13th Biosimilars Congregation 2019

#VIbsc

"Uniting industry leaders to analyse advanced commercial developments & to identify successful management strategies of Biosimilars"

11th & 12th June 2019,
Pestana Chelsea Bridge Hotel,
London UK

AGENDA AT A GLANCE

Key Speakers Include

SUE NAEYAERT
Global Head Government Affairs, Policy & Pharmaceconomics
Fresenius Kabi SwissBioSim

SHU-YI SU
Statistical Scientist
Novartis

IAN HENSHAW
VP, Global Head of Biosimilar Business Unit
Biogen

MAGNUS BODIN
Director, Market Access Biosimilars
Biogen

CHRISTIAN AGBOTON
Sr Global Brand Medical Director - Global Medical Affairs
Takeda

JOSEPH DUNFORD
European Biosimilar Franchise Manager
Accord Healthcare

VICTOR SASTRE
Senior MSL , Amgen Biosimilars, (Board Member, MSL Society Advisory)

FREDRIK SUNDBERG
Director Strategic Customer Relations
GE Healthcare

HANMANT BARKATE
Vice President & Head Medical Services, (India, MEA)
Glenmark (India)

JOSEPH SALAMEH
Medical Lead
Alnylam Pharmaceuticals

STEINAR MADSEN
Medical Director
Norwegian Medicines Agency

LOUIS BOON
CSO
Bioceros

LIZ POLLITT
Director
BPCRCS

LENNEKE DE WINTER
USP Director
Bioceros

CORNELIA ULM
VP Regulatory Affairs Biosimilars
Biotec Regulatory Consulting

KARL DAVISON
Business Development Officer
NIHR Clinical Research Network

JUSTIN STEBBING
Professor of Cancer Medicine and Oncology, Consultant Oncologist
Imperial College Healthcare NHS Trust

MARIE MANLEY
Partner, Head of the UK Life Sciences Practice
Sidley Austin

JACQUELINE MULRYNE
Counsel
Arnold & Porter LLP

Plus many more COMING SOON.....

WHO ATTENDS?

- 25+ Speakers
- 70% Pharma / Biotech
- 6+ Hours of Networking
- 2 Days
- 1 Golden Opportunity

www.virtueinsight.com

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"I think the event was great and really threw insight on positioning biosimilars vis a vis other drugs on the regulatory side in India and World and what are challenges faced by industry as well as government and also regulators It was a great learning"

Head – Medical Affairs, Wockhardt

AGENDA AT A GLANCE

SUPPORTED BY

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"Excellent workshop. It did meet our expectation in term of complete representation of the biosimilar development"

Senior Manager, Regulatory Affairs Sanofi

AGENDA AT A GLANCE

CONFERENCE INTRODUCTION:-

The development of the Biosimilars market is growing exponentially with the industry forecast to be worth $25 billion by 2020. The global biosimilar market is estimated to register a CAGR of 39.53% over the forecast period of 2017-2023. The growth in the market may be attributed to the cost-effectiveness of the biosimilars when compared to reference biologics coupled with the patent expiration of the many blockbuster biologic drugs. By 2018, biologics worth more than US$68 billion annual sales will lose patent protection. Due to structural complexity of the biosimilar drugs, multi-layered manufacturing and risk of immunogenicity, separate regulatory pathways have been drafted to introduce them into the market. Increasing investment by the companies for the development of biosimilars will also be the key factor driving the market.

Our 13th Biosimilars Congregation 2019 will provide insight into the current state of play in the EU and stimulate debate, in a multi-stakeholder setting, on the vital role of biosimilar medicines in the sustainability of healthcare systems. Beyond a comprehensive outlook of key European market access policies, our speakers will outline the key recent developments in regulatory science and regulatory policy in the EU and other international jurisdictions. Special emphasis will be placed on strengthening the link between regulators and medical communities as an essential basis for greater understanding and acceptance of biosimilar medicines. This Biosimilars conference will focus on multiple aspects of Biosimilar product development to successfully deliver safe, Biosimilar products to the market place. By attending this conference, you will gain a comprehensive outlook on the key issues surrounding Biosimilars. This event will provide an important platform for Biosimilars stakeholders to discuss and share best practices in furthering Biosimilars development.

It gives me great pleasure in welcoming all of you to the Virtue Insight's 13th Biosimilars and Congregation 2019.

KEY THEMES DISCUSSED IN THIS CONFERENCE:-

- Strategies for market access and expansion by identifying key changes and future projections
- Consequences of Brexit on Biosimilars
- Current Challenges and Opportunities for future- Strategies in developing Biosimilars
- A Clinician's Guide to Biosimilars in Oncology: understanding the Science of Extrapolation and Interchangeability
- Biosimilars – Pricing & Market access - Bringing it faster into market
- GMP, GCP, QC & R&D
- Current challenges and opportunities - strategies to develop Biosimilars
- Payer perspective on biológics and Biosimilars
- Biosimilar Interchangeability: The newest regulation
- Biosimilar - Physicians and Patients perspective
- CMC, Preclinical and clinical considerations for Biosimilars and Follow-on Biologics
- Impact of Technology
- Commercial landscape & market access for Biosimilars: Predicts to prepare for a suceesful tomorrow
- Hear case studies on biosimilars drug development from pre-clinical to clinical and the various testing required such as immunogenicity and bio-similarity tests
- Research-based industry Biosimilar strategies
- Considerations for the analytical similarity assessments when designing a Biosimilar development program
- Determining the right investments & potential returns from Biosimilars
- Latest developments in regulation to increase speed of entry and compliance
- Future of next generation biosimilars
- Be part of a major networking opportunity

AN EVENT TO VOW

Get more from the event, enjoy and make the best out of our dedicated networking drinks time, meet the leading international vendors showcasing the products of tomorrow in the co-located exhibition. Expand your knowledge of the latest business models and strategies in the high-level conference. Whether you are on the branded or generic side, you cannot afford to miss this opportunity to benchmark your tactics and strategies against the industry leaders who will be the first to traverse the pathway. Devise an immediate action plan for your biosimilar prosecution and litigation strategies in light of the barriers to entry, research and development costs, and regulatory hurdles, which are balanced against an enormous potential for increased profit margins.

WHY EXHIBIT?

Make Sales
Debut new products
Profile your brand
Meet new business partners
Develop key relationships
Educate pharma and biotech companies

WHO WILL YOU MEET

CSOs, CMOs, Vice Presidents, Presidents, Heads, Directors, Team Leaders, and Senior Scientists from the following roles:

Biopharmaceuticals/ Biotherapeutics, Follow on Biologics/Follow on Proteins/Biosimilars, Biologics/Biotechnology/ Biogenerics, Legal Affairs, Intellectual Property, Health Economics, Pricing and Reimbursement, Clinical Immunology, Principal Scientist, Chief Scientific Officer, Process Control and Analytical Technologies, Analytical Characterisation, Regulatory Compliance, Pharmacovigilance, Drug Safety & Risk Management, Quality Affairs/ Quality Control, New Product Development, Process Science, Portfolio Management, Research & Development, Business Development, Business Operations, Scientific Affairs, Commercial Affairs, Marketing

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"It was a splendid show yesterday, and esp with you and Sid managing the whole show so smoothly, was very well seen. Virtue Insight Staff were very helpful all through-out"

Director, VIaTAL Pharma Consulting

AGENDA AT A GLANCE

DAY ONE - 11th June 2019

08:30 – **Coffee and registration –** An opportunity to meet and network with your conference colleagues.

09:20 **LOUIS BOON**
CSO
Bioceros

Chairperson opening remarks

MARKET OVERVIEW & ANALYSIS

09:30 **FREDRIK SUNDBERG**
Director Strategic Customer Relations
GE Healthcare

Bioprocessing Innovation & Novel Analytical Strategies to Improve Biosimilar Development

- Market Overview & Current Trends.
- Process Intensification and Accelerating Time-to-Market.
- Novel Assay Approaches to Establish Bio-similarity

PAYER'S PERSPECTIVE

10:10 **Biosimilars – Bringing it into the market quickly**

- Strategies in overcoming obstacles in Biosimilar development
- Effective strategies for product design
- How Payers are aligning biosimilars?
- Global impact of biosimilars over generics
- Requirements for product development program
- Bridging the 'uncertainty gap' between payers & pharma - the shifting paradigm
- What to expect in the next 2 years?

10:50 – **Morning Coffee/Tea & Discussion**

CHALLENGES & OPPORTUNITIES

11:20 **Keynote Panel Discussion: Current Challenges and Opportunities for future- Strategies in developing Biosimilars**

- Latest developments, Trends and Future of Biosimilars
- Current Challenges and Research trends in Biosimilars & Biologics
- Issues to overcome to increase uptake of biosimilars
- Generate enough interest and enthusiasm for biosimilars
- Lack of stakeholder confidence – what does this lead to?
- Consequences of Brexit on Biosimilars

Moderator:

LOUIS BOON
CSO
Bioceros

Panellists:

IAN HENSHAW
VP, Global Head of Biosimilar Business Unit
Biogen

SHU-YI SU
Statistical Scientist
Novartis

JOSEPH DUNFORD
European Biosimilar Franchise Manager
Accord Healthcare

12:00 **STEINAR MADSEN**
Medical Director
Norwegian Medicines Agency

From biosimilars to biogenerics?

- Switching and interchangeability
- Are «generic prices» sustainable?
- Is there a future for new biosimilars?

12:40 – **Networking luncheon**

PATIENT'S PERSPECTIVE

13:40 **Analysing Physicians and Patients perspective**

- National and International developments in biosimilar medicines
- Physicians education - Challenges
- Importance of Physician and Patients inputs to shape the international standards for biosimilars
- Encouraging physicians - Policies
- Physicians / pharmacist collaboration
- Harmonizing global standards to ensure safety and efficacy of biosimilars

14:10 **SHU-YI SU**
Statistical Scientist
Novartis

Statistical Considerations for Analytical Biosimilarity Assessments

14:40 **VICTOR SASTRE**
Senior MSL , Amgen Biosimilars, **(Board Member,** MSL Society Advisory)

Biosimilars. Are the MSLs needed?

- Everyone is aware of the importance of the MSL teams in the pharmaceutical industry. Currently it is a fully consolidated role that helps in any innovative drug that comes to market.

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"All the topics picked up very good and were pretty informative. The panel discussions brought very nice views and insights on agenda points"

BUSINESS DEVELOPMENT & PM, LUPIN BIOTECH

AGENDA AT A GLANCE

DAY ONE - 11th June 2019

- Due to the idiosyncrasy of the biosimilar market, many people wonder if their responsibilities and tasks in this field are different from a typical MSL and their role in this field is even questioned.
- Differences that exist in our figure due to the appearance of this new scenario and discuss the need or not of our involvement in the biosimilars world.

15:10 – **Afternoon Tea/Coffee**

COMMERCIALISATION & MARKET ACCESS

15:30 **MAGNUS BODIN**
Director Market Access Biosimilars
Biogen

Commercialization of Biosimilars in Europe: The anti-TNF success story

- The evolution of the European biosimilar landscape
- The anti-TNF journey from infliximab to etanercept to adalimumab
- Is there a perfect system to drive the uptake of biosimilars?

16:10 **Panel Discussion: Commercial landscape & market access for Biosimilars: Predicts to prepare for a successful tomorrow**

- Comparison of US/EU biosimilar developments, policies and guidelines
- The impact of Biosimilars on the competitive landscape of biological products
- Challenges and obstacles faced by manufacturers in developing biosimilars
- Bringing the next generation of Biosimilars to the market
- Ensuring market access and reimbursement
- Evidence generation will be the key to future success
- Stakeholders approach in successfully bringing Biosimilars to the market

Moderator:

LOUIS BOON
CSO
Bioceros

Panellists:

JUSTIN STEBBING
Professor of Cancer Medicine and Oncology, Consultant Oncologist
Imperial College Healthcare NHS Trust

KARL DAVISON
Business Development Officer
NIHR Clinical Research Network

16:50 – **Chairperson's closing remarks and end of conference day one**

17:00 - 18:00 **Networking Drinks - Take your discussions further & build new relationships in a relaxed & informal setting**

NETWORKING DRINKS

Meet with your industry peers for a relaxed drink at the end of day one

FOR DELEGATE REGISTRATIONS:-

Our potent conference agenda delivering the latest information and the world class leaders as speakers attract delegates to attend from around the world. We aim for our attendees to be equipped with knowledge of latest developments & enable them to network with the industry key personnel.

Delegate Registration - delegate.uk@virtueinsight.com

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"The programme and the format were very good and the atmosphere provided great encouragement for the networking. It was timely organised allowing the participants to exchange opinions on very recent regulatory changes in the US and the EU"

Scientific & Regulatory Director, Regem Consulting Ltd

AGENDA AT A GLANCE

DAY TWO - 12th June 2019

08:30 – **Coffee and registration** – An opportunity to meet and to network with your conference colleagues.

09:20 **LOUIS BOON**
CSO
Bioceros

Chairperson opening remarks

MANUFACTURING

09:30 **Developmental challenges to enlarging biosimialrs market growth**

- Issues and challenges for manufacturers
- Overcoming the hurdles
- Bringing next generation of Biosimilars to the market
- Quality by Design for Biologics & Biosimilars
- Reducing cost
- Effective manufacturing operations

10:10 **SUE NAEYAERT**
Global Head Government Affairs, Policy & Pharmaceconomics
Fresenius Kabi SwissBioSim

"Biosimilars and policies that help uptake or not"

10:50 – **Morning Coffee/Tea & Discussion**

BUSINESS MODELS

11:10 **CHRISTIAN AGBOTON**
Sr Global Brand Medical Director - Global Medical Affairs
Takeda

JOSEPH SALAMEH
Medical Lead
Alnylam Pharmaceuticals

Biosimilars: Are biologics becoming a commodity? A medical perspective.

- What is needed (efficacy, safety), how to differentiate?
- The challenges of not being the first biosimilar on the market: how to tackle?
- Interchangeability, Education of physicians, Real world evidence data generation, Tender dossiers
- Strategic thinking: biosimilars, a final destination or the beginning of the journey?

12:00 – **Solution Provider Presentation**

For sponsorship opportunities please contact info.uk@virtueinsight.com

12:20 – **Solution Provider Presentation**

For sponsorship opportunities please contact info.uk@virtueinsight.com

12:40 - **Networking luncheon**

CLINICAL

13:50 **HANMANT BARKATE**
Vice President & Head Medical Services, (India, MEA)
Glenmark (India)

What Physicians' want to know about Biosimilars

- Current level of understanding of biosimilars among different Specialities of physicians
- Need gap of understanding Biosimilars among Physicians
- Understanding of Chemical vs Biologics/Biosimilars, Biosimilarity: Totality of Evidence, Rationality of extrapolation of data, Interchangeability, Regulatory approval process etc.

14:30 **LENNEKE DE WINTER**
USP Director
Bioceros

Using SPOT™ and SLIM™ technology and upstream process modulation to reduce cost of goods of biosimilars

- Increase specific productivity using SPOT™
- Increase specific productivity and biosimilar product quality using upstream process modulation
- Reduce process issues using SLIM™
- Reducing cost of goods of biosimilars

15:10 – **Afternoon Tea/Coffee**

15:40 – **Solution Provider Presentation**

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REGULATION OVERVIEW & UPDATE

16:00 **Panel Discussion: The developing regulatory frame work in advanced and developing markets**

- Market and regulatory developments in the Europe and globally
- Predicting the post Brexit changes in biosimilars regulation in UK
- EMA's act on switching & interchangeability?
- How regulators, payers and policy makers take initiatives to make healthcare more sustainable
- Collaboration with HTA's for patients benefit

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"The Biosimilars Congregation proved to be an insightful range of presentations which covered the most important aspects of the biosimilars field. I'd recommend it to all stakeholders, manufacturers and regulators alike, who wants to network and gain more up-to-date knowledge in this exciting business area of biologics"

Director, Corporate Business Development, CMC Biologics A/S

DAY TWO - 12th June 2019

- CMC regulatory considerations for Biosimilar products development
- Regulatory changes necessary to maximize biosimilars potential
- The way forward

Moderator:

LOUIS BOON
CSO
Bioceros

Panellists:

CORNELIA ULM
VP Regulatory Affairs Biosimilars
Biotec Regulatory Consulting

LIZ POLLITT
Director
BPCRCS

MARIE MANLEY
Partner, Head of the UK Life Sciences Practice
Sidley Austin

JACQUELINE MULRYNE
Counsel
Arnold & Porter LLP

16:40 - 17:00 **– Chairperson's closing remarks and end of 13th Biosimilars Congregation 2019 conference**

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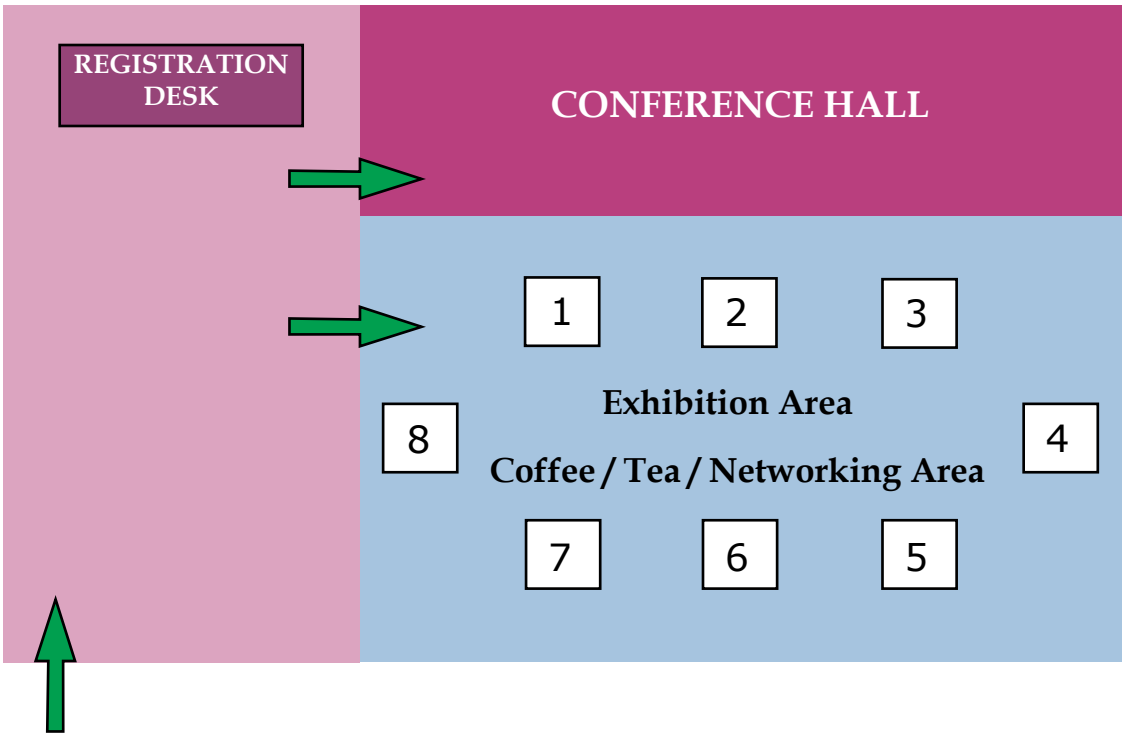
London UK

"The presentations were informative and the panel discussions engaging, covering key and important topics of debate. The food and wine reception were excellent and allowed for relaxed networking opportunities"

Director, Voisin Consulting Life Sciences

AGENDA AT A GLANCE

FLOOR PLAN - Book your stalls now before they run out !!!



1 4 7

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Note :- The floorplan is subject to change at the discretion of the organisers.

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London UK

"Well done, most of the speakers selected for the conference were excellent and there was informative as well as participative discussion"

MANAGER - BD & PROGRAM MANAGMENT, LUPIN

AGENDA AT A GLANCE

For Multiple Bookings - Photocopy this form and send it to delegate.uk@virtueinsight.com; Tel:+44 2036120886

Delegate Details:

Title Mr ☐ Mrs ☐ Ms ☐ Dr ☐

First Name

Surname

Company

Position

Address

Pincode

Telephone

Fax

Email

How to Pay
(Choose one of the following payment options)

RESERVATION PRICING:

Super Early Bird

1 Delegate @ £750 + VAT (Valid till 1st April 2019)

3 Delegates @ £1500 + VAT (Valid till 1st April 2019)

Standard Rate

@ £1150 + VAT per delegate

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Special Offer:

3 for 2 Offer

*Only few more seats left

TERMS AND CONDITIONS:

Payment terms: Virtue Insight requires the full amount to be paid before the conference. We may refuse entry to delegates who have not paid their invoice in full.

Cancellations: Delegates and vendor are subject to the following charges and refunds upon withdrawal or cancellation.Between 2-3 month's prior 75% cancellation fee/ 25% refund.Less than 2 months prior to the event Full cancellation fee / No refund.

Administration Fee: If you cancel your participation (once confirmed) and haven't paid the attendance fee you will be liable to pay an administration fee of £200 + VAT

Substitutions/Name Change: If you are unable to attend you may nominate, in writing, another delegate to take your place at any time prior to the start of the event. This can be done at not extra cost.

Presentation: If you cannot attend the conference, you can still purchase the presentations for £400 + VAT

Indemnity: Virtue Insight reserves the right to make alterations to the conference/executive briefing content, timing, speakers or venue without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of Virtue Insight. If such a situation arises, we will refund your registration fee and we will try to reschedule the event.

Fee: The conference fee includes lunch, refreshments and conference papers provided on the day. This fee does not include travel or hotel accommodation.

VENUE

Pestana Chelsea Bridge Hotel

Address: 354 Queenstown Rd, London SW8 4AE, UK

Phone: +44 20 7062 8000

MAP & DIRECTIONS

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