conferenceseries.com
1094th Conference

August 2017 | Volume 9 | Issue 5 | ISSN: 1948-593X
Journal of Bioanalysis & Biomedicine

Proceedings of

8TH ASIAN BIOLOGICS AND BIOSIMILARS CONGRESS

August 10-12, 2017 Beijing, China

Conference Series

One Commerce Center-1201 Orange St. #600, Wilmington, Zip 19899, Delaware, USA
Kemp House, 152 City Road London EC1V 2NX, UK

Toll Free: Japan: 81-345780247 | Singapore: +65 8008526126 | USA/Canada: 1-800-216-6499 | UK: 0-800-098-8455
General Number: 1-650-889-4686

Email: asianbiosimilars@pharmaceuticalconferences.com | biosimilarsasia@pharmaceuticalconferences.org

8th Asian Biologics and Biosimilars Congress

August 10-12, 2017 Beijing, China

Keynote Forum

(Day 1)

Kamali Chance, J Bioanal Biomed 2017, 9:5 (Suppl)
DOI: 10.4172/1948-593X-C1-031

Kamali Chance

Quintiles IMS, USA

FDA/EMA current thinking on total evidence for development of biosimilars

The regulatory landscape for the development of biosimilars in the US and EU is dynamic as many of the guidance issued by European Medicines Agency (EMA) have recently undergone revisions and the FDA has issued number of revised guidelines for quality and scientific considerations as well as updated questions and answers documents that lend much needed clarity. FDA has also issued final guidelines for nonproprietary naming of biological products as well as draft interchangeability guidance. This session is designed to provide current status of biosimilar guidelines in the US and EU. The focus will be to identify major updates in order to help sponsors navigate through the complex requirements for the regulatory approval of biosimilars in the US and EU.

Biography

Kamali Chance is the Vice President and Head of Global Biosimilars Regulatory Strategy, Biosimilars Center of Excellence. She has over 25 years of work experience in the healthcare industry, including the last 18 years in regulatory affairs/regulatory strategy. She has extensive experience working with the FDA and EMA. She advises pharmaceutical and biotechnology companies in the development of region specific and/or global regulatory strategy for the development of biosimilar products. She has authored/co-authored number of articles on the development of biosimilars and has PhD in Nutrition/Nutritional Biochemistry and Masters of Public Health and Regulatory Affairs Certification.

kamali.chance@quintilesims.com

Notes:

Jianguo Yang, J Bioanal Biomed 2017, 9:5 (Suppl)
DOI: 10.4172/1948-593X-C1-031

Jianguo Yang

Abpro, USA

Strategic partnership for biologics RD

Biologic drugs on the market now have been results of some partnership from RD to commercialization. Increasing complexity of biologic drug development requires more collaborations or partnerships in biopharma industry. This presentation will review current status of biologic drugs market and articulate landscape and importance of strategic partnerships in biologic research and development, and future trends.

Biography

Jianguo Yang has obtained his PhD in Cell/Molecular Biology from Illinois Institute of Technology, USA. He has over 20-years extensive experience in biopharma industry. Currently, he is the President/CEO Abpro, China. Before joining Abpro, he was CSO/VP Biologics in Qilu Pharmaceuticals and also had scientific leadership positions in several global pharmaceutical companies, including in Abbott Lab Pharma Division (current AbbVie), MedImmune/AstraZeneca, Genzyme/Sanofi. He has published numerous patents and scientific papers and is an Editor Advisor and Reviewer for *Bioprocess International* journal, Executive Director of Sino-America Pharmaceutical Association-NE (2012-2014) and Reviewer for several scientific journals.

yangjg98@yahoo.com

Notes:

Raymond A Huml, J Bioanal Biomed 2017, 9:5 (Suppl)
DOI: 10.4172/1948-593X-C1-031

Raymond A Huml

Quintiles IMS, USA

Biosimilars: Accelerating early clinical development

This presentation will discuss how early clinical development with biosimilars is paramount to later development and registration success. It will provide an overview of ECD services successfully used for implementing Phase-I biosimilar trials in Asia Pacific as well as the West (e.g., US and EU) for global registrations. It will present an overview of site selection and feasibility data using a Next Generation approach driven by IMS legacy data to aid recruitment especially in tough areas to recruit patients for biosimilar trials such as the US and Europe. Finally, a model to accelerated biosimilar development will be presented that has been successfully used by one of the world's largest providers of pharmaceutical services.

Biography

Raymond A Huml is the Vice President, Strategic Drug Development and Head, Global Biosimilars Strategic Planning at QuintilesIMS. He has written over 60 articles on a variety of subjects and three books. He has more than 27 years of experience in the biopharmaceutical and healthcare industries and holds an MS in Biology from East Stroudsburg University, a DVM from the North Carolina State University College of Veterinary Medicine and has earned the RAC (US) certification.

raymond.huml@quintilesims.com

Notes:

8th Asian Biologics and Biosimilars Congress

August 10-12, 2017 Beijing, China

Keynote Forum

(Day 2)

Oxana Iliach, J Bioanal Biomed 2017, 9:5 (Suppl)
DOI: 10.4172/1948-593X-C1-031

Oxana Iliach

Quintiles IMS, Canada

Strategy for the global development of biosimilars: Putting it all together

Growing numbers of companies are pursuing a global development of biosimilars for multiple markets. This global approach presents multiple challenges from selecting a reference product for biosimilar development to designing and conducting a clinical trials including a marketing strategy development and pharmacovigilance program. How to ensure that the global development results in successful marketing authorization in each jurisdiction? How to incorporate specific country requirements for biosimilar development at the early stages of biosimilar program? The strategic approach to the alignment of product development, regulatory activities and clinical program provides an answer to these questions. This presentation will discuss strategy of the biosimilar product development through earlier development to regulatory approval and provide some practical examples.

Biography

Oxana Iliach is a PhD in Pharmaceutical Science from St. Petersburg Chemical and Pharmaceutical Academy, Russia and the Senior Director Global Regulatory Strategy and CMC at the Biosimilar Center of Excellence, QuintilesIMS, Canada. She has more than 15 years' experience in healthcare industry, including the last 10 years in regulatory affairs. Her expertise lies in the development of global regulatory strategy for biosimilars with the focus on overall quality and CMC compliance. She has a particular focus and expertise in regulatory and CMC requirements for biosimilars and regularly presents and writes on the topic. Presently, she is a Professor at Seneca College of Applied Arts and Technology, Toronto, Canada and a Member of CAPRA (Canadian Association of Professionals in Regulatory Affairs) and RAPS.

oxana.iliach@quintilesims.com

Notes:

Charu Manaktala, J Bioanal Biomed 2017, 9:5 (Suppl)
DOI: 10.4172/1948-593X-C1-031

Charu Manaktala

Quintiles IMS, India

Clinical development of biosimilars for Western markets: Planning for success

Clinical development of biosimilars is an expensive and time consuming undertaking. The biosimilars space continues to evolve rapidly and presents a number of unique challenges and fierce competition. There are as many as 20 biosimilars in development for some of the top-selling biologicals creating an intense race for the sponsors, especially those wishing to enter the Western markets. To avoid any delays, biotech companies need solid clinical development plans built on the latest regulatory guidance with intimate knowledge of the clinical trial landscape. This presentation will discuss how companies could design their clinical development plans to meet the Western regulators expectations. It will share insights on determining the extent of clinical data requirements, design of clinical studies, considerations on the study population/indication, endpoints, evaluation of risk of immunogenicity and designing global development programs. Further, the presentation will share insights on efficient operational delivery of the safety and efficacy studies and outline best practices for accessing and retaining patients in biosimilars clinical studies.

Biography

Charu Manaktala is an MD in Pediatric Medicine, the Senior Director, Strategic Drug Development (Asia) and Head of Asia Pacific Biosimilars Centre of Excellence at QuintilesIMS, Canada. She has over 20 years of work experience in the healthcare and pharmaceutical industry and has worked in all stages of clinical drug development from Phase-I through commercialization. Her experience spans a variety of disciplines including drug development, medical writing and pharmacovigilance. She has comprehensive experience in clinical development of pharmaceutical/biopharmaceutical products and advises biotechnology companies on region specific and/or global clinical strategies for the development of biopharmaceutical products with a special focus on biosimilars.

Charu.manaktala@quintilesims.com

Notes:

8th Asian Biologics and Biosimilars Congress

August 10-12, 2017 Beijing, China

Keynote Forum

(Day 3)

Hossein Pakdaman, J Bioanal Biomed 2017, 9:5 (Suppl)
DOI: 10.4172/1948-593X-C1-031

Hossein Pakdaman

Shahid Beheshti University of Medical Sciences, Iran

Biosimilars in treatment of multiple sclerosis

The landscape of multiple sclerosis treatment has changed dramatically over the last decade. As of November 2014, nine disease-modifying therapies (DMTs) for MS have been approved by the US Food and Drug Administration (FDA). Despite the availability of more treatment options, costs for all MS DMTs have increased sharply. First-generation DMTs, originally costing $8,000 to $11,000, now cost about $60,000 per year. Costs for these agents have increased annually at rates 5 to 7 times higher than prescription drug inflation. Newer DMTs commonly entered the market with a cost 25-60% higher than existing DMTs. It is predicted that biosimilars will lead to a $44.2 billion reduction in direct spending on biologic drugs from 2014 to 2024 or about 4% of total biologic spending over the same period, with a range of $13 billion to $66 billion in USA. While the EU biosimilars market is relatively new, studies suggest that biosimilars in some therapeutic areas are priced below reference biologics, often with discounts of 25% or more. At the present time, approximately 50% of patients with multiple sclerosis in Iran are on treatment in which 2/3 are on biosimilars. Of note, the efficacy and safety of such products were assessed and established in different experimental and clinical controlled studies. Biosimilars will need to compete with their reference product on the basis of quality, price and manufacturer's reputation with physicians, insurers and patient groups. The prospects for significant cost savings from the use of biosimilars appear to be limited for the next several years, but their use should increase over time because of both demand and supply side factors.

Biography

Hossein Pakdaman was graduated in Neurology from the Pennsylvania and Henry Ford University in 1976. He is a Professor of Neurology affiliated to Shahid Beheshti University School of Medicine since 1990, President of Iranian Neurological Association since 1991 and the Director of Iranian Neurological Board Examination since 1978. Also, he has published more than 40 papers in international journals and is the Chairman of *Iranian Journal of Neurology* since 1998.

hpakdaman20@gmail.com

Notes: