Ricardo Ibarra-Cabrera, Pharmaceut Reg Affairs 2014, 3:3
http://dx.doi.org/10.4172/2167-7689.S1.014

OMICS Group Conferences
Accelerating Scientific Discovery

4th International Conference on
Pharmaceutical Regulatory Affairs
September 08-10, 2014 DoubleTree by Hilton Hotel Raleigh-Brownstone-University, USA

# Business and regulatory environment of biopharmaceuticals and biosimilars in Latin America

**Ricardo Ibarra-Cabrera**
INBIOXICA SA de CV/Asociacion Mexicana de Comites de etica en Investigacion, Mexico

The biopharmaceutical industry is at the forefront in the fight against complex diseases such as cancer, rheumatoid arthritis, diabetes, and neurodegenerative disorders. Not only does it represent a promising alternative to chemically synthesized small molecules, but also a rapidly growing business sector. Biopharmaceutical sales in seven emerging markets, including Mexico and Brazil, are expected to nearly triple from $5.3 billion USD in 2010 to $13.5 billion in 2015. Moreover, patent expirations represent a huge opportunity for the development and commercialization of biosimilars. Latin American countries have shown important progress in the development and establishment of clear regulations for biopharmaceuticals and biosimilars. Mexico and Brazil have already established regulations based on international standards as well as local requirements; while Argentina, Chile, Panama, Costa Rica, Guatemala and Peru follow WHO and EMA guidelines. Therefore, some companies have already commercialized up to 170 biopharmaceuticals and biosimilars of rituximab and etanercept, in these countries. The purpose of this speech is to review the regulatory environment in Latin America and to analyze the business opportunities and trends of the biopharmaceutical industryin this region.

## Biography

Ricardo Ibarra-Cabrera is a Biotechnology Engineer from the Instituto Tecnologico y de Estudios Superiores de Monterrey, Mexico City Campus, and is a candidate of MSc in Innovation and Business Development from the same University. He has experience in pharmaceutical clinical trials and consulting services to Total Quality Management for clinical studies units. He is the Director of INBIOXICA, S.A. de C.V., a Mexican R&D and innovation consulting firm. His area of interest includes biopharmaceuticals and bio-based products.

ricardoibarra27@gmail.com