



## 1<sup>st</sup> International Symposium and Advanced Course

# “Active Pharmaceutical Ingredients from Bioprocesses: from research to industrial and regulatory issues”

**APIB-2009**  
*June 3-6, 2009*

**Aula Foscolo**

**University of Pavia  
Via Strada Nuova 65  
Pavia, Italy**

## SCIENTIFIC PROGRAMME



Master di 2° livello in  
Progettazione e Sviluppo dei Farmaci



Master Biennale di II livello in  
Discipline Regolatorie “G. Benzi”



**SCIENTIFIC WORKSHOP:  
RESEARCH AND DEVELOPMENT OF NEW BIOPROCESSES AND PRODUCTS**

**Wednesday 3 June 2009**

PL = Plenary lecture  
OP = Oral presentation  
IL = Invited lecturer

**Opening Session**

- 9h00-10h40 Registration
- 10h30-10h50 Opening Session: Welcome of the Authorities
- 10h50-11h10 **Presentation of IBIOCAT**  
Prof. Massimo Pregolato, University of Pavia, Pavia, Italy
- 11h10-11h30 Presentation of the Congress:  
**Research, production and Quality of Active Pharmaceutical Ingredients**  
Prof. Marco Terreni, University of Pavia, Pavia, Italy
- 11h30-12h20 PL1: **Rational strain and fermentation improvement for antibiotic production: from old successes to novel tools**  
Prof. Flavia Marinelli, DBSM, University of Insubria, Varese, Italy
- 12h20-12h40 OP1 **Optimization of a fermentation process for production of Tacrolimus.**  
Dr. Catia Piola, Biofin Laboratories s.r.l., Porto Mantovano (MN), Italy

**12h40-14h00: Lunch**

**Afternoon session**

**Chairman:** Prof. Flavia Marinelli, University of Insubria, Varese, Italy

- 14h00-14h40 IL1: **New insights on the optimizing and monitoring of biotransformation processes using systems biology**  
Prof. Manuel Canovas, Universidad de Murcia, Murcia, Spain
- 14h40-15h10 OP2: **Strategies for fermentative production of Superoxide Dismutase with *Kluyveromyces* spp.**  
Prof. Maddalena Rossi, Università di Modena, Modena, Italy
- 15h10-15h30 OP3: **Whole genome shuffling and fermentation media improvement as efficient tools for the rapid scaling up of production of drugs of microbial origin**  
Dr. F. Beltrametti, Actygea Srl, Gerenzano (VA), Italy.

**15h30-16h00 Coffee Break**

**Chairman:** Prof. Francesco Molinari Università di Milano, Milano, Italy

- 16h00-16h30 OP4: **Chemoenzymatic synthesis of (4a*S*,7a*S*)-octahydro-1*H*-pyrrolo[3,4-*b*]pyridine, chiral building block for the preparation of Moxifloxacin;**  
Dr. Riccardo Motterle, F.I.S. Fabbrica Italiana Sintetici, Alte di Montecchio Maggiore, Vicenza, Italy.
- 16h30-17h00 OP5: **Sustainable chemistry to the square: lipase catalysis in a green solvent for the preparation of drug intermediate**  
Prof. Andres R. Alcántara, Complutense University of Madrid, Madrid, Spain
- 17h00-17h20 OP6: **Enzymatic Synthesis Of Butyl Butyrate: Response Surface Methodology**  
Dr G. Vijaya Kumar, Vikas Institute of Pharmaceutical Sciences, Rajamundry – 533103 (India)
- 17h20-18h00 IL2: **Stabilization-reactivation of lipases by promotion of multipoint covalent immobilization**  
Dr Jose M. Guisan, CSIC, Madrid, Spain

**19h00-21h00 Welcome Cocktail**

## Thursday 4 June 2009

### Morning Session

**Chairman:** Prof. Andres R. Alcántara, Complutense University of Madrid, Madrid, Spain

9h30-10h20 PL2: **Enzymatic approaches in the preparation of oligosaccharides and glycoconjugates**  
Prof. Maria Josefa Hernaiz Gomez-Degano, Universidad Complutense, Madrid, Spain

10h20-10h50 OP7: **Synthesis of Fludarabine 5'-monophosphate (FAraA 5'-Mp) catalyzed by immobilized fruit fly deoxyribonucleoside Kinase (*Dm-Dnk*)**  
Prof. Jure Piškur, Lund University, Lund, Sweden

**10h50-11h20 Coffee Break**

11h20-12h00 IL3: **Evolution of new enzymatic activities: a case history**  
Prof. Loredano Pollegioni DBSM, University of Insubria, Varese, Italy

12h00-12h30 OP8: **Improved catalyst for the synthesis of Cephalosporins obtained by rational site-directed mutagenesis and immobilization of PGA**  
Prof. Marco Terreni, IBIOCAT; University of Pavia, Pavia, Italy

**12h30-14h00: Lunch**

### Afternoon Session

**Chairman:** Dr José Manuel Guisan CSIC; Madrid; Spain

14h00-14h30 OP9: **Biocatalysis for the manufacture of pharma intermediates**  
Prof. Francesco Molinari, University of Milan, Milan, Italy

**14h30-15h30 Presentation of selected Posters**

SP1: **Low-Cost production of industrial enzymes: the optimization of Acylase expression in *E. Coli***  
Dr F. Volontè, Università degli Studi dell'Insubria, Varese, Italy

SP2: **Chemo-enzymatic deracemization methods for the preparation of enantiopure non-natural alpha-amino acids**  
Dr D. Tessaro, Politecnico di Milano, Milano, Italy

SP3: **Synthesis of monodeprotected disaccharides by regioselective enzymatic hydrolysis of their peracetylated precursors**  
Dr Paolo Bonomi, IBIOCAT, Università degli Studi di Milano, Milano, Italy

**15h30-16h00 Coffee Break**

**Chairman:** Dr Sergio Riva, CNR, Milan, Italy

16h00-16h30 OP10: **One-Pot multistep enzymatic synthesis of steroid derivatives**  
Dr E. E. Ferrandi, Istituto di Chimica del Riconoscimento Molecolare, C.N.R. Milano, Italy

16h30-16h50 OP11: **New Nutritional Supplement: Georgian Zeolites Enriched With Extracts Of The Edible Plant**  
Dr J. Putkarade, Tbilisi State Medical University, Tbilisi, Georgia

16h50-17h30 IL 3: **Overview on new trends related to the role of biocatalysis on nutraceutics and nutraceutics industrial production**  
Dr Aurelio Viglia, IBIOCAT, Milan, Italy

**17h30 Closure of session**

**17h30-18h30 AIBB MEETING**

**20h30 Social Dinner**

**ADVANCED COURSE:  
INDUSTRIAL BIOPROCESSES AND QUALITY OF ACTIVE INGREDIENTS**

**Friday 5 June 2009**

**Morning Session**

8h30-9h30     Registration

**Chairman:** Dr Isabella Marta, EDQM/Council of Europe, Strasbourg, France

9h30-10h20     **Improvement of enzyme properties via immobilization techniques**  
Dr José Manuel Guisan, CSIC, Madrid, Spain

10h20-11h10    **Production of polypeptide antibiotics by biotransformation processes**  
Dr Auro Tagliani, ACS Dobfar, Tribiano, Milan, Italy

*11h10-11h40: Coffee Break*

11h40-12h10    **Products of fermentation: Monographs of European Pharmacopoeia;**  
Dr Hélène Bruguera, EDQM/Council of Europe, Strasbourg, France

12h10-13h00    **Development of industrial bioprocess and quality of active ingredients**  
Prof. Marco Terreni, University of Pavia, Italy

*13h00-14h10: Lunch*

**Afternoon Session**

**Chairman:** Marco Terreni; University of Pavia; Italy

14h10-14h40    **Microbial producers: from identification to development**  
Prof. Flavia Marinelli, DBSM, University of Insubria, Varese, Italy

14h40-15h10    **Basic procedures and control for fermentation processes**  
Prof. Francesco Molinari, University of Milan, Italy

15h10-15h40    **GMP for APIs manufactured by fermentation: Anthracyclines key study**  
Dr Fulvio Carlotti, Pierrel Spa, Capua, Italy

*15h40-16h10 Coffee Break*

16h10-17h00    **Innovative strategies for development and production of recombinant protein for therapeutic use**  
Dr Maria Luisa Nolli, Areta International s.r.l., Gerenzano (VA), Italy

**17h00-18h20 CONFERENCE ROUND TABLE**

# Saturday 6 June 2009

## Morning Session

**Chairman:** Dr Carla Caramella, University of Pavia, Italy

9h30-10h00 **Certificate of Suitability at the European Pharmacopoeia and revisions**  
Dr H el ene Bruguera, EDQM/Council of Europe, Strasbourg, France

10h00-10h30 **Sterility assurance: approach and risk management of an aseptic process**  
Dr Tony Valente, Pierrel Spa, Capua, Italy

**10h30-11h00: Coffee Break**

11h00-11h30 **EDQM inspection program**  
Dr Isabella Marta, EDQM/Council of Europe, Strasbourg, France

11h30-12h00 **Regulatory and practical aspects of potential leachables and extractables from elastomeric closures of injectable**  
Dr Bernardo Verrengia, Chief Regulatory Officer, Pierrel Spa, Capua, Italy

## **12h00-13h00 CONFERENCE ROUND TABLE**

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## **Partners**



Chemical Pharmaceutical generic Association



Italian Chemical Society  
Division of  
Medicinal Chemistry



PROVINCIA  
di PAVIA

AIBB (Italian Association of Biocatalysis and Bioseparations)  
CPA (Chemical and Pharmaceutical Association)  
SCI (Italian Chemical Society, Medicinal Chemistry Division)  
AIDIC (Italian Association of Chemical Engineering)  
SEBIOT (Spanish Society of Biotechnology)

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