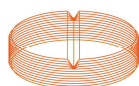
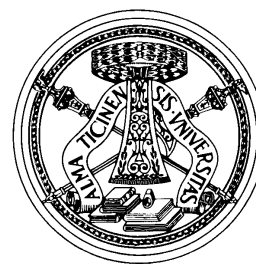
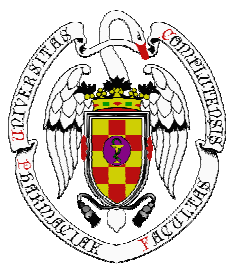




APIB-2011
“Active Pharmaceutical Ingredients from Biotechnology:
from research to industrial and regulatory issues”

2nd Edition

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



MEDICAMENTOS INNOVADORES
Plataforma Tecnológica Española

farmaindustria



Italian Chemical Society
Division of
Medicinal Chemistry

Aim of the meeting

Technology for the production of Active Pharmaceutical Ingredients (APIs) is improving, with the aims of developing new products and bio-products, of reducing production costs and improving 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 it is also increasingly employed for the synthesis, semi-synthesis or modification of several products for clinical use, including different bio-polymers with biological activity (oligosaccharides, glycopeptides and peptides), and in the production of chiral building blocks for drug synthesis.

Critically, drugs that do not meet official standards for quality, purity, packaging and labelling, can lead to serious health consequences including lack of efficacy, adverse effects, increased morbidity, mortality, as well as the development of drug resistance.

Bioprocessing offers significant advantages in terms of high performance (*i.e.* production of high purity, obtained with high yields). Regulatory requirements, however, should take account of the changing technological tools of biotechnology to ensure adequate control systems. Similarly, R&D activities should consider the need for proper process controls and product quality.

Therefore, regulatory authorities should engage closely with industrial applied research, development and production facilities to ensure a mutual exchange of information.

The 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), have organised the APIB 2011 meeting. The aim of this meeting is to bridge the information gap in the field of biotechnology 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 biotechnology R&D, as well as information on the most important rules and technical aspects that should be considered for quality control in the bio-production of APIs.

Topics

SCIENTIFIC WORKSHOP: RESEARCH AND DEVELOPMENT OF NEW BIOPROCESSES AND PRODUCTS

14-16 June 2011

- **Applied research for new products and bio-active polymers:**
 - Fermentation products;
 - Fermentative and semi-synthetic antibiotics and anti-tumoural drugs;
 - Bio-active polymers: peptides (and peptidomimetics), oligosaccharides, glycopeptides and oligonucleotides;
 - Proteins and glycoproteins;
 - Nutra/Nutriceutic ingredients.
- New and improved strains and fermentation processes.
- New and improved bio-catalyst and enzymatic bioprocesses.
- New bioprocesses for biosynthesis, semi-synthesis and modification of Active Pharmaceutical Ingredients.

Call for Abstracts (oral communications and posters) and deadlines:

Deadline for abstract submission: 20 March 2011

Decision for abstract acceptance: 31 March 2011

Abstract Submission: <http://www.gestorsiasa.com/?congreso=22&opcion=2>

ADVANCED COURSE: INDUSTRIAL BIOPROCESSES AND QUALITY OF ACTIVE INGREDIENTS 17 June 2011

- Quality of active ingredients: general concepts and specific topics:
 - Quality of fermentation products.
 - Quality of recombinant proteins.
- Certificate of Suitability (CEP): general concepts and specific topics:
 - CEP for fermentation products (antibiotics, statins, amino acids, *etc.*).
 - CEP for peptide products.
- Industrial processes for biosynthesis and semi-synthesis of Active Pharmaceutical Ingredients.
- General regulatory requirements for industrial production of drug substances (current Good Manufacturing Practice, cGMP).
- Recombinant proteins: regulatory requirements for production of bio-active proteins and biosimilars.
- Regulatory and industrial aspects for sterile products.

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>

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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.

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Ms. Francine Baumgarthen (EDQM; Council of Europe; Strasbourg, France)

Prof. José M. Sánchez (SEBiot, Complutense University of Madrid; Spain)

Prof. Isabel de la Mata (SEBiot, Complutense University of Madrid; Spain)

Organisation

EDQM (Council of Europe)

Spanish Society of Biotechnology (SEBiot)

Italian Biocatalysis Centre (IBC)

Complutense University of Madrid

University of Pavia

Partners

FARMAINDUSTRIA (Spanish Association for the Pharmaceutical Industry)

ASEBIO (Spanish Society of Biotechnological Industries)

SCI Division of Medicinal Chemistry

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