Biosimilar DRUG DEVELOPMENT WORLD

Europe 2015

Collocated with

World Generic Medicines Congress Europe 2015

Navigate development and launch strategies for biosimilars

4-5 March 2015
Sheraton Madrid Mirasierra Hotel
Madrid, Spain

Sponsored by

Catalent

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Your event, your way

The earlier you book, the more you save

The industry is rapidly changing, which provides a unique set of challenges for those developing and manufacturing biosimilars. Gain true insight on winning development, manufacturing, clinical and commercialisation strategies for biosimilars in the global market.

Navigate the challenges in the clinic, the manufacture and development of biosimilar medicines as well as explore the commercial aspects of the industry. This is your best chance to find out where the true biosimilar industry growth opportunities lie and what role they can play in your portfolio.

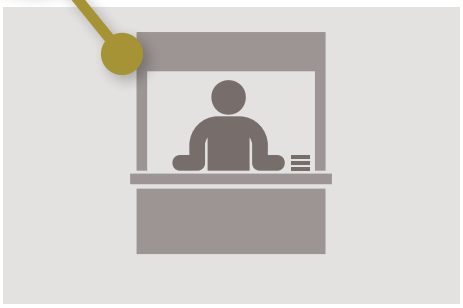
Big picture and vision

Debate key topics with your peers

Visit providers of latest industry solutions and technologies

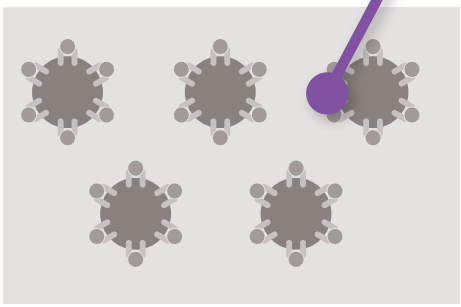
Keynotes

Exhibition



World GenericMedicines Congress Europe 2015

Roundtables



Networking

Biosimilar DRUG DEVELOPMENT WORLD Europe 2015

Expert Panels

Party

Challenge their views and ask your burning questions

Choose which sessions are relevant to you

Develop your business relationships

Unwind with your peers and continue conversations in good company

The speakers and topics were very useful for my business and development

Senior Manager, Cubist Pharmaceuticals

It was well organized and helpful in understanding the key trends in biosimilars

Scientific Director, ADE Pharma Ltd

Very nice congress, good speakers, interesting colleagues, well organized

Strategic Alliance Manager Clinical Sciences, Bayer AG

Keynote speakers

Raj Kannan

Global Commercial Head, Biosimilars

Merck Group

Opening the event is Raj Kannan, a senior global pharmaceutical executive with significant leadership experience across several therapeutic areas including biosimilars. Raj is skilled at commercialising development assets from preclinical to phase 3 and operating on a global scale building high performance teams. He will bring his wealth of expertise to share his thoughts on commercial input into biosimilars drug development.

Orlando Jaquez

Process Development Scientist and Biosimilars Purification Lead

Biogen Idec

Orlando Jaquez is the Process Development Scientist and Biosimilar Purification Lead at Biogen Idec and will provide a glimpse into innovations in biosimilar development. He will dip into his expertise in CMC, purification development, process characterization and process validation and discuss the latest mindsets and innovative strategies.

Yariv Hefez

Vice President Business Development, Portfolio Management, Strategy and Partnering, Biosimilars

Merck Serono

Yariv Hefez will be leading the keynote panel discussion with a strong panel of industry experts. This exciting panel discussion will open up the discussion about if, and how biosimilars will meet the expectations surrounding their impact on global healthcare systems. Yariv will pull from his experience of the biosimilars business and partnering strategies gained through his contribution to the growth of Merck Serono's biosimilar business.

Paul Coleman

CEO

Hanwha Biologics

Dr Paul Coleman joined Hanwha Biologics based in Seoul, Korea in January 2011 as the newly appointed Chief Operating Officer and in March 2012 he was appointed Chief Executive Officer. Additionally, he has vast experience working for other key industry players including Biogen Idec and Parexel. His commercially minded presentation will be analysing recent market trends and what the biosimilars industry of tomorrow looks like, while predicting how the industry can prepare to make the most of opportunities.

Sol Ruiz

Head of Sector of Biotechnology and Advanced Therapies

Spanish Medicines Agency (AEMPS)

Sol Ruiz is taking a deep dive look at how to best demonstrate biosimilar comparability. She is an expert in the field. As well as her role as the Head of Sector of Biotechnology and Advanced Therapies at AEMPS, she is the chair of the Biologics Working Party at the European Medicines Agency. She will be discussing comparability techniques and quality attributes as well as an update on EMA guidance.

Virginia Acha

Director, Regulatory Affairs

Amgen

Virginia Acha leads Amgen’s Regulatory Policy Team for Europe, Middle East and Africa, advocating for science-led robust regulatory policy that sustains innovation. She is also part of the Innovation and Entrepreneurship Group at Imperial College London. She will be sharing her insight on the current and future European regulatory setting for biosimilars.

Day One Wednesday 4 March 2015

8:00 Registration opens

BIOSIMILAR INDUSTRY OPPORTUNITIES FOR GROWTH AND INNOVATION

9:00 Opening remarks from the Chair
Dr Michel Mikhail, Expert in Biosimilars, **Independent Consultant**

9:10 Commercial input in biosimilars drug development
Raj Kannan, Global Commercial Head, Biosimilars, **Merck Group**

9:40 Keynote panel discussion: Will biosimilar's transform the global biologics market as forecasted? A reality check….

Panel Chair: **Yariv Hefez,** VP Business Development, Portfolio Management, Strategy and Partnering, Biosimilars, **Merck Serono**
Panellists: **Cyrus Karkaria,** President, Biotech, **Lupin Pharmaceuticals**
Sol Ruiz, Head of Sector of Biotechnology and Advanced Therapies, **Spanish Medicines Agency (AEMPS)**
Orlando Jaquez, Process Development Scientist and Biosimilars Purification Lead, **Biogen Idec**
Francisco Rebollo Laserna, Medical Manager Biosimilars, **Sandoz**
Alan Herman, Chief Scientific Officer, **Coherus Biosciences**

10:30 Investor's financial forecast: opportunities for biosimilar medicines in the global healthcare marketplace
Jesus Carrasco Abad, Director Healthcare Investment Banking, **RBS**

11:00 Speed networking

11:30 Morning refreshments

BIOSIMILAR PRODUCT & PROCESS DEVELOPMENT

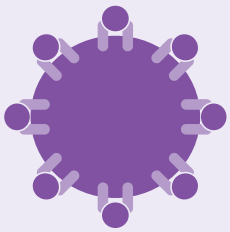
12:00 Innovations in biosimilar development
Orlando Jaquez, Process Development Scientist and Biosimilars Purification Lead, **Biogen Idec**

12:30 Upstream processing considerations in biosimilar manufacture
Matthew Cheeks, Head of Upstream Processing, **Polpharma Biologics**

1:00 Understanding the impact of temperature excursion on biosimilar product stability and significance of excursion tracking systems
Rajiv Dua, Analytical and Stability Coordinator, Biotech Division, **Lupin**

1:30 Lunch

2:30



Peer to peer roundtables

- Analytical development for biosimilars
  Alok Sharma, Ph.D., Head, Analytical Development Lab Biotech Division, **Lupin Limited**
- Biosimilars portfolio planning
  Yariv Hefez, VP Business Development, Portfolio Management, Strategy and Partnering, Biosimilars, **Merck Serono**
- The long term outlook for biosimilars
- Biosimilar market access and pricing strategies

3:30 Afternoon refreshments

COMMERCIAL STRATEGIES FOR BIOSIMILARS

4:00 Current market trends and future challenges for biosimilar success
Paul Coleman, Chief Executive Officer, **Hanwha Biologics**

4:30 Redesigning the biosimilar business model: uniting the scientific, partnering and business expertise
Alan Herman, Chief Scientific Officer, **Coherus Biosciences**

5:00 Educating towards acceptance: paving the way to clinical and thus commercial success
Dr Uwe Gudat, Head of Safety, Biosimilars, **Merck KGaA**

5:30 Evening networking party

Day Two Thursday 5 March 2015

BIOSIMILARS CLINICAL STRATEGIES

9:00 Opening remarks from the Chair

9:05 Non-clinical regulatory requirements and other challenges related to biosimilar approval in Europe
Asterios Tsiftsoglou, Professor of Pharmacology, Department of Pharmaceutical Sciences, **Aristotle University of Thessaloniki**

9:30 Panel discussion: Exploring the challenges and opportunities that face biosimilar clinical development programmes
Markus Fido, Chief Operating Officer, **Meridien Biopharmaceuticals**
Dr Bernd Liedert, Senior Clinical Programe Leader Biosimilars, **Boehringer Ingelheim**

GAINING REGULATORY APPROVAL AND MARKET ACCESS

10:05 European regulatory requirements for biosimilars
Virginia Acha, Director, Regulatory Affairs, **Amgen**

10:30 The regulatory environment for biosimilars: a global picture
Andrea Laslop, Head of Scientific Office, **AGES (Austrian Agency for Health and Food Safety)**

10:55 **Morning refreshments**

BIOSIMILAR DEVELOPMENT AND COMPARABILITY

11:30 Demonstrating biosimilar comparability
Sol Ruiz, Head of Sector of Biotechnology and Advanced Therapies, **Spanish Medicines Agency (AEMPS)**

11:55 Accelerated biosimilar development
Christelle Dagoneau, Account Director, Biologics, **Catalent Pharma Solutions**

12:20 Analytics in biosimilar development: characterization and comparability
Rustom Mody, Senior Vice President and Head R&D, Biotech Division, **Lupin**

12:45 **Lunch**

1:45 Around the biosimilars world in 30 minutes... focus on Latin America
Teotónio Albuquerque, Associate Medical Director Biotherapeutics WE&C - EEMEA Global Medical Affairs, **Abbott Laboratories**

2:10 Around the biosimilars world in 30 minutes... focus on China
Daotian Fu, Executive VP, **Livzon Mabpharm**

2:35 USA regulatory and market access environment for biosimilars

3:00 **Afternoon break**

BIOSIMILAR SPECIAL INTEREST SESSION

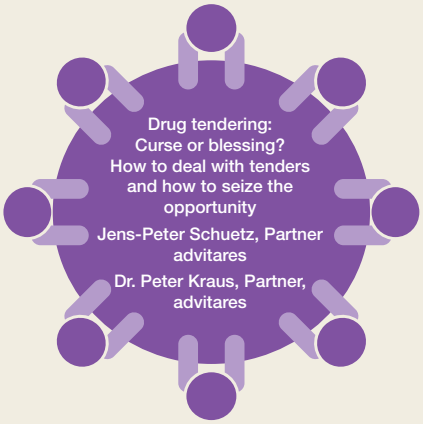
3:30 Development of a biosimilar insulin –a clinical pharmacologist's view
Dr Malcolm Mitchell, Senior Medical Fellow, **Eli Lilly**

4:00 Norwegian experience on the first use of biosimilar infliximab in Europe
Dr Steinar Madsen, Medical Director, **Norwegian Medicines Agency, Norway**

4:30 **Close of conference**

Roundtables

Peer to peer roundtables provide an interactive and engaging platform where biosimilar and generic medicine opportunities can be explored, challenges can be solved and emerging innovative approaches can be evaluated. Choose the topic relevant to you and join the discussion.



The Exhibition

The 4th annual Biosimilar Drug Development World Europe event is the leading biosimilar scientific and commercial strategy conference in Europe. Increase your brand awareness and demonstrate thought leadership in front of over 150 senior representatives from biosimilar and generic pharmaceutical companies.

Your opportunity

- Grow long term relationships by arranging meetings with top prospects
- Speak and demonstrate thought leadership
- Increase brand awareness and positioning
- Educate the biosimilars community on your products and services

Why sponsor

- Generate new business leads and develop relationships
- Build brand presence and raise brand profile
- Showcase latest products and innovations to prospective buyers
- Promote new services to prequalified clientele
- Meet new business partners and suppliers
- Educate pharma and biotech companies

Who will you meet

Senior scientific, clinical and commercial representatives from biosimilar organisations, including:

- Biosimilars/biotechnology
- CSO
- Formulation
- Regulatory Affairs
- Clinical/Pre clinical
- Immunogenicity
- Manufacturing
- Bioequivalence
- R&D/ CMC
- Commercial

Be seen at the forefront of the biosimilar industry.

Contact Roope Ghosh on +44 (0) 207 608 7037 or rghosh@healthnetworkcommunications.com to secure your place

Networking

We know the importance of networking and offer an experience which allows you to do just that. With the bespoke Total Biopharma mobile app, dedicated networking managers and peer-to-peer partnering, we ensure that you get the most from your time on site. With 2 events running in parallel, you will be able to meet more connections in one place.

Download our networking app

Download our networking app to get organised and get in touch with all attendees before the event.

Use the Total BioPharma portal to:

- Plan your sessions
- Build a personalised agenda
- Identify exhibitors to visit
- Set up onsite meetings with key executives
- Network with other attendees

Your networking manager

Take advantage of this dedicated and personalised meeting service. Hold meetings with pre-qualified partners arranged by your networking manager in your private on-site meeting room.
Keep all your messages, appointments and favourites at your fingertips and continue networking whilst you're there. You can still use the networking tool within the app for a full year after the event so you can follow up with anybody you've missed months down the line.

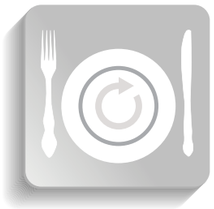
Bianca Geldenhuys

PARALLEL CONFERENCE TRACKS

One great interactive event with two complementary conference tracks. **Biosimilar Drug Development World Europe** brings together decision makers to provide true insight on the best development, manufacturing, clinical and commercialisation strategies for biosimilars in the global market. While **World Generic Medicines Congress Europe** shares the latest market trends, innovative commercial strategies and opportunities for growth.

ROUNDTABLE DISCUSSIONS

Pick a roundtable that focuses on the industry challenge of highest priority to you. Each round table host will open a topic up for discussion and debate. This is your opportunity to contribute, discuss, engage, share ideas and learn directly from your peers. This informal setting may generate some different perspectives and innovative solutions you haven't considered before…



NETWORKING LUNCHES

Make the most of your time outside the conference room with our networking lunches. This is your opportunity to benefit from informal chat, explore the exhibition hall and meet some new business contacts

PARTY

Let your hair down after a busy day at our fun party. Join us at the end of day 1 for drinks, music, nibbles, and a few surprises.

SOLUTION PROVIDER EXHIBITION

Explore the exhibition hall during dedicated breaks and meet with solution providers that offer innovative services and technologies. You can be sure to meet those that can help fast-track your biosimilar commercial and scientific strategy.

SPEED NETWORKING

Put some faces to names with this fast and fun networking session. Rotate around the room and meet, greet and exchange business cards as you go. Create the first links with potential business partners.

10 reasons to attend

1. Dig deep into the scientific foundations at the core of biosimilar development
2. Understand how to translate regulatory expectations into trial concepts with global best practice strategies in clinical trial design and execution
3. Master biosimilar manufacture, process development and scale up
4. Find out where the true biosimilar industry growth opportunities lie and what role they can play in your portfolio
5. Identify innovative tools and techniques for immunogenicity
6. Understand how to operate in the regulatory environment in Europe, Asia and America with input from key regulatory bodies
7. Gain an investor's perspective and understand what this means for your business
8. Review recent partnering and M&A activities and the resulting impact on the biosimilar industry
9. Transform good science into a better approval process and increase patient access
10. Double your opportunities - choose to attend Biosimilars Drug Development World or the parallel World Generic Medicines Congress to learn and network with colleagues across both events

Reserve your place today

The earlier you book the more you'll save.

It's really easy to register online.

And our online calculator will ensure you take advantage of the best deal.

Go to and register www.healthnetworkcommunications.com/biosimilar

Register now and get the offer price - on your phone

Scan this QR pattern with the camera on your smartphone and register.

Don't have a QR reader app? You can download one for free from App Store. Don't have a smartphone? You can also register and get the offer on our website www.healthnetworkcommunications.com/biosimilar

Package	FULL PRICE
2 day conference	£1,595

VAT is charged at the current rate and is subject to VAT legislative changes.
All bookings will be invoiced at the rate applicable when the booking is made.

BOOK NOW

Go to www.healthnetworkcommunications.com/biosimilar and register

Or call +44 (0)207 092 1000

BRING YOUR TEAM

There's so much great content, you can't possibly cover it all alone! Bring your team and get an extra discount.

There are special group packages available call +44 (0)207 092 1000 for more details or go to www.healthnetworkcommunications.com/biosimilar