



Newsletter March 2010

Dear EAPB member,

In the March edition of EAPB's newsletter the following information waits to be discovered by you:

EAPB's recently held Science to Market 2010 conference in Vienna was a successful event, you can find the panel presentations [here](#) and a short review in this newsletter.

As well the two special interest groups "Current Regulatory Aspects during Biopharmaceutical Development" and "Regenerative Medicine" have been inaugurated in February 2010. What was presented and how we started is documented on EAPB's website. How do we continue – you find in this newsletter.

As EAPB was partner for the conference "7th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology" – Malta, March 8 – 11, 2010, we provide a short comment on this conference.

EAPB reviews a book on "Protein Biopharmaceuticals".

And last but not least we want to draw your attention to upcoming events mentioned on EAPB's [website](#)

I hope you enjoy reading the spring edition of EAPB's newsletter, because it provides additional information which is not available on other occasions or platforms. I'm open to getting your feedback, comments, opinion – and contribution to the next EAPB newsletter which is planned for July 2010.

Yours sincerely,

[Marion Kronabel](#)
Managing Director EAPB

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Science to Market 2010, Vienna – impressions and wrap up

(by Marion Kronabel, Managing Director, EAPB)



The third Science to Market Conference just took place in Vienna (February 24 – 25). The aim of Science to Market is the promotion of cooperation between academia and industry in the area of pharmaceutical biotechnology. New in the concept was the focus on one item: "Posttranslational Modification" (PTM), since PTMs have a strong impact on the biologic activity of proteins and in consequence on their therapeutic potential.

With the "Science to Market" conference EAPB aimed at contributing to measures countering the European commercialization deficiency in biotechnology research and promoting the industrial application of scientific inventions. Dr. Wieland Wolf, president of the EAPB, resumed, "Only if we use the whole potential created by the results of public research we will reach the target of the "Lisbon Strategy of Growth and Employment", meaning the development of Europe to the most competitive and dynamic knowledge-based economic area of the world."

The conference laid emphasis on the poster presentations of scientists from universities and research institutions about their research and development projects to a forum of experts from the biotech and pharma industry, accommodating to the claim of networking. Topics were "Novel Therapeutics, Vaccines and Diagnostics" and "Novel Technologies", covering new up- and downstream developments, drug formats and analytical tools. The plenary lectures gave an overview about the diversity of posttranslational modifications and what they mean for the mode of action of biopharmaceutical products concerning efficacy and compatibility of therapeutically applied proteins.

The concept of diversity of conference locations and the concept to have a special conference focus can be regarded as successful. Therefore, EAPB starts working on the 4th Science to Market which will be in 2011 – location and item to be published soon.

Detailed information about former, the current and future Science to Market conferences and general information about the principal and ongoing activities of EAPB are available on the EAPB [website](#).

Accompanying the S2M conference two special interest groups were inaugurated with focus on "Regenerative Medicine" and "Regulatory Aspects during Biopharmaceutical Development" respectively.

These working groups want to constitute the link between regulatory specialists and developers / manufacturers of biopharmaceuticals and to work on joint fields of interest.

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SIG Regenerative Medicine

(by Joachim Noeller, Leipzig University)

The new Special Interest Group (SIG) had its inauguration meeting in Vienna, February 23, 2010, as a pre-meeting to the "Science to Market 2010" conference (February 24 -25, 2010). In the open forum on "Regulatory Aspects using Biopharmaceuticals in Europe" we discussed with Dr. Lucia D'Apote from the Committee for Advanced Therapy (CAT) Secretary of the European Medicines Agency (EMA) in London the important question "The Advanced Therapy Medicinal Products (ATMP) Regulation – the last step or hurdle to commercialisation of the scientific work?". Lucia D'Apote provided an excellent overview on the ATMP regulation along with the functions of the CAT, an expert-panel for the consultation of the corresponding decision makers, like the Committee for Medicinal Products for Human Use (CHMP). Companies should feel encouraged to address their questions as early as possible in the development process of a new advanced therapy and to use the chance of receiving a classification for their therapy, certification of quality issues (non-clinical as well as clinical) and the final evaluation of non clinical and clinical data.

The discussion specifically addressed the impact of new ATMP regulation on small and medium enterprises in Europe: this wealth of licensing requirements was not meant to stop or mediate research and development in regenerative medicine. Moreover, the ATMP regulation will strengthen the position of the companies and accelerate the development process in the future.

In a second talk, Timo Faltus from the Translational Centre for Regenerative Medicine in Leipzig focused on stem cell law in his overview "How can iPS-Cells be used for Regenerative Medicine Approaches – the situation within the European Community". He evaluated how stem cells and the recently discovered iPS-cells can be used for regenerative medicine approaches, provided first aspects as a key to translate conceptual research into clinical practice and raised excellent questions regarding the intellectual properties of iPS-cells and legal issues of this emerging technology in the future which stimulated a lively discussion of the audience.

In 2010 the group intends to promote the discussion and dissemination of new information related to stem cell technology for non- and therapeutic applications, addressing in this context also questions related to manufacturing and regulatory processes. Plans for next activities are proceeding in order to determine the right format of the next group discussion. The goal is to create a community of scientists working in regenerative medicine, stem cell biology and drug discovery. Next meeting will be published on the EAPB website and group members will get an email invitation.

If you are interested in contributing your input, please contact [Joachim Noeller](#) or fill out and send the SIG [registration form](#).

The next meetings of each SIG will be communicated via email (members) and posted on the EAPB website. Presentations for both SIGs are available on the EAPB [website](#).

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SIG Current Regulatory Aspects during Biopharmaceutical Development

(by Karoline Bechtold-Peters, Boehringer Ingelheim and Axel Wenzel, Pharma Scientific Services Team)

Organised by EAPB's two Vice presidents - Karoline Bechtold-Peters (1st VP) and Axel Wenzel (2nd VP) of EAPB and Director and Board member of EAPB's collaborating Regulatory Affairs Professionals organisation TOPRA) - the regulatory part of the afternoon session was dedicated to quality issues during drug development with special emphasis on Biotech product development.

Competent speakers had been recruited and gave their talks to initiate an intense discussion in the field:

- I.G. Reischl from AGES (Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH) on "Development of Biotech Products –The Clinical Trial Perspective"

- D. Kasulke from Boehringer Ingelheim on "Goals and status of the Mock submission document on monoclonal antibody products by EFPIA"

- M. Kaszkin-Bettag on "ATMP and the challenges for the design of clinical studies"

Dr. Reischl explained some of the major mistakes which she experienced for submission documents of biopharmaceuticals: Inadequate analytical methods, e.g. assessment of purity and product related impurities by SDS page only, or the batch characterized in detail is not the material used in preclinical or clinical studies. Furthermore, Dr. Reischl compared the US and the European regulatory and review system. Since national agencies in Europe accept individual clinical studies, the inadequacy of the whole body of data for submission of a biological may be evident only very late as opposed to the US system where the review process is more a continuous system often not changing even reviewers.

Dr. Kasulke described the EFPIA's attempts to provide a template for submissions of biologicals ("Mockstuzumab"). Based on Risk Assessments in which prior knowledge should be well considered, Critical Process Parameters (CPPs) are defined and their impact studied in process characterization studies. The Mock P2 document gives examples of how a QbD approach could be applied to an injectable. It outlines proposals for a systematic, knowledge driven approach including QbD principles and tools (risk assessment, DoE, design space etc.) which lead to a science and risk based assurance of quality. There are still items under discussion / not finally defined, such as the strategy for commercial scale process validation, or the Post Marketing Management Plan. More experience is eligible for such type of submission on both industry's and regulator's sides.

Prof Kaszkin-Bettag highlighted practical aspects. In practice there are still different unsolved problems, to numerous deviations in the development process, to reduced yields and rising costs than primarily to assurance of the product quality. Thus, for the MA applicant, it is questionable if there is any benefit in reality. There exists large scepticism whether the more information in the submission documents and the development studies to establish Design Space will bring more freedom during change control. So far there are little concrete executive instructions of the regulatory authorities how the permission requested flexibility is handled. For such cases the SIG can be a platform where legislators and industry can discuss together and find solutions coming from the practice.

Presentations are on EAPB's website, however the vivid discussions during and after the talks require personal participation. If further members are interested to actively contribute to the subjects of the SIG, to bring in further hot topics for discussion or simply want to be always informed about the newest regulatory developments, then feel invited to join the SIG. Contact one of our VPs [Karoline Bechtold-Peters](#) or [Axel Wenzel](#) or fill and send the SIG [registration form](#).

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7th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology (PBP), 8th to 11th March, 2010 in Malta

(by Karoline Bechtold-Peters, Boehringer Ingelheim)

More than 1100 scientists from academia and industry participated in the 7th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology organised by APV (International Association for Pharmaceutical Technology) and APGI (Association de Pharmacie Galénique Industrielle). EAPB co-sponsored this event.

During the four days of the conference, besides the more classical pharmaceutical topics also Protein and Gene Delivery as well as Nano and Microparticle Technology were given a broad forum. Two symposia on "Biopharmaceuticals" were well attended (more than 200 participants) and included talks on high concentrated formulations of proteins, protein coated microparticles, nasal delivery and delivery by nanocapsules. Hundreds of posters revealed that at universities plenty of research activities are underway essentially as regards these hot topics. The gala dinner in the medieval Knights' Hall of the Conference Center was impressing and enabled great discussions between the participants. Overall, the conference was well organized and appreciated by the participants. The next World Meeting will take place in Istanbul in 2012.

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Book Review

"Protein Pharmaceuticals - Formulation, Analytics and Delivery"

H.-C. Mahler, G. Borchard, H.L. Lueßen Editio Cantor Verlag, Aulendorf, Germany, ISBN 978-3-87193-382-0 Prize 126.- €

With more and more "biopharmaceuticals" - mostly protein drugs - entering the development pipelines and the market, this book comes at the right time. Containing contributions by more than 30 renowned authors from academia and industry, the current hot topic of protein drug development, its opportunities and challenges are discussed from various perspectives. Providing valuable inside information, this book covers the whole range of topics from protein chemistry to pharmacokinetics/ pharmacodynamics PK/PD, from protein analytics to packaging, and from protein formulation including various aspects in proven and emerging drug delivery approaches to regulatory issues. The major goal of this book, its practical relevance, is achieved and granted by the hands-on experience of all authors, who are directly involved in the various aspects of protein drug development.

This book has been evolved from several courses organized by the non-profit organization APV (International Association for Pharmaceutical Technology, one of EAPB's collaborating partner associations). Based on this experience, discussions between the speakers and the audience, the framework of the book has been created and it took three years of careful preparation until the result was finally out. The book is now the third edition of the APV pharmareflexions series and published by the ECV in 2010.

Here you find first impressions about [content](#) and an [excerpt](#).

For ordering and more information on the APV pharmareflexions series please follow the [link](#).

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