The Middle Eastern and Turkish biotech market is expected to **exceed $15 billion within the next 12 months:** Maximise R&D and manufacturing capabilities to ensure market access

Biopharmaceutical Production Series

Informa Life Sciences' Inaugural

Biological Production Strategies in Turkey and MENA

Bringing together Europe and the Middle East to establish beneficial partnerships for speedy and cost-effective biological production and to ensure product approval

Co-Located with **Biosimilars Turkey & MENA**

www.informa-ls.com/biotechmena

6-7 November 2013, Radisson Blu Conference & Airport Hotel, Istanbul, Turkey

Reduced rates for SMEs and Academia

11+ Hours of Partnering & Networking - 10 Local Biotech Companies - 5 Global Pharmaceutical Players

Sameh Rakha, *Chief Scientific Officer,* **Novartis Pharma,** Egypt

Penelope Shihab, *CEO,* **Monojo,** Jordan

Hasan Ersin Zeytin, *Director, Medical Investigations,* **Nobel,** Turkey

Elif Elkin, *Business Development Manager,* **Abdi İbrahim,** Turkey

Yasser Sharif, *Section Head,* **Abu Dhabi Health Authority,** UAE

Burak Ergenoglu, *Head, Strategic Planning & Portfolio Management Department,* **Sanofi,** Turkey

15 Leading Local & International Companies

- ✔ **Irem Yenice,** *Biotechnology Division Manager,* **Sanovel,** Turkey
- ✔ **Khaled M. Al-Qaoud,** *Associate Prof. Immunology, Research and Development (R&D) Manager,* **Monojo,** Jordan
- ✔ **Kilian Mullet,** *Technology Transfer Leader, Emerging Markets,* **Pfizer,** Ireland
- ✔ **Devrim Satik,** *Managing Director, Regulatory Affairs Manager, Medical,* **Sanofi,** Turkey
- ✔ **Gavin Fitzgerald,** *Associate Director, Regulatory Affairs,* **Abbvie,** UK
- ✔ **Jan Rohde,** *R&D Manager,* **Minapharm Pharmaceuticals, Rhein-Minapharm Biogenetics,** Egypt
- ✔ **Richard DiCicco,** *Chairman,* **Harvest Moon Pharmceuticals,** USA
- ✔ **Abdullah Baaj,** *CEO,* **Boston Oncology,** USA

Biotech Professionals

- ✔ **Chris Hentschel,** *Chief Scientific Officer,* **BioCity Development,** Turkey
- ✔ **Yasser Sharif,** *Section Head, Medication & Medical Products Safety, Medication & Medical Products Safety Section, Emergency & Disaster Management Department,* **Abu Dhabi Health Authority,** UAE
- ✔ **Waleed Danho,** *President,* **DANHO Associates Inc.,** *Distinguished Research Leader (Retired) at* **Hoffmann-La Roche Inc.,** USA

Benefits of Attending in 2013

- **Gain access to** leading international players and local biotech companies: Dedicated **partnering and high speed networking sessions** with professionals over 11+ hours of partnering time
- **Discover successful biological production strategies** in the Turkey and MENA regions: Hear leading international pharma insight from **Sanofi, Novartis** and **Pfizer**
- Learn about **novel technologies for accelerated development** of biosimilars, peptides and antibodies for improved quality and first to market
- Gain insight to **biological development plans** from early cell line choice, clinical development to manufacturing facility design: Case studies from **Abbvie** and **Sanovel**
- Better understand the **enablers for technology transfer** and practical considerations with a featured presentation from **Pfizer**
- **Avoid costly** production delay with **local regulatory knowledge** of approval criteria and recommended analytical strategies: **Abu Dhabi Health Authority** and **Sanofi Turkey** present

Maximise your Time Out of the Office with 3 Interactive Training Days

Pre-Conference Workshop W: Tuesday 5th November 2013

Successful Development of Biological Medicinal Products

Leaders: **Christopher Holloway,** *Owner,* **ERA Consulting,** UK

A-Z of Biological Development, Analysis & Manufacture

Pre-Conference Workshop Y: Tuesday 5th November 2013

Introduction to Biosimilars: From Development to Market

Leader: **Cecil Nick,** *Vice President,* **Parexel Consulting,** UK

Moving into Biosimilars

Evening Seminar X: Wednesday 6th November 2013

Meet the Experts: Biotech Technology Transfer

Leaders: **Siegfried Schmitt,** *Principal Consultant* & **Cecil Nick,** *Vice President,* **Parexel Consulting,** UK

Practical insight on Tech Transfer of Biotech

informa life sciences

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Exhibitor: AsahiKASEI Asahi Kasei Bioprocess

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Tuesday 5th November: Pre-Conference Workshop

A-Z guide to biological process development

Successful Development of Biological Medicinal Products: Regulatory, Manufacturing and Analytical Considerations

Option W

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

Topics will include:

- Overview of regulations and guidelines relating to biological medicinal products and their practical application
- Manufacturing and analytical requirements for the successful development of biologics
- Characterisation, control and stability testing strategies for biologics
- Comparability associated with changes to biological processes and products
- Analytical challenges associated with demonstrating biosimilarity vs comparability
- Interpreting and presenting analytical data - Case studies presented

Workshop Leader: **Christopher Holloway,** *Owner,* **ERA Consulting,** UK

OR

Introduction into Biosimilars

Introduction to Biosimilars: From Development to Market

Option Y

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

Topics will include:

- Introduction to Biosimilars: Identifying the key differences between small molecules and biologics development
- EU biosimilar experience and successful development plans to date
- Preparing your own development plan
- Define a target product profile
- Understand the market and competition?
- Who is already targeting that product? What stage of development are they in?
- 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

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

DAY 1: WEDNESDAY 6TH NOVEMBER 2013

08.00 Registration and Morning Coffee

08.55 Opening Remarks from the Chairperson

Manufacturing and Development in Turkey & MENA

09.00 **Medical affairs and biotech development: The Egyptian market**

This presentation will address an overview of the Egyptian pharmaceutical market, current product demand, clinical development, lifecycle management and key regulatory affairs considerations in product development.
Sameh Rakha, *Chief Scientific Officer,* **Novartis Pharma,** Egypt

Establishing Successful and Cost-Effective Biological Production Partnerships

09.35 **Current biotech capabilities in Turkey and advantages of registering your product through a local partner**

Biomedical research in Turkey has improved due to various sources of funding provided, leading to the integration of research labs with their counterparts in Europe, the USA and the Far East .Turkey has a big potential in biotechnology due to existing human resources and knowledge base. With developed long-term state policy to improve infrastructure in this area by allocating appropriate funds, Turkey will take its place among advanced countries in biotechnology.
Devrim Satik, *Managing Director, Regulatory Affairs, Manager, Medical,* **Sanofi,** Turkey

10.10 **Speed Networking Session and Morning Coffee**

- With HIGH SPEED NETWORKING you can make more new business contacts in one session than most people will make in 6 months!
- Network with other professionals, one-on-one, a few minutes at a time working specifically in the biosimilars and biotech field
- Leave with a pocket full of business cards and numerous new business connections

Be quick, ...the clock is ticking!
Register on Wednesday 6th November at morning registration

11.15 **An effective outsourcing and co-development strategy can increase productivity**
This presentation will provide an overview on global pharma market, a look at changing health care systems and the potential for reshaping the pharma industry. In addition, a solution for co-development and outsourcing will be discussed, including key drivers for co-development and outsourcing, risks and whether there is sustainable growth for pharma or not.
Elif Elkin, *Business Development Manager,* **Abdi brahim,** Turkey

11.50 **Struggles and benefits of developing biologicals in the Turkey & MENA**

Understanding how to best develop biologicals and the key struggles and considerations in starting production is essential to develop in Turkey and MENA. Financial possibilities in biological production and biosimilar products and the current opportunities to find a niche in a specific market will be discussed.
Richard DiCicco, *Chairman,* **Harvest Moon Pharmceuticals,** USA

12.25 **SPOTLIGHT PRESENTATION**
Informa's Biological Production Strategies 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. For further information on Sponsorship and Exhibition opportunities, please contact: Ben Edwards:
Tel: **+ 44 (0)20 7017 4447** Email: **ben.edwards@informa.com**

13.00 Lunch and Networking Opportunities with Biosimilars Turkey Meeting

Understanding you Market, Meeting Demand and Gaining Investment

14.00 **Understanding your market and tailoring product development**

JORDAN CASE STUDY

Dr Penelope Shihab, *CEO,* **Monojo,** Jordan

14.35 **Executive decision-making: Biosimilars in emerging markets**

SAUDI ARABIA CASE STUDY

This presentation will serve as a guide to decision-making in the Biosimilars landscape. The updated commercial opportunity and regulatory environment, examination of conducting clinical trials and manufacturing facility design (stainless steel capacity vs. single-use agility) and production CapEx consideration will be discussed, closing with analysis of market structure and the competencies of eventual participants.
Abdullah Baaj, *CEO,* **Boston Oncology,** USA

15.10 **Gaining investment through understanding available funding and support**
This presentation will address biological products of preference for different regions, regarding gaining Government incentives for developing biotech products and venture capitalist insight and support.
Salim El Labban, *Director, Business Development,* **BroadMed,** Lebanon

15.45 Afternoon Tea and Networking

Successful Biological Development and Manufacturing Strategies

16.10 **Moving from small molecules to biologicals and current development capabilities**

Local Industry Case Study

This presentation looks at choosing what biological to develop and what indication to develop for, regarding feasibility studies, cell line development and clone selection. It will also address essential animal studies and experience in current capabilities. Finally development from the bench to the clinic and current potential to perform clinical trials will be discussed.
Hasan Ersin Zeytin, *Director, Medical Investigations,* **Nobel,** Turkey

16.45 **A focus on biosimilar development**

Local Industry Case Study

Sanovel have been working on Biosimilar develop projects for around 5 years. It has a dedicated cGMP manufacturing facility for large molecules since 2011. Manufacturing process development studies, physicochemical characterisation studies, functional activities of the biosimilars and comparability studies have been performed in the labs. Preclinical and clinical development programmes are also followed according to EMA guidelines. Currently, Sanovel biosimilar projects are in progress.
Irem Yenice, *Biotechnology Division Manager,* **Sanovel,** Turkey

17.20 **Q&A Discussion Panel: Small biotech v.s big pharma**

DISCUSSION PANEL

- Key differences and how to learn from each company
- How to best complement capabilities through effective partnerships
- Where to go to now? Future efforts for independent manufacture v.s continued partnerships

Contribution from Speakers of the Day

17.40 Closing Remarks from Chairperson

17.45 End of Conference Day One and Networking Drinks with Biosimilars Turkey Meeting

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Networking Dinner included

Evening Seminar X: Wednesday 6th November 2013

Practical Insight for Improved Tech Transfer

MEET THE EXPERTS: BIOTECH TECHNOLOGY TRANSFER

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

Topics to be included:

- Essential recommendations from experts on best practice
- Current regulatory requirements on how to best perform Technology Transfer
  - Quality system elements
  - Data and records management
  - Applying GMP consistently
  - Quality assurance across boundaries
  - Comparability considerations
- Cost considerations involved in performing Technology Transfer
  - Design control and documentation
  - Project Management best practices
  - Manufacturing and technical support
- Key bottlenecks and how to best overcome
- Evaluating current capabilities and whether you can efficiently replicate methods

Seminar Leaders: **Siegfried Schmitt,** *Principal Consultant,* **Parexel Consulting,** UK & **Cecil Nick,** *Vice President,* **Parexel Consulting,** UK

DAY 2: THURSDAY 7TH NOVEMBER 2013

08.55 Opening Remarks from the Chairperson

Biotech Future in Turkey

09.00 **Future efforts of biotech development in Turkey: Bio Instanbul**

This presentation will look at the latest Bio Istanbul project, which is a public-private partnership to develop the largest biomedical research park and biomedical innovation cluster in Turkey and the wider MENA region. It looks to host Turkey's first comprehensive, tertiary care pediatric research hospital alongside commercial R&D centres, incubation space that will provide support to emerging companies, as well as a graduate research university that will focus primarily on biomedical research and clean technologies.

Chris Hentschel, *Chief Scientific Officer,* **BioCity Development,** Turkey

Technical Approaches to Biological Production: Implementing Novel Technologies and Single-Use Systems

FEATURED PRESENTATION

09.35 **Key enablers for Technology Transfer of biotechnology products in country**

The presentation will address the key requirements: People, infrastructure and products to enable a technology transfer in a new location. Each will be addressed with some suggestions as to how to address to best leverage and enable a successful Technology Transfer.

Kilian Mullet, *Technology Transfer Leader, Emerging Markets,* **Pfizer,** Ireland

10.10 **Accelerating biosimilar Mabs to market: A predefined DSP process with optimal COGS**

This presentation will look at a scalable and optimised downstream process template saves time in parameter selection and optimisation, and reduces risk in scaling and tech transfer, including CQA data is presented for two Mabs at bench scale as well as pilot scale, showing consistent scalability and yield, and finally COGS data is presented at bench and pilot scale, with estimations for larger scale manufacturing

Jennifer Campbell, *Director, WorldWide Biosimilars Market, Process Solutions,* **Merck Millipore,** USA

10.45 Morning Coffee and Networking with Biosimilars Turkey

Biological Development: From Generation to the Clinic to Market

11.15 **Local Biotech: Minapharm - A biotechnology case study**

Minapharms subsidiary, Rhein-Minapharm, is the first company in Egypt and the Middle East dedicated to the development and production of recombinant drugs. To accommodate the high prevalence of HCV in Egypt, Minapharm developed its own pegylated interferon representing the gold standard therapy for this disease, with an innovative expression system, the single cell yeast, Hansenula polymorpha, where processing of the drug product is faster, cheaper, and avoids critical impurities usually found in bacterial expression. Combined those characteristics result in a high quality product to fight HCV.

Jan Rohde, *R&D Manager,* **Minapharm Pharmaceuticals, Rhein-Minapharm Biogenetics,** Egypt

11.50 **Indication extrapolation for biosimilar products**

BIG PHARMA

This presentation will look at biotherapeutics and biosimilar regulatory requirements, indication extrapolation, interchangeability and substitution and pharmacovigilance and naming.

Gavin Fitzgerald, *Associate Director, Regulatory Affairs,* **Abbvie,** UK

SPOTLIGHT PRESENTATION

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13.25 Lunch and Networking Opportunities with Biosimilars Turkey Meeting

13.50 **Antibody based biotherapeutics in targeting IgE in asthma and allergy treatment**

LOCAL BIOTECH

Treatment of asthma and other IgE mediated allergic diseases can be either chemotherapeutic "general" or immunologic "specific". Chemotherapeutic treatment is not adequate to control the symptoms of severe asthmatics. Thus, there is urgent need for more effective and specific therapies and treatment strategies. This presentation will address the international immunotherapeutic trials targeting IgE or anti-Fc receptor binding site as well as a local experience on the production of camel based immunotherapeutic targeting human IgE.

Khaled M. Al-Qaoud, *Associate Prof. Immunology, Research and Development (R&D) Manager,* **Monojo,** Jordan

14.25 **Peptide therapeutics as additional modality to small molecules (SM) and biologics in addressing unmeet medical needs and mitigating risk in drug development**

The peptide market is growing nearly twice as fast as overall pharmaceuticals due to increased number of therapeutic targets, and improved delivery methodologies. Is there an unmet medical needs for the indication of interest? What is the marked size? Is this target amenable for small molecule approach? What are the de-risking approaches vs. small molecules and monoclonal antibodies? These considerations will be discussed in the presentation illustrated in an example in the field of Diabetes / Obesity.

Waleed Danho, *President,* **DANHO Associates Inc.,** *Distinguished Research Leader (Retired) at* **Hoffmann-La Roche Inc.,** USA

15.00 Afternoon Tea & Networking

Effective Testing Strategies to Ensure Product Quality and Comparability

15.40 **Toxicity and safety profiles of Over the Counter (OTC) products**

This presentation reviews the pharmacologic components found in over-the-counter medicines, the increasing trend of abuse of these medications, addresses contributing factors and provides measures for preventing their toxicities.

Yasser Sharif, *Section Head, Medication & Medical Products Safety, Medication & Medical Products Safety Section , Emergency & Disaster Management Department,* **Abu Dhabi Health Authority,** UAE

16.15 **Trends in global pharmaceutical industry, emerging markets and Turkey**

To find out more about this presentation, please visit the conference website at www.informa-ls.com/biotechmena

Burak Ergenoglu, *Head, Strategic Planning & Portfolio Management Department,* **Sanofi,** Turkey

16.50 Closing Remarks from Chairperson

17.00 End of Conference

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Reasons why you should choose this event:

- 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
- Co-located with **Biosimilars Turkey & MENA** and **Pharmaceutical Law in Turkey & MENA** - Network and partner with 3 markets at the same time

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