Informa Life Sciences' 3rd Annual

Industry's Only Event Dedicated to the Development of Biosimilars in Turkey and MENA

Biosimilars and Biotech in Turkey and MENA

Tuesday 18 - Wednesday 19 November 2014 • Radisson Blu Hotel Istanbul Sisli, Istanbul, Turkey

Save up to £1100! Special prices for Turkish and North African Small and Start up companies

Explore the critical business, regulatory, technical and market access opportunities facing the growth of biosimilars and biotech in Turkey, the Middle East and North Africa

Our Most Senior-Level Speaker Faculty to Date:

Dr Rony Touma, *General Manager, North Africa,* **Sandoz, a Novartis Company,** Morocco

Dr Claudia Palme, *Industry Expert, Former Senior Strategic Officer,* **Amgen,** Saudi Arabia

Dr Michel Mikhail, *Chief Regulatory Officer, Executive VP, Global Regulatory,* **Fresenius Kabi. Member, EGA Executive Committee and Member of EGA Board**

Dr Cem Baydar, *Senior Principal, Head of Turkey and Middle East,* **IMS,** Turkey

Dr Devrim Satik, *Head, AIFD Biologicals & Biosimilars Working Group and Head, Regulatory Affairs and Product Patrimony,* **Sanofi,** Turkey

Dr Osama Nabulsi, *Vice President, Business Development and Alliance Management,* **Hikma Pharmaceuticals,** Jordan

Dr Wesal Haqaish, *Head Registration,* **Jordan Food and Drug Administration,** Jordan

Dr Abdullah Al Mesned, *Chairman,* **Mesned Pharma Consult Center,** Saudi Arabia

New for 2014!

- Keynote Presentation from Sandoz' Head of North Africa, Rony Touma
- "Meet the Experts" Discussion Panel on the Best Routes to Market
- In-depth Market Analysis from IMS

Reasons to Attend:

1. Benchmark your biosimilars business strategy against industry leaders – **Sandoz, Sanofi, Hikma, Abdi Ibrahim**
2. Find out what **Turkish, Jordanian** and **European Regulators** want to see in your dossier - are you in line with expectations?
3. Develop a high-quality, cost-effective biologic production strategy with case studies from **Benta** and **Sanovel**
4. Form winning local and international partnerships with insight from
5. **Identify, establish and secure a winning partner** to implement your biosimilar strategy

Pre-Conference Symposium – 17 November 2014

Accessing the European Biosimilars Market – Regulatory, CMC and Quality Expectations

Leader: **Cecil Nick,** *Principal Consultant,* **Parexel,** UK

Evening Seminar – 18 November 2014

Understanding and Accessing the Iranian Biosimilars Market

Leader: **Dr Haleh Hamedifar,** *CEO,* **CinnaGen Co,** Iran

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PRE-CONFERENCE SYMPOSIUM X: MONDAY 17TH NOVEMBER 2014

How to Develop for the European Biosimilars Market

Registration 11.30 – Start 12.00 – End 18.00 – Workshop material, refreshments and an evening meal will be provided

Developing a biosimilar is not a simple process but one that requires significant investment, technical capability and clinical trial expertise. Average cost estimates are extremely high and even higher when manufacturing plant development is needed. This symposium aims to identify the hurdles which generic and pharmaceutical industries will face and how to successful implement strategies to overcome them.
This workshop will help to develop an expert understanding of biosimilars including development requirements, strategies, costs, and timelines.

Specifically this workshop will cover:

- Development and establishment of biopharmaceutical production
- Choosing the optimal cell line
- Demonstrating physicochemical and biological comparability
- Process optimisation, qualification and validation
- Formulation development
- Design of clinical development program
- Method qualification and validation (according to ICH Q2(R1))
- Selection and procuring reference product
- Selection and auditing of contract manufacturer (CMOs) & analytical service labs (CROs)
- Outsourcing Management - drafting of contracts and negotiations
- Project management - portfolio management - interims management
- Creation and/or reviewing technical documentation for CT Approval IB, IMPD("eCTD Module 3")
- Interaction with regulatory agencies, presentations and discussions (international)
- Potential pitfalls in biosimilar development in the EU
- Setting up the necessary infrastructure
- Storyboarding, submitting and supporting the marketing authorisation application

Workshop Leader: **Dr Cecil Nick,** *Vice President,* **Parexel,** UK

DAY 1: Tuesday 18th November 2014

08:00 Registration and Morning Coffee

08:55 Opening Remarks from the Chairman

Business Opportunities in the Turkey, Middle East and North Africa Biotech Market

09:00 **Market opportunities for biosimilars in the Turkey/MENA Region**
Biosimilars present a significant upside potential for Turkey and MENA Region. However compared to more developed markets, several markets currently lack a customized registration and approval process and guidance for biosimilar products. IMS Consulting group believes that with the required policy and pricing reforms as well as government incentives, the uptake of Biosimilars in Turkey and MENA would be significant and companies should start preparing their strategy aligned to this seize this opportunity

Dr Cem Baydar, *Senior Principal, Head of Turkey and Middle East,* **IMS Consulting Group,** Turkey

09:40 **Biosimilar development in the Middle East**
- Why should companies do business in Turkey and MENA?
- What regions offer the best return on investment?
- Regulatory and financial support available for companies in the Turkey/MENA regions
- Barriers to entry

Dr Claudia Palme, *Industry Expert, Former Senior Strategic Officer,* **Amgen,** Saudi Arabia

10.10 Morning Coffee and Speed Networking Session

FEATURED PRESENTATION

11:00 **Biosimilar Development in North Africa**
- Potential of North African biosimilars market
- How to get into the North African biosimilars market
- Business models in North African biosimilars market
- Overview of Sandoz's products and offering in the region

Dr Rony Touma, *General Manager, North Africa,* **Sandoz, a Novartis Company,** Morocco

11:35 **Counter strategies made by innovator companies in the biosimilars market**

Dr Osama Nabulsi, *Vice President, Business Development and Alliance Management,* **Hikma Pharmaceuticals,** Jordan

11.50 "Meet the Experts" Panel
Biosimilar Business Development in the Turkey/ MENA region

Dr Rony Touma, *General Manager, North Africa,* **Sandoz, a Novartis Company,** Morocco

Dr Claudia Palme, *Former Senior Strategic Officer,* **Amgen,** Saudi Arabia

Dr Ferhat Farsi, *IEIS R&D Working Group Member and RD and BD Director,* **Abdi Ibrahim Pharmaceuticals,** *Turkey*

Dr Cem Baydar, *Senior Principal, Head of Turkey and Middle East,* **IMS,** Turkey

Dr Amr Kandeel, *Head, Biosimilars Oncology, Egypt and Sudan,* **Sandoz**

Dr Osama Nabulsi, *Vice President, Business Development and Alliance Management,* **Hikma Pharmaceuticals,** Jordan

12:20 **SPOTLIGHT PRESENTATION**
This conference brings together key decision-makers from across strategy, technical and regulatory is the ideal platform for showcasing your latest technologies and services. For further information on Sponsorship and Exhibition opportunities, please contact: kirriane.marshall@informa.com, Tel: + 44 (0)20 7017 7129

12:50 Lunch and Networking

Regulatory Strategies for Accessing the Turkey and MENA Regions

14:00 **What is on the horizon in the biosimilars' market?**
- Global pharma outlook
- Biotechnology based products
- Drivers and opportunities for pharma companies; Growing importance of biosimilars;
- Future directions; Sustainable growth for Biosimilars or not?

Dr Ferhat Farsi, *IEIS R&D Working Group Member and RD and BD Director,* **Abdi Ibrahim Pharmaceuticals,** *Turkey*

14:35 **Regulatory environment for the development, manufacturing and registration of Biotech & Biosimilars products in Turkey**
- Existing framework for Biosimilar development in Turkey
- Forthcoming Guidelines and what they will mean for industry
- How can companies access Government support for Biosimilar development?
- Update on current submissions with the Turkey regulators
- Partnerships

Dr Devrim Satik, *Head, AİFD Biologicals & Biosimilars Working Group and Head, Regulatory Affairs and Product Patrimony,* **Sanofi,** Turkey

15:10 **Biosimilar Guideline update from Jordan**
- Updates on the Guidelines
- What is required for biosimiar approval in Jordan
- Quality standards for biosimilars in Jordan

Dr Wesal Haqaish, *Head Registration,* **Jordan Food and Drug Administration,** Jordan

15:45 Afternoon Break

Establishing Successful Technology Transfer

16:15 **Protective national policies and their role in technology transfer**
- What are the national policies that must be considered for carrying out tech transfer?
- How do these policies impact the role of technology transfer?
- What are the best strategies to overcome these hurdles?

Dr Zakia Kurdi, *Licensing Director,* **JPM,** Jordan

16:50 **Discussion Panel: Establishing Successfull Technology Transfer in MENA**
- Setting up a Tech Transfer process in MENA
- What are the best partnership opportunities?

Dr Osama Nabulsi, *Vice President, Business Development,* **Hikma,** Jordan
Dr Zakia Kurdi, *Licensing Director,* **JPM,** Jordan

17:25 Closing remarks from the Chair

17:30 End of Day One followed by Networking Drinks

18:15 Registration for **Accessing the Iranian Biosimilars Market** Evening Seminar

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EVENING SEMINAR S: TUESDAY 18TH NOVEMBER 2014

Understand and Accessing the Iranian Biosimilars Market

Registration 18.30 – Start 18.45 – End 20.30 – Dinner and refreshments will be provided

Iran is making significant advances in medicine production, especially in the fields of biosimilar and biotechnology drugs. According to analysts, the Iranian drug market will be worth $5.42 billion by 2019 representing a compound annual growth rate (CAGR) of 13.4% in local currency and 10.3% in US dollar terms.

The Iran government has also allocated substantial resources for supporting local pharmaceutical companies to manufacture biopharmaceuticals.

This Evening Seminar, a combination of presentations, break out groups and in-depth discussion, is designed for companies looking to find out more about the Iranian biotech market, the opportunities available, the regulatory and business frameworks and partnership opportunities in the region.

Workshop Facilitator
Dr Haleh Hamedifar, *CEO,* **CinnaGen Co,** Iran
Plus other contributors

DAY 2: Wednesday 19th November 2014

08:55 Opening remarks from the Chairman

How to Access the MENA Biosimilar Markets

09:00 **Successfully accessing the GCC Biosimilar market**
- Opportunities for entering the GCC Biosimilars market?
- Regulatory strategies for accessing the GCC region?
- What is required to achieve market penetration?
- Partnership opportunities in the GCC region?

Dr Abdullah Al Mesned, *Chairman,* **Mesned Pharma Consult Center, Saudi** Arabia

09:35 **Succeeding and partnering in the MENA regions – Market Penetration of Biosimilars, IFN beta a case study**
Biosimilar role in health care budget becomes more and more significant and payers all over the world find them a promising way to skip crisis due to new expensive medicines come to the market day by day. However the way, time, and manner for entering to the market is the key factor to have a portion of this complicated biopharmaceutical market.
Dr Haleh Hamedifar, *CEO,* **CinnaGen Co,** Iran

10:10 Morning Break

Global Strategies for Accessing the Biosimilars Market

11:00 **Global updates on biosimilars regulatory development**
- Current uptake of biosimilars in Europe – which products are succeeding well and why?
- Pricing and reimbursement strategies
- Examples of good partnerships and why they are working
- Future trends in the European biosimilars market

Dr Michel Mikhail, *Chief Regulatory Officer, Executive VP, Global Regulatory, Fresenius Kabi. Member,* **EGA Executive Committee and Member of EGA Board**

11:35 **A global overview of biosimilars and an update on the status of the US FDA Guidance on biosimilars**
This presentation will examine the biosimilar pathways available worldwide, whether data or market exclusivity is available for reference biological products, patent and litigation issues affecting biologics and what the future holds for biosimilars, particularly in the emerging market countries. Additionally, this presentation will review the latest US FDA guidance on biosimilars, whether any applications for approval of a biosimilar have been filed with the FDA and if not, who might file the first to file an application.
Lisa Mueller, *Partner and Chair of the Life Sciences and Chemical Practice Group,* **Michael, Best & Friedrich,** USA

12:10 **SPOTLIGHT PRESENTATION**
Please contact: kirriane.marshall@informa.com, Tel: + 44 (0)20 7017 7129

12:45 Lunch and Networking

Technical Challenges when Manufacturing and Developing Biosimilars

14:00 **Biosimilar development and manufacturing – Case study from Lebanon**
Choices, challenges and know-how are some of the main important factors affecting the development of a Biosimilar manufacturing site. Moreover, what will be the single most important factor affecting the Biomanufacturing capacity in the region? What are the most common and biggest challenges in Biosimilar production and manufacturing in the emerging markets? What is the impact of the Regulatory Agencies of the MENA Region on the manufacturing and technical development? Finally, what and how should be the role of the suppliers in our region?
Dr Marcel Bassil, *Associate Director, Biotech,* **Benta Pharma Industries,** Lebanon

14:35 **Biosimilar development and manufacturing – Case study from Sanovel**
- Benefits and limitations of setting up a process development strategy from scratch
- Validation of a biological process design
- Cell Line development
- Practical advice for adhering to EU regulations
- GMP requirements and further considerations for clinical trials

Dr Ireme Yenice, *Biotechnology Divisional Manager,* **Sanovel,** Turkey

15:10 **Key requirements for building quality material in Turkey, MENA, GCC and Russia**
- Outline of the key EU/US guidelines on biological quality testing
- QC testing strategies for product release and stability testing
- Ensuring high quality products and effectively matching the demands of your market
- Ensuring validated testing facilities: Current regulatory requirements and ISO standards
- Key differences in QC assessment of a small molecule vs. biological

Dr Devrim Demir, *Consultant,* **Akdeniz University, Turkey,** *Former quality assessor* **at Turkish Ministry of Health,** Turkey

15:45 Afternoon Break

Establishing Manufacturing Networks and Partnerships in the Turkey and MENA Region

16:15 **Fast track development and registration of your product through a local partner**
- Benefits and limitations of working with a local partner
- Finding the best partner for your product: Key considerations
- Reality of partnering for product development and the time benefits
- What are current biotech capabilities and what level of partnership is available?

Dr Erbru Oney, *Consultant,* **Pharmanet Consulting,** Turkey (TBC)

16:50 **Commercialisation activities at Ege University**
This presentation will look at the commercialisation and licensing strategies of the inventions that are created in Ege University focusing on the biotech and pharmaceutical area. Some technical and commercial Information about these inventions will be presented including how companies and universities work together in the Turkey region.
Dr Fazilet Vardar, Professor at Ege University, Turkey

17:25 End of Day Two

> *"Good event providing up-to-date information from skilled professionals"*
> **2013 Attendee, CMC Biologics**

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Informa's Biosimilars in Turkey, MENA conference brings together key decision-makers from across regulatory, technical and strategic departments and is the ideal platform for showcasing your latest technologies and services.

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Reasons why you should choose this event:
- Meet the key decision-makers shaping the future of biotech and biosimilars in Turkey and MENA

Promote your services to key regulatory and industry leaders from the biosimilar community in these new rapidly expanding markets.
- Educate the market and regulators on the benefits of your new technology or service

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Biosimilars and Biotech in Turkey and MENA

Tuesday 18 - Wednesday 19 November 2014

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