

Strategies for commercial success of biosimilars in an increasingly crowded market place

Thursday, 19 April 2012

The Penridge Suite, 470 Bowes Road, London N11 1NL

Whilst biopharmaceuticals remain a major component of the global therapeutics market, the ever expanding portfolio of products losing patent protection and with increasing healthcare costs remaining a poignant issue, the opportunity for development of competing, follow on biologics remains an attractive proposition for both Biotech and Pharma companies alike. This Euroscicon biosimilars conference will focus on multiple aspects of biosimilar product development to successfully deliver safe, biosimilar products to the market place.

This event has CPD accreditation and will have a discussion panel session.

On registration you will be able to submit your questions to the panel that will be asked by the chair on the day of the event

Meeting Chair: Dave Simpson PhD, Director, Virodigm Ltd

- 9:00 – 9:45 Registration
- 9:45 – 10:00 **Introduction by the Chair:** *Dave Simpson* PhD, Director, Virodigm Ltd
- 10:00 – 10:30 **Biosimilar Development: How do all the pieces fit together for registration in the EU.**
Dr Anita Bate, Chief Scientific Officer, Eden Biodesign, UK
Development of any biological product through to registration is a multi-disciplinary exercise. Careful planning with all teams involved is required to ensure that the required elements for product registration are addressed. This presentation will provide a top level overview of how all the pieces fit together and some of the pitfalls to avoid along the way.
- 10:30 – 11:00 **Early Stage Process Development of Biosimilars**
Mrs Andrea Salmén, Cobra Biologics, Sweden
Early process development to ensure similarity to the originator product is key in Biosimilar development. Cobra Biologics has created a generic platform approach for early process development of biosimilars which includes strategies to ensure comparability. Automation of cell line development using robotics (CELLOTM) enables screening of a large number of transfectants, thereby enhancing the chances of finding high producing stable cell lines. The AmbrTM Micro Bioreactor system from TAP has been integrated into the platform process together with a package of analyses required to define the critical quality attributes desired. This enables multiple process parameters to be evaluated simultaneously and a bioreactor process to be defined rapidly and early in the process. The use of the high throughput and representative scale-down system also generates early data on stability of the cell lines, process economics and key analytical outputs of the product.
- 11:00 – 11:30 **Speakers' photo then mid-morning break and trade show**
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- 11:30 – 12:00 **Analytical challenges in biosimilar characterisation & comparability**
Dr Gerrard Powell, Senior Analytical Scientist Eden Biodesign
An overview of the challenges presented in the full characterisation of a biosimilar product and also those of demonstrating similarity to innovator products will be discussed. This will include an in-depth discussion around methods for the characterisation of complex glycoproteins at the amino acid and carbohydrate level that can be used in comparability studies and challenges that we have encountered in demonstrating essential similarity will be highlighted.
- 12:00 – 13:00 **Lunch and trade show**
- 13:00 – 14:00 **Question and Answer Session**
Delegates will be asked to submit questions to a panel of experts. Questions can be submitted before the event or on the day

- 14:00 – 14:30 **Label Free Intrinsic Imaging in the Analysis of Biosimilars**
Mei-an Sung, Deltadot Ltd, UK
- 14:30 – 15:00 **Afternoon Tea/Coffee and trade show**
- 15:00 – 15:30 **Biosimilars: Development Challenges and Considerations**
Dr Raymond Donninger, Covance Inc, UK
 Biosimilars are the next evolution in biopharmaceutical development and present unique challenges as well as opportunities. This talk focuses on the main considerations both in nonclinical and early clinical development of these compounds. The regulatory environment will also be discussed as this is a fundamental consideration in the development of any therapeutic product but in the field of biosimilars regulatory uncertainty drives a number of key challenges.
- 15:30– 16:00 **Device development for biosimilars**
Andrew Pocock, Team Consulting Ltd, Cambridge, UK
- 16:00 – 16:30 Chairman's summing up

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This meeting was organised by Euroscicon (www.euroscicon.com), a team of dedicated professionals working for the continuous improvement of technical knowledge transfer to all scientists. Euroscicon believe that they can make a positive difference to the quality of science by providing cutting edge information on new technological advancements to the scientific community. This is provided via our exceptional services to individual scientists, research institutions and industry.

About the Chair

David's background is in cell line, process and analytical development, Tech Transfer and manufacturing of clinical products. Formerly of Eden Biodesign, David led the process development capabilities and post-acquisition by Watson Pharmaceuticals led the development and manufacturing of a recombinant FSH biosimilar product. David now owns an independent consultancy supporting all aspects of biopharmaceutical product and commercial development needs.

About the Speakers

Anita Bate is a co-founder of Eden Biodesign and is responsible for ensuring that the company maintains its technical skills for product development. In addition she has overall responsibility for CMC technical regulatory and technical diligence activities. Anita has a very broad skill base having held senior positions in the pharmaceutical industry managing both process and analytical development groups. She has worked on over 60 wide ranging client projects for Eden Biodesign as both consultant and project manager and has particular expertise in development genetics, due diligence for in licensing, viral safety strategy and CMC technical regulatory affairs.

Andrea Salmén is a Project Manager at Cobra Biologics. She has a MSc in Engineering Biology from Linköping University and has several years of industrial experience in cell line development, cell culture process development and integration of advanced automated cell culture systems. Andrea is currently managing several early stage biopharmaceutical projects.

Andrew Pocock's background is in industrial design and engineering having a 1st Class degree from Teesside Polytechnic, and a Master of Design from the Royal College of Art, London. With over 20 years' experience in product development consulting, Andy has encountered a range of technical and user based design challenges across a range of industries. He was Director of the Design

Research Centre before coming to Team as Senior Consultant in 2000. He has since managed major medical device projects for international clients, with a particular focus in drug delivery.

Raymond Donninger joined Covance in January 2008 as an Early Development Program Manager with a particular focus on large molecule programmes. He has been involved in drug development in various forms for 16 years and specifically biotechnology product development for the past 9 years.

His experience ranges from manufacturing through to marketing of biotechnology products. Raymond has spent 9 years working in the field of biosimilar therapeutic proteins and has development, clinical use and commercial experience with these compounds in developing and developed markets. He is currently managing 6 biosimilar early development programmes that include fully integrated programme design, CMC, toxicology and clinical aspects.

He has experience in the fields of therapeutic proteins, nucleic acid therapeutics, small peptides, immunotherapies, cell therapies, vaccines and biosimilars. He has been responsible for the design, monitoring and reporting of GCP clinical studies as well as providing input on early biotechnology product development strategies. Raymond holds a B.Sc. Honours degree in Medical Biochemistry, a Medical degree and a Masters degree in Business Administration.

Gerard Powell is a Senior Analytical Scientist at Eden Biodesign. He has a PhD in Protein Biochemistry from the University of Liverpool and has several years of industrial experience in analytical development, particularly in HPLC and mass spectrometry based techniques. He is currently involved in product characterisation and similarity assessment.

Keywords: biopharmaceutical, drug delivery, Biosimilar, Regulatory, CMC,EU, Product registration, Biosimilars, Biologicals, Regulatory, Monoclonal antibodies, process development, automation, cell line, bioreactor, Characterisation, Biosimilarity, Comparability

Registration Web Site: www.regonline.co.uk/biosimilars2012

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- You will be issued with a FULL delegate list within 14 days of the event, which will include the email addresses of the delegates (we are sorry that there is this delay in emailing the list, but we need to make sure that it takes into account any late arrivals). You will not be included in this list if you have opted out and you can do this by logging into your registration details. This list will not be sold or ever give out to third parties. Only people attending or sponsoring the event have access to the list
- There may be an independent meeting report published within a few months of this event. If this is published we will send you an email to let you know the reference details
- Notepads and pens are available from the Euroscicon reception desk
- We cannot give out the slides from our speaker's presentations as they are deleted immediately after each event. If you require a particular set of slides please approach the speaker
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- We may take pictures during the meeting. These pictures will be used to promote our events and placed on our various websites and the closed Euroscicon group on Facebook. If you do not want your photograph distributed please let one of the Euroscicon staff know.