European Directorate for the Quality of Medicines & HealthCare

Italian Biocatalysis Center

APIB 2011-Madrid

2st International Symposium and Advanced Course

"Active Pharmaceutical Ingredients from Biotechnology: from research to industrial and regulatory issues"

APIB-2011

2nd Edition
SCIENTIFIC PROGRAMME AND CALL FOR ABSTRACTS

June 14-17 2011
FACULTY OF PHARMACY, COMPLUTENSE UNIVERSITY.
MADRID

MEDICAMENTOS INNOVADORES
Plataforma Tecnológica Española

Italian Chemical Society
Division of
Medicinal Chemistry

AIM OF THE MEETING

The technology for the production of Active Pharmaceutical Ingredients (APIs) is improving with the aim of developing new products and bio-products, to reduce the process costs and improve the quality of final products. In this context, biotechnology plays a crucial role.
Bioprocesses based on modern biotechnology or conventional fermentations are often employed for the production of APIs. The use of bioprocesses is common for recombinant human proteins (including bio-generics) and traditional fermentation products, but is also becoming more and more employed for the synthesis, semi-synthesis or modification of several products of clinical use, including different biopolymers with biological activity (oligosaccharides, glycopeptides and peptides), and in the production of chiral building blocks for drug synthesis.
High performances (i.e. high product purity, quality control, reproducibility) are major issues of these processes. Regulatory requirements should take into account the constantly changing technological tools of biotechnology for ensuring suited control systems; on the other hand, R&D activities should consider right from the start the constraints of quality control.
EDQM (Council of Europe) in collaboration with the Spanish Society of Biotechnology (SEBiot), the Complutense University of Madrid, University of Pavia and the Italian Biocatalysis Centre (IBC) organize the APIB 2011 meeting, aimed at bridging the information gap in the field of biotech between people working in the fields of R&D, production and regulatory affairs. The symposium will cover the more recent improvements in the field of biotech R&D as well as information on the most important rules and technical aspects that should be considered for quality control in the bioproduction of APIs.
The symposium will cover the more recent improvements in the field of biotech R&D as well as information on the most important rules and technical aspects that should be considered for quality control in the industrial bioproduction of APIs.

More information and registration fees are available on the web page:
http://www.edqm.eu/en/APIB-2011-Madrid-Spain-14-17-June-2011-1405.html

SCIENTIFIC WORKSHOP:
RESEARCH AND DEVELOPMENT OF NEW BIOPROCESSES AND PRODUCTS

June 14-16, 2011

TOPICS

1) Research for new fermentative and semi-synthetic Active Pharmaceutical Ingredients and Nutra/Nutriceutic ingredients

2) Study and production of Bioactive polymers: Peptides (and peptidomimetics), oligosaccharides, and oligonucleotides

3) Proteins, glycoproteins and glycopeptides: vaccine and other therapeutic use.

4) New and improved strains and bioprocesses for biosynthesis and semi-synthesis of Active Pharmaceutical Ingredient

5) New and improved biocatalyst and enzymatic bioprocesses.

Call for Abstracts (oral communications and posters) and deadlines
Deadline for abstract submission : April 15, 2011
Decision for abstract acceptance: April 29 2011
on line submission: Click here

INVITED SPEAKERS

Prof. Peter H. SEEBERGER Max-Planck-Institute of Colloids and Interfaces Potsdam-Golm. (Germany) "Synthetic Carbohydrate Vaccines"

Prof. Loredano POLLEGIONI; University of Insubria; Varese; (Italy): "Enzymologists in wonderland: new biotech applications from evolved D-amino acid oxidases"

Prof. Francisco VALERO; Autonoma University of Barcelona (Spain); "*Pichia pastoris* as cell factory to produce recombinant proteins. Production and application of *Rhizopu oryzae* lipase".

Dr. Vitor Lino SOUSA Areta International; Gerenzano (Varese) Italy. "Needs and challenges for the development and GMP production of new biopharmaceuticals"

Dr. Fernando DE LA CALLE, PharmaMar, S.A.(Spain): "Production of a depsipeptide with antitumoral activity"

Prof. Jure PISKUR, Lund University, Sweden. "Plant thymidine kinases as suicide genes for anti-cancer therapy".

ADVANCED COURSE:
INDUSTRIAL BIOPROCESSES AND QUALITY OF ACTIVE INGREDIENTS

June 17, 2011

CONTENTS

- Industrial production and Quality of active ingredient: general concepts and specific topics for fermentation products, vaccines and recombinant proteins.
- Certificate of Suitability (CEP): general concepts and specific topics for fermentation (antibiotics, statins, aminoacids…. etc) and peptide products
- Industrial processes for biosynthesis and semi-synthesis of Active Pharmaceutical Ingredient.
- General regulatory requirement for industrial production of drug substances by fermentation processes (cGMP)
- Recombinant proteins: regulatory requirement for production of vaccines bio-active protein and biosimilars
- Regulatory and industrial aspect for sterile products.

INVITED SPEAKERS

Dr Sol Ruiz (Spanish agency of medicinal products-AEMPS; Madrid; Spain) "Quality of biotechnological products and biosimilars""

Dr. Carmen VELA; (Ingenasa; Madrid Spain). "Second generation vaccines: the long way to the market".

Dr. Carla Martino (European Medicinal Agency; London; England) "'Registration of biological medicinal products in EU: a regulatory perspective"

Dr Helene BRUGUERA (EDQM/Council of Europe; Strasbourg; France) The Ph. Eur and the monographs for fermentation products, peptides and biologicals – general concepts and practical examples

Dr Manuel IBARRA LORENTE (Spanish agency of medicinal products-AEMPS; Madrid; Spain) "General regulatory requirement for industrial production of drug substances by fermentation processes (cGMP)"

Prof Marco TERRENI; (University of Pavia; Pavia, Italy); Vice President of IBC "Biotransformation and quality of Active Pharmaceutical Ingredient."

Prof Flavia MARINELLI (University of Insubria; Varese; Italy) "Modulation of complex composition in fermentative industrial production of glycopeptides"

Dr. Fulvio CARLOTTI; (Gnosis S.p.a; Desio Italy) "Quality Risk Managment Process for multi product on fermentation and microfiltration equipment Case study from class B1 product to other products"

Corinne POUGET (Cunsaltant, Castres; France) "Quality problems for APi used in essential medicines for developing countries: role of WHO and its pre-qualification programme'"

Organizers

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Registration:

Spanish Society of Biotechnology (SEBIOT)
Registration by web: http://www.gestorsiasa.com/?congreso=22&opcion=1
Deadline for registration:
15 May 2011 without supplement.

Organization Committee

Ms Caroline Larsen Le Tarnec (EDQM; Council of Europe; Strasburg, France)
Ms. Francine Baumgarthen (EDQM; Council of Europe; Strasburg, France)
Prof. José M. Sánchez (SEBiot, University Complutense of Madrid; Spain)
Prof. Isabel de la Mata (SEBiot, University Complutense of Madrid; Spain)

Organization

EDQM (Council of Europe)
Spanish Society of Biotechnology (SEBiot)
Italian Biocatalysis Centre (IBC)
University Complutense of Madrid
University of Pavia

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