



EUROPEAN ASSOCIATION OF
PHARMA BIOTECHNOLOGY



Newsletter July 2009

Dear EAPB member or friend,

summer time we are enjoying and before you leave for well deserved vacation, EAPB wants to address you with 2009's second newsletter.

'How to improve and increase the benefits for EAPB members'

is in the focus of our interest. Therefore we are going to ask you about your opinion in the next newsletters for several items. In this issue we address the question of a members' journal. We thought about

'European Biotechnology News'.

The idea is to strengthen our EAPB members' network

- to give you as our members more visibility, beside our own website an additional platform to disseminate and publish your press releases, articles and products, your ideas and opinion
- to strengthen our communication in the European area
- to gain better contacts to other European networks, organizations, authorities and create stronger bonds to European bodies in Brussels or Strasbourg.

Well, we invite all of you to be part of this experiment! Give us your feedback! If you want to be reader and if you want us to be partner of 'European Biotechnology News', please send your reply with your contact data to managing.director@eapb.org by August 14, 2009. Get your impression via online version: <http://www.eurobiotechnews.eu/>. If there is a majority for a 'yes', we will have a test run for it. - I keep you posted!

Enjoy reading this newsletter!

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PharmSciFair, June 8 - 12, 2009, Nice - report and impression

PharmSciFair is the premier European Platform for Advancing Pharmaceutical Sciences, initiated by

EUFEPS taking place in Nice from June 8 - 12, 2009.

EAPB was responsible for the sessions 'Biotech derived Products' and 'Nano Delivery Systems'

Biotech derived Products

Jan van de Winkel focused in his keynote lecture on **Therapeutic Antibodies: trends & future developments**: 25% of all drugs in development are presently based on antibodies, 24 mAbs have currently been FDA approved for a wide range of diseases. Improvement of the therapeutic potential goes along with the modification of antibody effector function and the development of novel antibody formats, e.g. fully human therapeutic antibodies derived from human Ig-transgenic mice.

Carina Sonnega reported in the subsequent **Minisymposium: Cmc Aspects of First-In-Human (FIH) Studies with Biopharmaceuticals** on **CMC requirements for FIH studies with Biopharmaceuticals**. She provided an overview of the current global regulatory climate and focussed on particular quality aspects of pharmaceutical products derived from biotechnological processes. This was illustrated with a case study, accompanied by practical hints based on own experience.

Stefan Bassarab concentrated on the aspects of **formulation and process development for first-in-human biological products**. Predictability for small molecules is generally better than for biologics. The effective strategy for first-in-human formulation goes along with the analytical methods development, standard characterization methods and risk reduction by choice of reliable process equipment.

Key note lecture and minisymposium were well attended. On the ground of excellent lectures, intensive discussions and interactions with the participants followed.

Nano Delivery Systems

Cornelia Keck gave an overview about the **physicochemical characterization of nanoparticles**, i.e. size, charge and surface hydrophobicity. These characteristics determine the protein adsorption pattern in the body, and therefore e.g. tolerability and organ distribution. Optimized analytical procedures and characterization methods were introduced and evaluated.

Rainer Mueller reviewed **nanocrystals versus lipid nanoparticles as delivery systems** so far accepted at the market. Nanocrystals are the formulation of choice for biotechnological or plant derived molecules being poorly soluble in water or organic media. The lipid nanoparticles are suitable for drugs being lipophilic or soluble in lipophilic media and peptides which can be dissolved in the lipid matrix by solubilisation.

Robert Landsiedel reported about the **safety assessment of nanomaterials**, toxicity testing and the importance of understanding their uptake and distribution in the body indicating effects of the agglomeration state, surface area and the surface chemistry of uptake, distribution and effects of nanomaterials.

The **final EAPB presentation** by Cornelia Keck and Rainer Müller presented strategies **how to enter the market**, using as examples solid lipid nanoparticles and drug nanocrystals. Particularly addressed aspects were intellectual property, transfer to industry, state of excipients, large scale production and first product realization.

All abstracts of the conference you get [here](#). If you want more detailed information about special EAPB presentations please send your request to managing.director@eapb.org.

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Science to Market 2009

As a platform for European scientific research and biopharmaceutical industry the European Association of Pharma Biotechnology (EAPB) organizes the conference 'Science to Market' which takes place during

BIOTECHNICA on October 6 - 7, 2009.

The goal of this European event is the promotion of collaborations between science and industry in the sector of pharmaceutical biotechnology to enhance the economical output of scientific research and direct them into marketable technologies and biopharmaceutical products. The two day conference focuses on innovative biopharmaceutical drug and diagnostic developments and novel technologies for the development and production of those products.

In lectures, panel discussions and poster presentations second generation biopharmaceuticals, novel vaccines, gene therapy and many more topics will be discussed. CVs of speakers and abstracts of the presentations are available [here](#).

Find further [information](#) about the programme, sponsoring opportunities, poster contributions, prices, how to [register](#), etc.

Deadline for posters' submission: September 20, 2009!

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General Meeting EAPB, October 6, 5 pm, Hannover Convention Center

The EAPB Members' Assembly will be held in conjunction with Science to Market 2009 in advance of key note of Ernst Peter Fischer: 'How do we stay healthy? Dr. Darwin explains our evolutionary heritage' and the networking reception of this conference. We invite the attendees of members assembly to the key note and the reception as well!

Please reply by September 30, 2009 to managing.director@eapb.org and get the chance to win one of the five prizes we draw by the first 30 replies, a book of the keynote speaker of EAPB's Science to Market 2009, Ernst Peter Fischer. **'The Beauty and the Beast. The aesthetic moment in science'**. If you cannot attend personally, please use the [proxy](#) to send a substitute.

Agenda

1. Welcome by the President
2. Report by the President
3. Financial status of EAPB - report by the Treasurer
4. New location of EAPB
5. Election of board members
6. Amendment of constitution
7. Discharge of the Treasurer
8. Discharge of the Board
9. Miscellaneous
10. Key Note 'How do we stay healthy? Dr Darwin explains our evolutionary heritage' by Ernst Peter Fischer, University of Konstanz
11. Networking Reception

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If you find this newsletter interesting, feel invited to send me your feedback, we are open for further development to provide maximal value to all EAPB members. Feel also cordially invited to send articles for the next newsletter which is announced for October 2009. We appreciate your collaboration and input!

I look forward to hearing from you.

Yours sincerely,

Marion Kronabel

Managing Director EAPB



EAPB is the representative and central network to promote and develop Pharma Biotechnology in Europe, linking academia, industries and regulatory bodies.

Members are scientists (individual membership), companies, departments of companies and organizations from academia (corporate membership), but also industry, especially pharmaceutical industry and related sciences involved in pharma biotechnology.