



Biopharmaceutical
Production Series

Most up-to-date
feedback from Paul-
Ehrlich Institut on the
biosimilar MAb
guideline

Presenting Informa Life Sciences' 8th Annual

BIOSIMILARS

Latest on the EU MAb guidelines, US biosimilar pathway, quality,
non-clinical & clinical issues and global market access

Wednesday 8 - Thursday 9 June 2011, Maritim Hotel, Berlin, Germany

Highlights this year:

- ✓ First-hand regulatory feedback on the impending MAb guideline, non-clinical issues and comparability with **MHRA**, **Paul-Ehrlich Institut** and **FAHMP**
- ✓ Discover how **Mylan**, **Sandoz**, **Teva** and **Merck** approach global biosimilar regulations, branding and the challenges of varying market access
- ✓ Hear the views of leading originator companies **Amgen**, **Genentech** and **Biogen Idec** on the impending MAb guidelines, US and Japanese biosimilar approval pathways
- ✓ Gain in-depth knowledge on biosimilar analytics, pharmacovigilance and clinical risk development plans with feedback from **Baxter**, **Merck**, **Takeda** and the **NIBSC**
- ✓ How successful have biosimilars been to date? Latest data from **Datamonitor** and **TikhePharma**, plus an interactive discussion session on biosimilar substitution & interchangeability

Key Regulatory Speakers:

- **Dr Steffen Gross**, Scientific Assessor and Laboratory Head, Deputy Head Section Monoclonal and Polyclonal Antibodies, **Paul-Ehrlich Institut**, Germany
- **Dr Anne Cook**, Biologicals Quality Assessor, **MHRA**, UK
- **Dr Karen de Smet**, Non-clinical Assessor, Federal Agency for Medicines and Health Products – **FAMHP**, Belgium

Key Industry Speakers:

- **Dr Mark McCamish**, Head Global Biopharmaceutical Development, **Sandoz**, Germany
- **Dr Rasmus Rojkjaer**, Head Global Biopharmaceutical R&D, **Mylan**, Switzerland
- **Dr Sandy Eisen**, Chief Medical Officer, **Teva Pharmaceuticals Europe**, UK
- **Dr Gillian Woollett**, Chief Scientist, **Engel & Novitt**, USA
- **Janet van Adelsberg**, Senior Director, MBV & Early Biologics, **Merck**, USA
- **Dr Hartwig Gajek**, Medical Director, **Baxter**, Austria
- **Dr Alex Kudrin**, Medical Director, Clinical Science, **Takeda Global Research & Development Centre**, UK
- **Dr Earl Dye**, Director Technical Regulatory Policy & Strategy, **Genentech**, USA
- **Chris Walker**, Director Regulatory Affairs, **Amgen**, UK
- **Dr Mohamed Oubih**, Senior Manager, Regulatory Affairs Development, **Biogen Idec**, UK

Pre-Conference Workshop X: Tuesday 7 June 2011

Critical Analytical CMC Studies for Non-Antibody and Biosimilar Products: Why, When, and How?

Led by: **Nadine Ritter**, Senior CMC Consultant, **Biologics Consulting Group**, USA

Evening Seminar Y: Wednesday 8 June 2011

Regulatory Evening Surgery

Led by: **Dr Keith Chidwick**, Pharmaceutical Assessor, **MHRA**, UK

Dr Robin Thorpe, Head - Biotherapeutics Group, **NIBSC**, UK
Keith Watson, CMC Principal Consultant, **PAREXEL**, UK

Evening Seminar Z: Wednesday 8 June 2011

Biologics - How all Sponsors, Originator and Biosimilar, can Benefit from the Biosimilar Debate

Led by: **Dr Gillian Woollett**, Chief Scientist, **Engel & Novitt**, USA

Post-Conference Workshop W: Friday 10 June 2011

From Development to Market - Biosimilar Monoclonal Antibodies in the EU and US

Led by: **Dr Carsten Brockmeyer**, Biosimilar Expert & Managing Director, **Brockmeyer Biopharma**, UK

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Critical Analytical CMC Studies for Non-Antibody and Biosimilar Products: Why, When, and How?

Registration 09.30 • Start 10.00 • End 16.00 • Lunch, morning and afternoon refreshments provided

Topics to be covered:

This workshop will clearly outline the international regulatory requirements and key technical strategies for biotechnological/biological products for CMC analytical and stability studies needed to generate the data necessary to accomplish these objectives. Specific attention will be given to the comparability study plans necessary for biosimilar products, which have greater safety concerns than generic forms of chemical pharmaceutical products. While sponsors of biosimilar products typically obtain regulatory relief from large scale clinical efficacy trials, greater regulatory attention is placed on the CMC elements.

This workshop will present the product characterisation and comparability study designs with increased focus on product and process impurities, as well as the challenges of incorporating the reference licensed product in comparability studies. The staged implementation of these studies by innovator, biosimilar, and contract organisations during each phase of product development will be discussed, as well as the quality practices that should be applied in the labs that generate critical data for product regulatory dossiers.

Led by:

Dr Nadine Ritter, Senior CMC Consultant, **Biologics Consulting Group**, USA

DAY 1: Wednesday 8 June 2011

08.30 Registration

08.50 Opening remarks from the Chairperson

09.00 Keynote presentation

Challenges with biosimilar accessPlease visit www.informa-ls.com/biosimilars to view abstractDr Mark McCamish, Head Global Biopharmaceutical Development, **Sandoz**, Germany09.35 **One little piggy had roast beef: Global biosimilars and the path to market**Please visit www.informa-ls.com/biosimilars to view abstractDr Rasmus Rojkaer, Head Global Biopharmaceutical R&D, **Mylan**, Switzerland

10.10 Morning coffee break

Biosimilar Regulation Overview and Update - Europe

10.40 **Update on biosimilars in Europe**

This presentation will review the evolving regulatory landscape for biosimilars in Europe, covering current trends for EU biosimilar approvals, and new and future guidelines. In addition, scientific advice and how to achieve the best dossier will be reviewed along with a discussion of some of the additional hurdles for biosimilars to access European markets.

Dr Sandy Eisen, Chief Medical Officer, **Teva Pharmaceuticals Europe**, UK11.15 **The European biosimilar monoclonal antibody guideline – an industry view**

This presentation will review nonclinical/clinical and pharmacovigilance considerations and ask what the strengths and weaknesses of the guidance are. Anticipated usefulness of the guidance for product development will also be discussed.

Chris Walker, Director, International Regulatory Affairs, **Amgen**, UK11.50 **Evolving biosimilar regulations discussion session**

This session will provide a chance to discuss evolving biosimilar guidelines in the EU and how these have, or could, influence other worldwide biosimilar regulations. Key questions to be considered include:

- How do definitions and opinions of biosimilars vary across the EU and more globally?
- What sort of regulatory trends and influences have we already witnessed?
- Anticipated impact of the impending US approval pathway

This discussion will consist of speakers from the earlier sessions

12.10 Lunch

Biosimilar Regulation Overview and Update - US

13.15 **Update on the state of play in the US on biosimilars**

This session will discuss the state of play, what the likely next steps by the FDA will be, and how this does or does not constrain sponsors willing to file applications. It will also include a compare and contrast with Europe, and discuss issues that the US pathway raises with respect to the possibilities of global dossiers for biosimilars, comparable to nature and extent that we have them today for originator biopharmaceuticals.

Dr Gillian Woollett, Chief Scientist, **Engel & Novitt**, USA13.50 **The new US biosimilar statute - What does it all mean?**

The US Patient Protections and Affordable Care Act of 2010 established an abbreviated approval pathway for biosimilar biologics. Although modelled after the Hatch-Waxman Act that governs approval of generic small molecules, the Biosimilars Act has unique provisions specific to approval of biosimilar biologics. An overview of the legal requirements for an application of a biosimilar biologic, including the intellectual property implications, will be given.

Dr Paul Calvo, Attorney, **Sterne, Kessler, Goldstein & Fox P.L.L.C.**, USA14.25 **Industry perspective on implementation of a US biosimilar approval pathway**

Enactment of the Biologics Price Competition and Innovation Act (BPCIA) in March 2010, established the legal framework for an abbreviated approval pathway for Biosimilars in the US. However, BPCIA contains only very general instructions regarding the expectations for a biosimilar application and authorises FDA to determine the amount of data required. This presentation will describe key aspects of the legislation, discuss FDA implementation activities, and address uncertainties regarding expectations for demonstrating biosimilarity, extrapolation of indications, interchangeability, naming, and selection of reference standards.

Dr Earl Dye, Director Technical Regulatory Policy & Strategy, **Genentech**, USA15.00 **Brand development of biosimilars -- The power of perception**Please visit www.informa-ls.com/biosimilars to view abstractEric Sjogren, Director, Strategic Business Intelligence, **Merck & Co.**, USA15.35 **Afternoon coffee break**

Join us for HIGH SPEED NETWORKING



Quality & Pre-Clinical Studies of Biosimilars

16.10 **SPOTLIGHT PRESENTATION**

These presentations are hosted by leading companies who work in the area of biosimilars and offer an opportunity to learn about the latest developments and technological advancements in the industry. If you would like to host a spotlight presentation, please contact james.miguel@informa.com or Tel: +44 (0) 207 017 5011

16.45 **Structural characterisation of biosimilar products**

Any manufacturer seeking to market a biosimilar product requires comprehensive physicochemical structural characterisation of the (glyco)protein. This is performed at three distinct stages of development: initially to determine the expected sequence of the target originator molecule, then to confirm the structure of the biosimilar and finally to provide comparative data for the biosimilar side-by-side with the originator molecule as required by various regulatory guidelines. Strategies for primary and higher order structure determination will be discussed particularly for antibodies where the size and complexity of the molecule requires LC/MS/MS approaches.

Dr Fiona Greer, Global Director, Biochemical Services, **SGS M-Scan**, UK17.15 **Unwanted immunogenicity of biosimilars & other biologicals**

This presentation will review the problem of unwanted immunogenicity for biologicals and how this specifically relates to biosimilars. Regulatory advice available on unwanted immunogenicity will be reviewed and the technical challenges with assessing the unwanted immunogenicity of biosimilars will be considered.

Dr Robin Thorpe, Head - Biotherapeutics, **NIBSC**, UK

17.50 Closing remarks from the Chairperson and end of conference day one

18.15 Registration for evening seminars

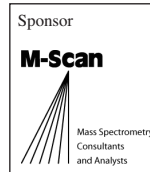
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EVENING SEMINAR AND DINNER Y • Wednesday 8 June 2010

Regulatory Evening Surgery

Registration 18.15 • Start 18.30 • End 20.30 • Dinner and refreshments will follow

This evening seminar will provide an opportunity for attendees to discuss regulatory challenges encountered specifically when working with non-antibody proteins and biosimilars. The leaders of this seminar will provide initial feedback on commonly encountered regulatory hurdles, before inviting the group to share individual issues.

Key areas that this seminar will focus on include:

- Biosimilars: how similar is similar? What is likely to be accepted by the regulator?
- Comparability: regulatory guidance on how to practically carry out comparability studies and get it right first time
- QbD: how applicable is QbD to non-antibody proteins? How can you ensure it is done correctly?
- Immunogenicity: how can key concerns and risks be measured and addressed? Can you predict this?

The above themes will constitute the main focus of the seminar however, there will also be an opportunity to discuss other issues that attendees wish to specifically mention.

Led by:

Dr Keith Chidwick, Pharmaceutical Assessor, **MHRA**, UKKeith Watson, CMC Principal Consultant, **PAREXEL**, UKDr Robin Thorpe, Head - Biotherapeutics Group, **NIBSC**, UK

Biologics - How all Sponsors, Originator and Biosimilar, Can Benefit from the Biosimilar Debate

Registration 18.15 • Start 18.30 • End 20.30 • Dinner and refreshments will follow

The development of biosimilars in the highly regulated markets has changed the prospects for originator biologics from indefinite monopolies to products requiring life cycle management. But, it has also led to a closer examination on the approval criteria for all biologics. What has the biosimilars debate meant for originator approval prospects, especially in the US? Will they make it easier for the way-cool-never-been-seen-before-in-nature-biologics ("way cools"), those truly innovative next generation of biotech products, to be approved, or will they make it more difficult?

Key areas that this seminar will focus on include:

- The FDA has yet to approve its first biosimilar, or even receive a 351(k) biosimilar application – does this mean the pathway is a failure? Should FDA encourage 351(k) applications and if so how?
- FDA can uniquely approve biosimilars as interchangeable, does this matter without any (k) applications?
- What do the BPCIA statutory requirements mean for all biologics - are the standards consistent for 351(a) "full BLAs" and 351(k) biosimilars? How can (k)s help (a)s, even though so far they have hurt them?
- How can biosimilars help us revisit our regulatory expectations, and make all applications, (k)s and (a)s more cost effective and timely?

Led by: **Dr Gillian Woollett, Chief Scientist, Engel & Novitt, USA**

DAY 2: Thursday 9 June 2011

08.20 Opening remarks from the Chairperson

Feedback from the Regulators

08.25 **Special requirements for demonstrating biosimilarity of monoclonal antibodies**

The current EMA guidance on similar biological medicinal products (EMA/BMWP/42832/2005) states that the comparative toxicity profile should be established in at least one repeat-dose study and that the studies should be of sufficient duration to allow detection of relevant differences in toxicity and/or immune response between the biosimilar and the reference product. Normally other routine toxicological studies such as safety pharmacology, reproduction toxicology, mutagenicity and carcinogenicity studies are not required for similar biological medicinal products, or might be included into the repeat toxicity study unless indicated of results of repeat dose studies, e.g. due to a different formulation used for a Biosimilar compared to the reference product. Finally, the current draft guideline on Similar Biological Medicinal Products Containing Monoclonal Antibodies also addresses clinical endpoints and potential extrapolation to certain indications.

Dr Steffen Gross, Deputy Head Section Monoclonal and Polyclonal Antibodies, Paul-Ehrlich Institut, Germany

09.00 **Quality issues with biosimilar products**

The EU guidelines for Similar Biological Medicinal Products are fairly broad and can be difficult to interpret in particular cases. What constitutes 'biosimilarity' and what type/how many differences are acceptable? The choice of expression system can also have an impact on the product quality and should be carefully considered, especially for glycosylated proteins. Product lifecycle changes are expected to occur, but may impact quality parameters in the Originator product. How might this affect the development of biosimilar products? These issues will be discussed with reference to case studies.

Dr Anne Cook, Biologicals Quality Assessor, MHRA, UK

09.35 **Non-clinical issues of biosimilars**

What are the current requirements for comparison of the pharmacodynamic effects, pharmacokinetic properties and toxicities of the biosimilar and the reference product? An overview will be given of non-clinical development of approved biosimilars. New proposals with respect to non-clinical guidelines for guidelines under development will be discussed (i.e. first discussions after release of Concept papers on rFSH, rIFN beta and the Draft Guideline on biosimilar mAbs).

Dr Karen de Smet, Non-clinical Assessor, FAMHP, Belgium, BMWP Member EMA

10.10 Morning coffee break

Clinical Studies for Biosimilars & Pharmacovigilance

10.40 **Case study: Biosimilar pharmacovigilance**

Please visit www.informa-ls.com/biosimilars to view abstract

Dr Hartwig Gajek, Medical Director, TA BioTherapeutics, Global Clinical and Medical Affairs, Baxter, Austria

11.15 **Clinical evaluation of biosimilars**

Please visit www.informa-ls.com/biosimilars to view abstract

Janet van Adelsberg, Senior Director, Merck BioVentures, Merck, Sharp & Dohme, USA

11.50 **SPOTLIGHT PRESENTATION**

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12.20 Lunch

Biosimilars Globally

13.20 **Case study: Global clinical development of mAb biosimilars by Celltrion**

Celltrion has successfully developed biosimilars of monoclonal antibodies in terms of structural, as well as functional comparability. Currently, Celltrion is successfully conducting global clinical trials of three lead mAb candidates, while two other products are in the preclinical stage. Other biosimilar candidates are in active development and being assessed for physicochemical comparability. We anticipate successful launch of the first two mAb biosimilars within a year.

Dr Stanley (SS) Hong, Senior Vice President, R&D, Celltrion, South Korea

13.55 **Insight into the Japanese Regulation & current market status**

The history of Japanese biosimilar market is quite recent but the market has witnessed dramatic developments with new entrants and alliances between Japanese and foreign bio-pharmaceutical companies. The two biosimilar products that have been approved so far in Japan are enjoying healthy growth. This presentation provides an overview of the regulatory framework of biosimilars in Japan, the latest trends in the Japanese biosimilar market and the impact of cultural aspects on the business

Dr Mohamed Oubih, Senior Manager, Regulatory Affairs Development, Biogen Idec, UK

14.30 **Regulatory challenges in extrapolation of new indications: Clinical data requirements and new concepts**

Please visit www.informa-ls.com/biosimilars to view abstract

Dr Alex Kudrin, Medical Director, Takeda Global Research & Development, UK

Biosimilar Market Overview & Analysis in the EU

15.05 **Biosimilars - The next big business**

We will assess the controversy of the promise of biosimilars vs their current performance in the EU market. Key success stories will be enlightened along with the lessons learnt. We will analyse the strategic impact of various factors affecting the uptake of current biosimilar brands with an in-depth overview of pricing & reimbursement policies. What have we learned so far? How is the market changing? Who will take the cream?

Mateja Urlep, Founder & CEO, TikhePharma, Slovenia

15.40 **Controversy of the biosimilars market - substitution/ interchangeability in the EU**

- Legal aspects
- Is it happening?
- How successful is this? How can we effectively gauge the success?
- How are biosimilars really viewed?
- Are some products more successful than others and why?

Led by: **Mateja Urlep, Founder & CEO, TikhePharma, Slovenia**

16.00 Afternoon coffee break

16.30 **Biosimilars: Disruptive challenge to the status quo or unmissable opportunity?**

Current market dynamics, key competitors and product approvals will be reviewed followed a look into a tale of two classes: commercial performance of EPO vs. human growth hormone. Key issues in relation to product attractiveness and potential hints on future performance will be discussed as well as understanding how much a biosimilar opportunity could be worth using NPV analysis. The question will be asked, what does the future hold for biosimilars, particularly the mAbs?

Dr Duncan Emerton, Principal Consultant, Datamonitor Healthcare Consulting, UK

17.05 **Differentiated biosimilars: Is it worth developing for incremental market share?**

Differentiated biosimilars are biosimilars which have a distinct marketing advantage created by a noticeable difference in product features meant to influence the clinician or the payer to prescribe or reimburse it based on these differentiated features. This presentation explores whether it is worth developing these differentiated biosimilars by examining the potential payoff in incremental market share in various world markets.

Richard DiCicco, President, Harvest Moon Pharmaceuticals, USA

17.40 Final Q&A and closing remarks from the Chairperson

POST CONFERENCE WORKSHOP W • Friday 10 June 2011

From Development to Market - Biosimilar Monoclonal Antibodies in the EU and US

Registration 09.30 • Start 10.00 • End 16.00 • Lunch, morning and afternoon refreshments provided

This workshop will help to develop an expert understanding of biosimilar and next-generation monoclonal antibodies, including development requirements, strategies, costs, and timelines.

The workshop participants will learn how to:

- Prepare a development plan
- Define a target product profile
- Lay out an analytical strategy and plan
- Select an appropriate cell line and manufacturing platform

- Evaluate biosimilarity, and to evaluate the value of non-clinical studies
- Plan and execute clinical studies
- Apply for extrapolation of indications
- Use data from global sourced reference products
- Design a pharmacovigilance plan and post-authorisation follow-up

Led by:

Dr Carsten Brockmeyer, Biosimilar Expert & Managing Director, Brockmeyer Biopharma, UK

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