



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 ***The role of Aschimfarma in Italian APIs' manufacturing scenario***
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 ***Quality problems for APIs used in essential medicines for developing countries: role of WHO and its pre-qualification program***
Dr. Corinne POUGET, Former EDQM Head of Certification Unit, Consultant in Castres, France
- 11:50-12:30 ***The EDQM Certification procedure and inspection program for API manufacturers***
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 perspective***
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.

Map



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) **not later than April 30th**.

Maximum Number of Participants: 60

For further information please contact:

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