

# 4th International Conference and Exhibition on Biologics and Biosimilars

Date & Venue: October 26-28, 2015 Baltimore, USA

(Theme: Current Challenges and Opportunities in Cost Effective and Affordable Biosimilars)

## About the Conference:

The 4th International Conference and Exhibition on Biologics and Biosimilars to be held at Baltimore, USA during October 26-28, 2015 hosted by OMICS Group Conferences through the theme "Current Challenges and Opportunities in Cost Effective and Affordable Biosimilars", conference will explore the advances in Biologics and Biosimilars. This conference could be an exceptional event that brings the experts in the biosimilar development, manufacturing and commercialization decision makers from all over the world creating the conference an ideal platform to share expertise, foster collaborations across trade and world, and assess rising technologies across the world. OMICS International Publishes 400+ Open access journals which contains over 30000 eminent personalities, reputed scientists as editorial board members and Organizes 300+ Conferences every year across USA, Europe & Asia with support from 1000 more scientific societies.

For more details please visit-

<http://biosimilars-biologics.pharmaceuticalconferences.com/>

## Importance & Scope:

Biosimilars are a true imitation of biopharmaceutical products that are set to replace 70% of global chemical drugs over the next couple of decades on account of safety parameters. Biologics are biological medical products made or derived from the active drug substance of a living organism by of recombination DNA or Controlled gene expression methods. Savings from small molecule generics are expected to peak in 2015, whereas demand for biologics is only set to continue its upward trend. Therefore, healthcare costs are expected to resume an upward trend unless the government promotes the consumption of biosimilars in order to moderate biologics spending growth.

There is great interest in increasing access to lower cost biological therapeutics for the treatment of human diseases. The Biologics Price

Competition and Innovation Act of 2010 ("Biosimilar Act") was enacted to create a pathway to obtain Food and Drug Administration (FDA) approval of biosimilar or "follow-on" versions of biological products based upon lesser showings of safety and efficacy.

Like the Hatch-Waxman Act for generic small molecule drugs, the Biosimilar Act: (1) establishes standards for application and approval; (2) provides a term of data exclusivity; and (3) establishes a scheme for handling patent disputes.

Under the Biosimilar Act, there is a certain amount of protection afforded through data exclusivity for a reference product. However, due to the complexity of biological molecules, it is feasible that a biosimilar may be similar enough to qualify as a biosimilar under the Biosimilar Act but not similar enough to be covered by a patent claim.

The Biosimilar Act is in the early stages of implementation with the goal of increasing access to biological therapeutics at lower cost while preserving safety and efficacy. The FDA has recently provided a very general framework for approaching the determination of biosimilarity through three guidance documents.

## Why Baltimore?

As many number of Pharma companies are situated at Baltimore, Biosimilars and Biologics-2015 will be organized at Baltimore, USA.

Biosimilars is a summit which will discuss over the market of medicines and the competitions that can be observed in the biomedical market for which, the numerous companies are in constant struggle to compete one another by effective reduction of medicine costs, expanding the accessibility of the medicines, increasing and developing the marketing strategies and commercializing the products maintaining all the legal concerns.

## Statistics of Biosimilars uptake globally

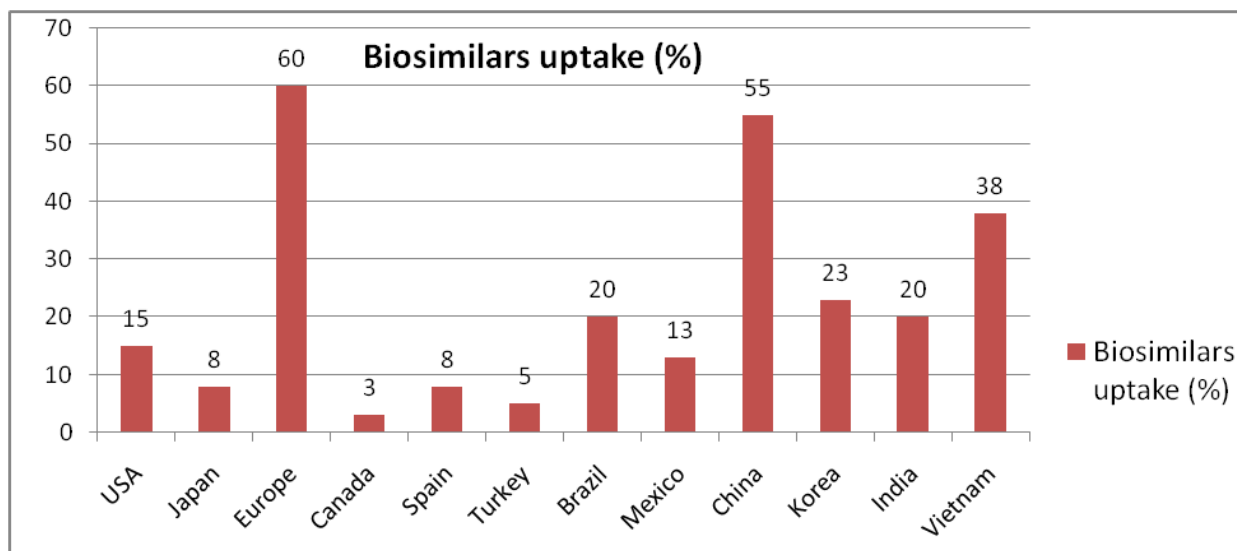


Figure 1: Biosimilars uptake

Source: Reference 1

### Conference Highlights:

- Challenges and Regulatory Approach for Biosimilars
- Emerging Biosimilars in Therapeutics
- Clinical Studies and Clinicians Prospects for Biosimilars
- Globalization of Biosimilars
- Biosimilars Innovator Pharmaceutical Products
- Analytical Strategies
- Bioequivalence Assessment
- BCS and IVIVC Based Biowaivers
- Intellectual Property Rights
- Pharmacovigilance and its Challenges
- Plant Produced Biosimilar Products

### Why to attend???

Biosimilars-2015 is being a remarkable event where entrepreneurs can expand their knowledge of the latest business innovative ideas and strategies in the development of Biologics and Biosimilars and small scale industries can plan for new biosimilar prosecution and litigation strategies along with the barriers to enter, know about the current research and development costs, and regulatory hurdles.

A Unique Opportunity for Advertisers and Sponsors at this International event:

<http://biosimilars-biologics.pharmaceuticalconferences.com/Sponsorship.pdf>

### Major Biosimilars and Biologics Associations in USA

- US Food and Drug Administration
- International Federation of Pharmaceutical Manufacturers & Association

- Generic Pharmaceutical Association (GPhA)
- International Network for the Rational Use of Drugs
- Office of Generic Drugs
- Biotechnology Industry Organization

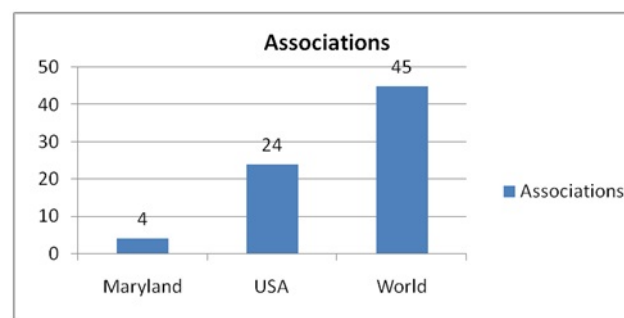


Figure 2: Biologics and Biosimilars Associations and societies in number

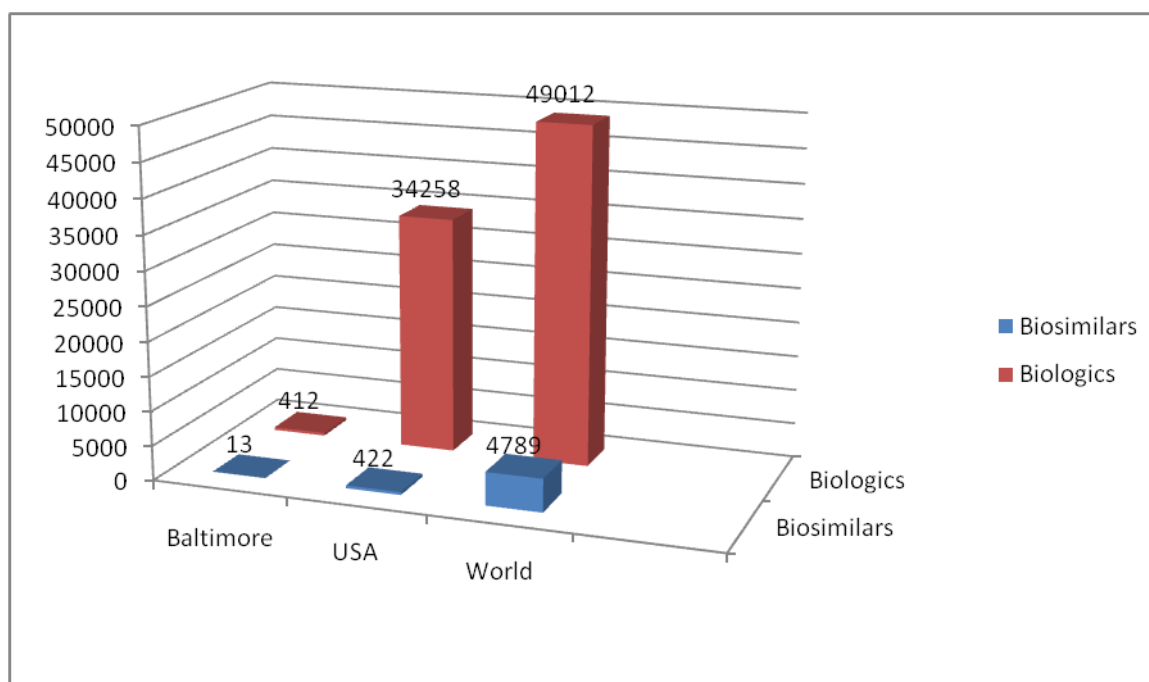
Source: Reference 2

### Target Audience:

Vice Presidents, Directors, CMOs, CROs, Research institutes, Investors and industry stakeholders, Intellectual Property, Business Development, Bioequivalence, API Manufacturers, Regulatory/Legal Affairs, Pharmacovigilance experts, etc..

### Total Biologics and Biosimilars Professionals

- Baltimore- 425
- USA - 34680
- World Wide- 53801



**Figure 3, 4:** Biologics and Biosimilars Professionals in number

Source: [Reference 3](#), [Reference 4](#)

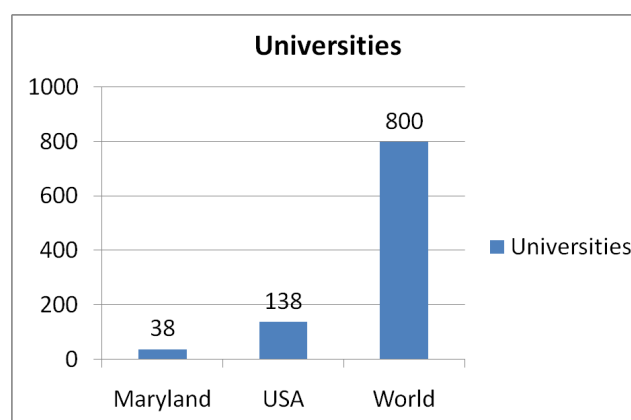
## Universities Associated with Pharma Research

### In and Nearby Maryland

- University of Baltimore
- University of Maryland, Baltimore

### Top Universities USA

- Rutgers University
- University of Cincinnati
- University of Toledo
- State University of New York at Buffalo
- University of Pittsburgh
- West Virginia University
- University of Wisconsin
- University of Connecticut
- Florida A & M University



**Figure 5:** Pharma Universities in Number

Source: [Reference 5](#)

## Companies Associated with Biologics and Biosimilars

- Hospira Inc.
- Biocon Ltd.
- Novartis AG
- Teva Pharmaceutical Industries Ltd.
- Intas Pharmaceuticals Ltd.
- Dr. Reddy's Laboratories Ltd.
- GE Healthcare Ltd.
- Merck & Co. Inc.
- Pfizer Inc.
- Wockhardt Ltd.

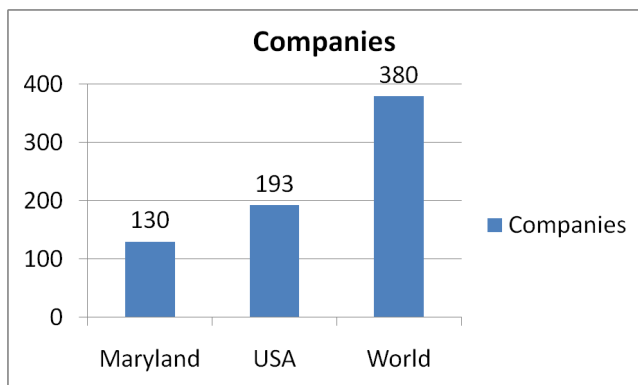


Figure 6: Companies associated with Biologics and Biosimilars

Source: Reference 6

### Biologics Software's

The following are some of the Biologics software produce by the companies

- BioLogic DuoFlow version 5.0
- Bio-Logic SAS
- MATLAB
- CAMAC Software

### Market Analysis of Biologics and Biosimilars

The global Biosimilars market is expected to reach \$19.4 billion by 2014, growing at an Annual Growth Rate (CAGR) of 89.1% from 2009. By 2020, the global market for Biosimilars will be reaching \$55 Billion. Biologic agents will continue to outpace overall pharma spending growth and are expected to represent 19-20% of the total market value by 2017.

### Global Biologics market sales in 150 USD

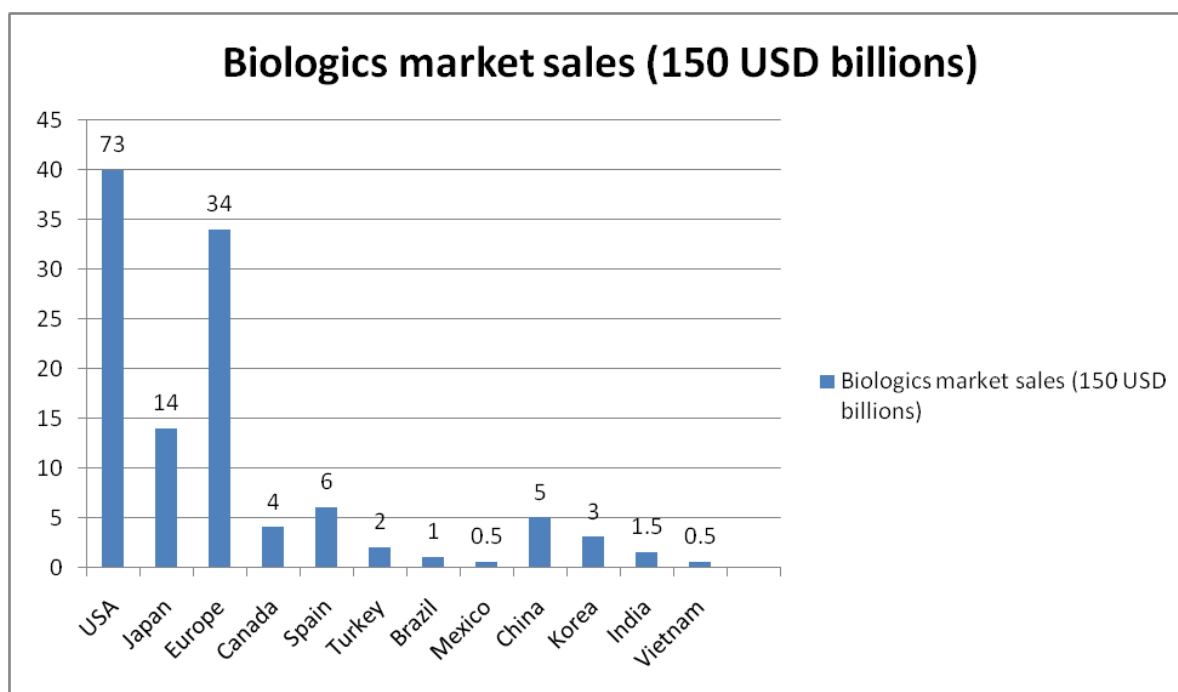


Figure 7: Biologics Market

Source: Reference 7

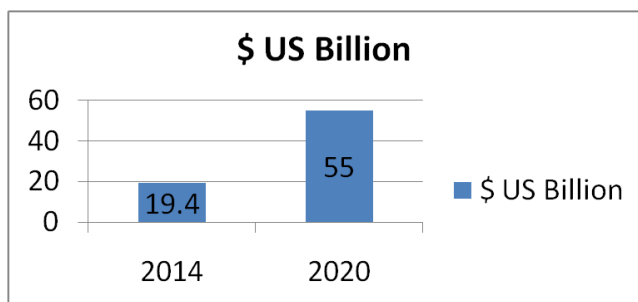


Figure 8: Biosimilars Market

Source: Reference 8

### References:

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