mail (maurid@unipv.it) or by fax (038263986385) <u>not later than April 30th</u>.

Maximum Number of Participants: 60

<u>For further information please contact</u>: Dr. Maurizia Dossena, PhD Dipartimento di Biologia e Biotecnologie "Lazzaro Spallanzani" Università degli Studi di Pavia Via Ferrata, 9 - 27100 Pavia Tel e Fax : + 39 0382 986442; cell: 335 6238850