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SMi presents the 2nd in its series of conferences on...

Biosimilars & Biobetters USA

Reviewing the State of the Nation: Regulatory Update, Development Review, Benchmarking

Renaissance Woodbridge Hotel, Iselin, New Jersey, USA

16th - 17th NOV 2015

Chairman for 2015:

Richard DiCicco, Chairman,
Harvest Moon Pharmaceuticals USA, Inc.

Key Speakers Include:

- **John Pakulski,** Head US Biopharmaceutical Regulatory Affairs, **Sandoz Inc.**
- **Chetak Buaria,** Director, Business Development (Biosimilars), **Merck Serono SA**
- **Carsten Brockmeyer,** CEO, **Formycon AG**
- **Sean Xue,** Director, Portfolio Management – Biologics, **Dr. Reddy's Laboratories, Inc.**
- **Andrea Laslop,** Head of Scientific Office, **AGES Regulatory Agency**
- **T.Shantha Raju,** Scientific Director, Biologics Research, **Janssen Research and Development, LLC**
- **Michael Kleinrock,** Research Director, **IMS Health**
- **Steinar Madsen,** Medical Director, **Norwegian Medicines Agency**

Business Benefits for 2015:

- **HEAR** the latest on the evolving regulatory biosimilar landscape and review the guidelines
- **GAIN** understanding on the barriers being faced for market access and commercialisation of products through case-study led presentations
- **FOCUS** on the global market developments with case studies on Emerging Markets of biosimilars and assessing the trends we are currently seeing
- **ASSESS** and review in-depth protein characterisation and analytical comparability to efficiently and effectively collect data

PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS
Wednesday 18th November 2015, Renaissance Woodbridge Hotel, Iselin, New Jersey, USA

A: A Regulatory Perspective on Biosimilars

Workshop leader: **Ravi S. Harapanhalli,** Vice President, **ParExel** and former Senior Executive, **FDA**
8.30am-12.30pm

B: Development, Regulatory & Commercial Needs for Global Biosimilars

Workshop leaders: **Gerry McGettigan,** CEO & Regulatory Expert, **Kinesys Consulting Ltd & Graeme Deuchar,** Product Development Expert, **Kinesys Consulting Ltd**
1.30pm-5.30pm

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Biosimilars & Biobetters USA

Day One | Monday 16th November 2015

8.30 **Registration & Coffee**

9.00 **Chairman's Opening Remarks**
Richard DiCicco, Chairman, **Harvest Moon Pharmaceuticals**

Assessing the Regulatory Landscape

9.10 **OPENING ADDRESS**
FDA's views on statistical analysis of quality attributes to establish biosimilarity

Ravi S. Harapanhalli, Vice President, **ParExel** and former Senior Executive, **FDA**

9.50 **From approval to clinical use - what are the differences between the US and Europe?**
- Approval - is it trusted in the medical profession and public?
- Labelling - what is the best way?
- Switching, substitution and interchangeability – what are the drivers?
- Discounts - what can be expected?
- What can US learn from Europe?


Steinar Madsen, Medical Director, **Norwegian Medicines Agency**

10.30 **Morning Coffee**

11.00 **SPOTLIGHT PRESENTATION:**
The first biosimilar approved by the FDA
- Looking at this case in detail, how did it progress and how will it develop
- How did the FDA interpret their own guidelines
- What can we learn from this first approval?
- Looking ahead, what's the future regarding more complex molecules?


John Pakulski, Head US Biopharmaceutical Regulatory Affairs, **Sandoz Inc.**

11.40 **The Great Debate - Interchangeability**
- The determination of interchangeability: satisfying the FDA definition to achieve automatic substitution by the pharmacy without physician consultation.
- Will interchangeability minimize the uncertainty of biosimilar adoption?
- How does INN naming affect automatic substitution?
- What will the FDA interchangeability guideline look like?
- Considerations in the design of switching studies
- How will interchangeability affect pricing and reimbursement?
- Differentiation between the designation or practice of interchangeability in the US and EU
- Which is more desirable for success: switching existing patients or interchangeability?


DISSCUSSION TO FOLLOW
Richard DiCicco, Chairman, **Harvest Moon Pharmaceuticals USA, Inc.**

12.20 **Networking Lunch**

1.30 **Perspectives on the evolving biosimilars landscape**
- The Global Biologic Market: understanding the place of biologics in medicine use around the world
- Learning from the biosimilar experience: European experience can offer some insights into the U.S. future (and some confusion too)
- Looking ahead to the next five years of biosimilar and biologic evolution


Michael Kleinrock, Research, Director, **IMS Health**

Challenges of Biosimilars

PART ONE

2.10 **Understanding the blurred lines between traditional innovators and generics**
- Scientific and quality considerations in demonstrating biosimilarity between the biosimilar and the reference product
- Reviewing the need to show bioequivalence to the innovator drug based on pharmacokinetic parameters such as rate absorption and bioavailability
- Understanding the complexity of biosimilar models from a clinical perspective


Andrea Laslop, Head of Scientific Office, **Austrian Agency for Health and Food Safety**

2.50 **Case Study: The First International Reference Standard**
- Importance of reference Standards for the Development of biosimilars
- First WHO International Standard (IS) for the TNF-alpha sRII receptor-Fc fusion protein (Etanercept).
- First International Reference (IR) Preparation for anti-drug (anti-Eprex) antibodies
- Other WHO IS & IRs for biosimilars currently in development


Michael Tovey, INSERM Director of Research, Laboratory of Biotechnology and Applied Pharmacology, **Ecole Normale Supérieure de Cachan**

3.30 **Afternoon Tea**

4.00 **Update: Can biobetters or biosuperiors meet the challenges of best in class molecules and cheaper biosimilars**
- Making biobetters or biosuperiors successful and cost effective through advances in protein engineering and pioneering technologies - case studies of biosuperior vs. biosimilars
- Evaluating the current innovations in improving existing biologics therapies in diseases with unmet medical needs
- Identifying which products have significant potential for 'biosuperior' development
- Developing biosuperior protein therapeutics that address sub-optimal, in-market characteristics of currently licensed biologics
- Examining current active projects in research and development of biosimilar and novel biobetter/biosuperior therapeutic proteins

Rakesh Dixit, Vice President, R&D, Global Head, Biologics Safety Assessment, **MedImmune**

4.40 **Impact of Glycosylation on the Biological Functions of Therapeutic Antibodies**

T.Shantha Raju, Scientific Director, Biologics Research, **Janssen Research and Development, LLC**

5.20 **Chairman's Closing Remarks and Close of Day One**

Who should attend this conference:

Job titles include but are not restricted to: CSOs, CMOs, Vice Presidents, Presidents, Heads, Directors, Team Leaders, from the following roles:

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- Regulatory Compliance
- Pharmacovigilance
- New Product Development
- Analytical Characterisation

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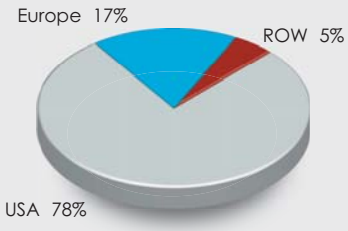

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Biosimilars & Biobetters USA

Day Two | Tuesday 17th November 2015

8.30 **Registration & Coffee**

9.00 **Chairman's Opening Remarks**
Richard DiCicco, Chairman, **Harvest Moon Pharmaceuticals**

The Legal Perspective

OPENING ADDRESS

9.10 **The litigation landscape in Europe: where are we now?**
- The patent cliff and the patent hurdle - is it real?
- When litigation begins, are the rules different?
- Patent challenges in Europe - the EPO and the national courts
- The future landscape - the Unified Patent Court

Dominic Adair, Partner, Patent Litigation, **Bristows LLP**

9.50 **Challenging the BPCIAs dispute resolution process**
- Reviewing the use of IPR at the US PTO PTAB as an alternative to the Patent Dance of the BPCI Act
- Claim term interpretation, what do these words mean?
- Touching on the use of amendments

Jim Nelson, Senior Principal and Owner, Adversarial Proceedings/ Pharma & Biotech, **Schwegman Lundberg Woessner**

10.10 **Assessing the BPCI and FDA requirements for obtaining the right to sell a Biosimilar in the US**
- Discussing semi-automated processes to identify and analyze US patents of interest to answer the question whether such patents should be listed on the biosimilar applicant's proposed list of patents during the BPCI exchange

Robin A Chadwick, Principal, Biotechnology, **Schwegman Lundberg Woessner**

10.30 **Morning Coffee**

Challenges of Biosimilars

PART TWO

11.00 **Case Study: Creating Biobetters with Improved Efficacy and Safety by Addressing Product Immunogenicity with Tolerogenic Nanoparticles**
- The forthcoming flood of biosimilars will create a highly competitive, low margin marketplace. There will be a competitive advantage for biobetters that are differentiated based on their efficacy and safety profile
- Anti-drug antibodies compromise the utility of many biologic drugs by neutralizing drug efficacy, modulating pharmacokinetics, and/or causing adverse events
- We have developed tolerogenic synthetic vaccine particles (SVP) that are capable of inducing durable immune tolerance to biologic drugs. We will present case examples using tolerogenic SVP with adalimumab and pegylated uricase

Kei Kishimoto, CSO, **Selecta Biosciences**

11.40 **The fingerprinting approach - Expediting development of Biosimilars**
- Because of the very high cost and length of time associated with biologics development, access to biosimilars at a lower cost with shorter development timelines would make these treatments more accessible to a greater number of patients
- To realize cost and time savings from biosimilars, the current development model needs to change to follow the generic product development paradigm which requires only one bioequivalence trial
- STC is currently working on fingerprinting approach to obtain approval on a biosimilar antibody product with only one clinial trial through the use of fingerprinting platform. This concept is described in a detailed publication by FDA's Steve Kozlowski, indicating that a rigorous "fingerprint" like analytical and nonclinical pharmacological similarity could help lift many of the uncertainties/risks of the biosimilar product compared to the originator, which would decrease the burden of clinical trials conducted only to address any "residual uncertainty" not addressable by in vitro studies

Magdalena Leszczyniecka, President & CEO, **STC Biologics Inc.**

12.20 **Networking Lunch**

Commercialisation Strategies and Market Development

1.30 **What are the opportunities in America - Where will we be in 2018?**
- Strengthening long-term strategy to maximise return on investment and to benefit patients
- How to seek partnership to develop and execute risk mitigation strategies
- Forecasting market penetration - What are the factoring barriers to entry?

Cliff Mintz, President & CEO, **BioInsights Inc.**

2.10 **Clinical & Regulatory Strategies Encompassing the Needs of East and West**
- What are the key features of a truly global development programme?
- What obstacles should US / EU biosimilars companies be aware of in Asia and emerging markets
- What changes do we need in development and regulatory requirements to facilitate truly global developments, and which the stakeholders need to make these changes happen?

Mr Gerry McGettigan, CEO, **Kinesys Consulting Ltd** (UK) & COO, **amp Biosimilars AG (Germany)**

2.50 **How partnerships can help biosimilar companies mitigating risks and maximising opportunities**
- How approaches could help big and small players to mitigate risks
- Different partnering models
- Learnings from experience

Chetak Buaria, Director, Business Development (Biosimilars), **Merck Serono SA**

3.30 **Afternoon Tea**

4.00 **Case Study: Where are we now and how will we develop?**
- Biosimilars will soon become number one products - but how to get there?
- Lessons learned from the first European & US biosimilars
- Creating a true global biosimilars strategy
- Similarity exercise, clinical data, extrapolation
- Monoclonal antibodies, a new milestone for the biosimilars market
- Why biosimilars have been more successful than biobetters
- Challenges and opportunities with third wave biosimilars

Carsten Brockmeyer, CEO, **Formycon AG**

4.40 **Assessing emerging markets and enhancing strategies**
- How are emerging markets shifting in BRIC countries
- Dealing with cost containment
- How do emerging markets compare to the EU and US regulations

Sean Xue, Director, Portfolio Management - Biologics, **Dr. Reddy's Laboratories, Inc.**

5.20 **Chairman's Closing Remarks and Close of Day Two**

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HALF-DAY POST-CONFERENCE WORKSHOP A
Wednesday 18th November 2015
8.30am - 12.30pm
Renaissance Woodbridge Hotel, Iselin, New Jersey, USA

A Regulatory Perspective on Biosimilars

Workshop leader: **Ravi S. Harapanhalli,**
Vice President, **ParExel** and former
Senior Executive, **FDA**

Overview of the workshop:

Run by one of the US's leading figures in regulatory approval processes and drug delivery systems, Dr Ravi Harapanhalli. This industry leading workshop will help you plan for smooth regulatory approvals and help with avoiding pitfalls that can cause expensive delays in taking your product to market.

Who should attend this workshop:

Job titles include but are not restricted to: CSOs, CMOs, Vice Presidents, Presidents, Heads, Directors, Team Leaders, from the following roles:

- Follow on Biologics/Follow on Proteins/Biosimilars
- Biologics/Biotechnology/Biogenerics
- Legal and Regulatory Affairs
- Intellectual Property
- Pricing and Reimbursement
- Clinical Immunology
- 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
- Scientific Affairs
- Commercial Affairs and Strategic Planning

Programme:

8.30 **Registration & Coffee**

9.00 **Introductions and Opening Remarks**

9.15 **Session 1: Assessing the compliance required for Biosimilar approval**
- Quality systems/GMPs for biosimilar programs
- Handling R&D analytical data for inspections
- Documenting method qualification studies for similarity tests

10.45 **Coffee break**

11.15 **Session 2: Evaluating how to avoid regulatory pitfalls all the rest as normal**
- Distinctions between product comparability studies and similarity studies
- Designing and conducting similarity studies- choosing adequate test attributes, comparators, and number of batches for similarity assessment
- Addressing residual uncertainties in the analytical similarity programs

12.00 **Discussion and Q&A**

12.30 **Close of Workshop**

About the workshop leader:

Dr. Ravi Harapanhalli advises bio/pharmaceutical companies on CMC regulatory strategies and Quality-by-Design approaches to medicinal product development and flexible regulatory approaches.

About ParExel:

Over the past 30 years, ParExel has developed significant expertise to assist clients in the worldwide pharmaceutical, biotechnology and medical device industries with the development and launch of their products in order to bring safe and effective treatments to the global market place for the patients who need them. Headquartered near Boston, Massachusetts, ParExel operates over 77 locations throughout more than 51 countries around the world, and has over 14,400 employees.
www.parexel.com

HALF-DAY POST-CONFERENCE WORKSHOP B
Wednesday 18th November 2015
1.30pm - 5.30pm
Renaissance Woodbridge Hotel, Iselin, New Jersey, USA

Development, Regulatory & Commercial Needs for Global Biosimilars

Workshop leaders:
Gerry McGettigan, CEO & Regulatory Expert,
Kinesys Consulting Ltd and
Graeme Deuchar, Product Development Expert,
Kinesys Consulting Ltd

Overview of the workshop:

This workshop aims to give participants an in-depth understanding of the regulatory and development fundamentals and expedients for global biosimilars, in addition to commercial imperatives. The development of biosimilars requires special studies and a robust process. This interactive workshop will enable you to gain a thorough understanding of the requirements and options available, including considerations leading to a successful global development programme, East and West.

Programme:

1.30	**Registration & Coffee**
2.00	**Introductions and Opening Remarks**
2.15	**Session 1: Regulatory fundamentals and expedients**
3.00	**Session 2: Commercial imperatives**
3.30	**Coffee break**
4.00	**Session 3: Development requirements and options**
5.00	**Discussion and Q&A**
5.30	**Close of Workshop**

About the workshop leaders:

Gerry McGettigan has 25 years' experience in the biopharmaceutical industry in a succession of Regulatory Affairs, Clinical and BD roles. Following Almirall (Spain) and Glaxo (UK) in the late 1980's and early 90's, Gerry was Director at The Liposome Company, a US biotech firm. In 1998 he founded GMG BioBusiness Ltd, a consultancy firm which he ran until its acquisition in 2005 by a major US CRO. In 2006, Gerry became the first CEO of Biocat, the Biotechnology Development Agency in Barcelona. He founded Kinesys Consulting in 2007. Kinesys specialises in biotechnology/biosimilars consultancy. Gerry is also COO at **amp biosimilars** (Germany).

Dr Graeme Deuchar - Graeme has over 15 years experience working as a biomedical research professional. Graeme's regulatory affairs experience with Kinesys is in a number of areas including biosimilars, scientific advice applications, CTAs and orphan product designations. He has also helped to design and now maintains the Kinesys Oncology & Orphan Products Database. Together with Gerry McGettigan, Graeme is co-founder of a recently formed biopharmaceutical company, Aurum Biosciences Ltd where he oversees the current and future research and development programme required to support continued progression of the company's key technology through to MAA.

About Kinesys Consulting Ltd:

Kinesys provides business support, regulatory affairs and product development support to a wide range of clients. Our product development knowledge is diverse and has been utilized by Pharma and Biotech companies alike to make a difference to their projects. We help you find answers to both the big, frustrating questions, as well as the often small but important and perplexing issues that arise in your regulatory and development strategies.
www.kinesysconsulting.com

BIOSIMILARS & BIOBETTERS USA

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