Evaluation Form

Biosimilars LatAm - Europe 2023

September 13th & 14th
Valencia, Spain

Eurostars Rey Don Jaime

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JackLeckerman GLOBAL HUMAN INTERACTION

Speaker Panel

Chairman

Roberto Funes
Biosidus, Spain
Director of Africa, Middle East & Euroasia

Hye-Na Kang
WHO, Switzerland
Scientist

Julie Marechal-Jamil
IGBA, Belgium
Biosimilars Committee member &
European Biosimilar medicines group

Encarnación Cruz Martos
BioSim, Spain
Director

Andres Gassert
ObserVa, Switzerland
Director

Eduardo Cioppi
mAbxience, Spain
Global Sales Director

Thiago Mares Guia
Bionovis, Brazil
Executive Vice President

Stefan Lutzmayer
IQVIA, Austria
Thought Leadership Consultant

Mauricio Rubio
Suanfarma, Colombia
Country Manager Colombia

José Luis Cárdenas
Teva Pharmaceuticals, Chile
Sr. Director Corporate Affairs
& Market Access LATAM

Mayra Pérez
UDIBI, Mexico
Founder and CEO

Marina Fayet
Merck Life Science, Switzerland
Program Leader Biosimilars Partnership, Global
Strategic Excellence - Business Operations & Strategy

Maria Jose Villarraza
Bioxentys, Argentina
CSO / Cofounder

Elif Ülkü
STADA Group, Germany
Director Global Commercial
Specialty Care/Biosimilars

Carlos Sancho Mateo
MEDICE Arzneimittel Pütter, Mexico
Area Director LATAM

Francisco Javier Domingo
Adamed Pharmaceutical, Spain
Business Unit Director Spain

Rui Seabra Ferreira Jr.
CEVAP-UNESP, Brazil
Main Researcher

Stephan Jarpa Cuadra, Chile
inHouse Agency, Chile
General Director

Day 1

13th September

JackLeckerman

Chairman

Roberto Funes
Biosidus, Spain
Director of Africa, Middle East & Euroasia

08:30 Registration & Networking

09:00 Opening Ceremony

09:30 Exploration of the Latin American Market and Comparison with the EU Market:

What does the Latin American market offer?

Reasoning behind the current market landscape in Latin America.

Comparision of the two regions.

Comprehensive database of analysis, assessments, leading information, critical parameters, unprecedented occasions, strategic positions and potential.

Eduardo Cioppi
mAbxience, Spain
Global Sales Director

Andres Gassert
ObserVa, Switzerland
Director

José Luis Cárdenas
Teva Pharmaceuticals, Chile
Sr. Director Corporate Affairs & Market Access LATAM

Moderator

Carlos Sancho Mateo
MEDICE Arzneimittel Pütter, Mexico
Area Director LATAM

11:00 Key Factors that Have Supported Policies to Improve the Use of Biosimilar.

Encarnación Cruz Martos
BioSim, Spain
Director

11:30 Networking & Coffee Break

12:00 Case Study

Mayra Pérez
UDIBI, Mexico
Founder and CEO

12:30 Challenges and Opportunities for the Manufacturing and Marketing of Biotechnological and Biosimilar Products in Colombia: A Long-term Vision for Establishing Health Autonomy.

Current initiatives for local production generation, as well as the challenges and opportunities that the industry, academia, government, and the pharmaceutical and healthcare sectors face in building a long-term project for local biotechnological production in Colombia, with the aim of meeting the healthcare needs of Colombian patients.

Mauricio Rubio
Suanfarma, Colombia
Country Manager Colombia

13:00 Lunch

14:30 Discovering the Latin American Alliances:

How to start a partnership in the region?

Partnerships for productive development, flow of information and relationships.

Benefits of mutual and fertile cooperation and enriching symbiosis.

Networking doors at local, regional, international level.

Carlos Sancho Mateo
MEDICE Arzneimittel Pütter, Mexico
Area Director LATAM

Thiago Mares Guia
Bionovis, Brazil
Executive Vice President

Moderator

Marina Fayet
Merck Life Science, Switzerland
Program Leader Biosimilars Partnership, Global Strategic Excellence - Business Operations & Strategy

16:00 Networking & Cocktail

18:00 Farewell

Day 2

14th September

JackLeckerman

Chairman

Roberto Funes
Biosidus, Spain
Director of Africa, Middle East & Euroasia

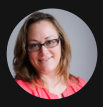
08:30 Registration & Networking

09:00 First Day Summary

09:15 Connecting Europe with LatAm. Global Biosimilars Policy, Standards and Experience as Backbone

The biosimilar history started over 20 years ago in Europe, and has its foundations in thorough science. Positive experience has cumulated yet heterogeneity in progress among regions remains the number one challenge standing in the way of global adoption of biosimilar medicines.

Hye-Na Kang
WHO, Switzerland
Scientist



Julie Marechal-Jamil
IGBA, Belgium
Biosimilars Committee Member

Stefan Lutzmayer
IQVIA, Austria
Thought Leadership Consultant

10:45 From University to Market. Introducing a Brazilian Biologicals CDMO

Rui Seabra Ferreira Jr.
CEVAP-UNESP, Brazil
Main Researcher

11:15 Networking & Coffee

11:45 Comparative View from Chile on Biosimilars Access. Learning and Actions.

Stephan Jarpa Cuadra, Chile
inHouse Agency, Chile
General Director

12:15 Regulatory Framework and Challenges:

How to get on and succeed on the road?

Implementation and pursuit of global broad and regulatory coverage.

European market achievements inspire Latin America.

Homogeneity, mutual cooperation, efficiency, flexibility, accessibility.

Francisco Javier Domingo
Adamed Pharmaceutical, Spain
Business Unit Director Spain

Maria Jose Villarraza
Bioxentys, Argentina
CSO / Cofounder

Roberto Funes
Biosidus, Spain
Director of Africa, Middle East & Euroasia

Moderator

Elif Ülkü
STADA Group, Germany
Director Global Commercial Specialty Care/Biosimilars

13:15 Closing Ceremony

13:30 Networking & Finger Buffet

14:30 Farewell

Biographies

Roberto Funes
Biosidus, Spain

Roberto has been working in the pharmaceutical industry with a focus on Biosimilars during the last 25 years.
He already developed businesses and projects in the field of Biosimilars in more than 50 international markets in Latin America, Asia, the Middle East, Africa and Europe.
As a consequence of this experience, he has developed knowledge regarding main challenges related to public purchases of biosimilar medicines as well as registration, distribution and marketing. Roberto developed comprehensive vision and cultural awareness to deal with technology transfer projects in emerging markets looking for government incentives for local manufacturing.

Hye-Na Kang
WHO, Switzerland

Dr Hye-Na Kang is a Scientist of WHO (Switzerland) since Jan 2009 and in charge of development/implementation of guidelines for regulatory evaluation of biologicals including biosimilars. She has organized many workshops and coordinated works to implement the evaluation principles of WHO guidelines into regulatory practices in countries. She is also a member of Biosimilar Working Group of the International Pharmaceutical Regulators Programme.
Prior to joining WHO, she was a scientific officer at Korea Ministry of Food and Drug Safety for twelve years. In 2004, she worked at the Vaccine and Infectious Disease Organization-International Vaccine Center in Canada.

Julie Marechal-Jamil
IGBA, Belgium

Biosimilars Committee member & European Biosimilar medicines group.
The International Generic and Biosimilar medicines Association (IGBA) strengthens cooperation between associations representing manufacturers of generic and biosimilar medicines from around the world. Adopting a patient centric approach, IGBA works to improve patients' access to quality-assured, safe and cost-effective medicines by promoting competition and enabling innovation in the pharmaceutical sector and sustainable economic contributions for all stakeholders.
In her European role, leading the European Biosimilar Medicines Group, a sector group of Medicines for Europe, Julie aims at creating and nurturing dialogue with experts and partners across healthcare systems. The main objectives of the European Biosimilar Medicines Group are to support and facilitate the design, evolution and implementation of policies aimed at fostering greater access to biologic therapies and other healthcare products and services, with biosimilar medicines use as catalyst for smart investment in health.

Encarnación Cruz Martos
BioSim, Spain

1998-1990. Scholarship from the Health Research Fund of the Social Security (FISS). Hospital October 12. Madrid.
1990-1993. Higher Public Health Technician: Pharmaceutical Management Service. Madrid's community.
1993-2002. Primary Care Pharmacist. INSALUD Primary Care Area 6 (Madrid).
2002-2004. Head of the Pharmaceutical Expenditure Assessment Area. General Directorate of Pharmacy. Madrid's community.
2004-2005. Head of the Pharmaceutical Provision Management Service. General Directorate of Pharmacy. Madrid's community.
2005-2008. Deputy Director General of Pharmaceutical Services. General Directorate of Pharmacy. Madrid's community.
2008-2015. General Deputy Director of Pharmacy and Health Products Purchasing. General Directorate of Economic Management and Purchasing of Pharmacy and Health Products. Madrid's community.
2015-2017. Deputy Director General of Pharmacy and Health Products General Directorate of Health Care Coordination. Madrid's community.
2017-2018. General Director of the Basic Portfolio of Services of the National Health and Pharmacy System. Ministry of Health, Social Services and Equality.
2018-2020. Advanced Therapies Coordinator. Ministry of Health. Madrid's community.
2020- Present. CEO. Spanish Association of Biosimilars.
More than 50 publications in the field of rational drug use in primary care, pharmaceutical service management and electronic prescription.
Extensive teaching experience with participation in more than 100 Congresses, Conferences, Courses and Masters

in the last 15 years (both national and international) focused mainly on aspects related to procedures for the management of pharmaceutical services, the treatment of chronic patients polypharmacy, safety in the use of medicines, studies on the use of medicines, clinical trials, health benefits, access to innovation.

Stefan Lutzmayer
IQVIA, Austria

Stefan Lutzmayer has over 8 years of experience working in academia and life sciences. He joined the thought leadership team in June 2021 where he creates content relevant to pharma executives and publishes articles, blogs, and white papers on therapeutic and biosimilar innovation.
Stefan is considered a subject matter expert in these areas. He frequently engages with senior client stakeholders, speaks at conferences, and supports consulting projects. Stefan has prior experience advising healthcare and life sciences clients. He holds a PhD degree from the University of Vienna, is trained in molecular biology and data analysis, and has published multiple peer-reviewed articles in internationally-renown journals..

Eduardo Cioppi
mAbxience, Spain

Global Sales Director at mAbxience - Seasoned professional with 30+ years of experience in commercial leadership, strategy, and operations within the pharmaceutical industry with experience in Executive Commercial, Business and Corporate Development global roles with strong experience in Market Access, Commercial Operations, Public Affairs, Quality/Regulatory Affairs, and Strategic Development roles.
Strong experience in Central Markets (EU/US) as well as proven successful track record in LATAM, MEA & APAC, having closed key deals expanding business and boosting sales, and having led the commercial and business operations for the last 15 years. Speaker at global and regional biosimilars forums and congresses for the last 5 years.
Strong knowledge of pharmaceutical sector and pharmaceutical product registrations in emerging markets and different regions.
Demonstrated capacity for building and maintaining internal and external relationships and networks with key stakeholders and influencers.

Marina Fayet
Merck Life Science, Switzerland

Marina has been working in the pharmaceutical industry for almost two decades. She has worked with MSD, Sandoz, Novartis, GSK and Merck covering Pharma, Generics, OTC and Biosimilars.
At the very beginning of her career, Marina has been part of the extended team at Sandoz developing the first biosimilars in the market (Somatropin approved in the EU in 2006). In her latest role at Merck she has contributed to the development of the first tocilizumab biosimilar, which has received a positive CHMP* opinion in July 2023.
*Committee for Medicinal Products for Human Use

Elif Ülkü
STADA Group, Germany

Elif Ülkü is a pharmaceutical professional with 6+ years experience in the Specialty Care and Biosimilars industry, having worked in business development, commercial, supply chain, innovation and strategy planning functions across multiple organizations.
In her previous roles, Elif led the initiative to define the corporate biotechnology strategy of Turkey's biggest pharmaceutical company, initiated the company's first biosimilar development program for global markets, led biosimilar localization projects, established and managed the strategic collaborations with leading biosimilar developers in oncology, immunology and ophthalmology therapy areas. She launched 3 biosimilars in Turkey and EU markets.
She actively contributed to the overall public ecosystem in Turkey, presented industry's needs and solutions to authorities and associations for optimal registration, fair competition, localization and affordability of biosimilars in the country.
She currently works in Stada as Director Global Commercial, Specialty Care and Biosimilars.

Andres Gassert
ObserVa, Switzerland

Senior quadrilingual consultant with 10 years of experience in the pharmaceutical industry.
Focused on strategy and investment (biotech/biosimilars/generics) and follow macro-economic trends and how they impact the pharmaceutical industry.
Expert in research and valuation of the global healthcare sector:
• Projections / Due Diligence

• Project in Equity Capital Markets
• Forecasting / Market Segmentation Analysis
• Competitive Intelligence
• Scenario Planning and Analysis

Maria Jose Villarraza
Bioxentys, Argentina

* Pharmacist - Biochemist
R&D Pharmaceutical Expert
RAPS Member
Executive EMBA Universidad Di Tella
Advisor in R&D for Medical Cannabis
* Extensive career of 30+ years in Multinational Pharmaceutical Companies, mostly dedicated to senior positions in R&D, Regulatory Affairs and Quality of Pharmaceutical and Cosmetic Products
* Great Expertise in Registration and Transfer Technology of Pharmaceutical Products including Biologic Products in LATAM, US, Europe and Asia countries, dealing with Regulatory Authorities
* Experienced in Successful Team Building and R&D Project Management
* Focused in adding global, strategic vision and quality/ financial value to R&D projects, achieving targets within tight deadlines.
* Skilled in working within a foreign environment with limited resources.
* Strong communication and negotiation skills
* Committed to build accurate Rationals and Scientific Support for Marketing Claims
* Great Expertise in Technical Audits according to local and global cGMP's.

José Luis Cárdenas
Teva, Chile

Pharmaceutical industry executive with over 17 years of experience in complex negotiations and management of public and market access policies in Latin America and beyond.
Involved in representing both trade associations and companies in public policy discussions and free trade agreements such as the Trans-Pacific Partnership or the Pacific Alliance in relation to Intellectual Property issues and pharmaceutical regulatory standards. Active in global forums such as the International Generic Medicines and Biosimilars Association (IGBA).
Leading role in the design and implementation of strategies for international tenders (e.g. Pan American Health Organization and United Nations Office for Project Services).

Doctor in Law (U. Chile), Master and Doctor in Law (U. Freiburg, Germany), Diploma in Pharmacology (U. of Chile), Diploma in Health Technology Assessment (Catholic University of Chile).

Thiago Mares Guia
Bionovis, Brazil

MD, PhD in Protein Biochemistry and Immunology with over 25 years of experience in pharmaceutical biotechnology and translational medicine/research. He was a postdoc in biotechnology and cell therapy at the University of São Paulo and a research fellow at the Diabetes Research Institute, USA.
Thiago currently is the Executive Vice President at Bionovis, a biopharmaceutical company focused in developing, manufacturing and marketing highly complex therapeutic biologics. At Bionovis has been responsible for technology transfer partnerships with Janssen, Merck, Samsung Bioepis, Sandoz/Novartis and Fresenius Kabi, involving innovative biologics and several biosimilars.
In addition to his role at Bionovis, Thiago is an invited professor at the Faculty of Medicine of Santa Casa de São Paulo, CEPIC and an associate researcher at Instituto Butantan.

Carlos Sancho Mateo
MEDICE Arzneimittel Pütter, Mexico

As the Area Director of Latin America, Carlos addressed over 16 countries, including the commercial oversight of Medice´s therapeutic portfolios and the development and implementation of growth strategies together with the distribution partners. Focusing on the identification of new business opportunities, partner selection, contract negotiations, and product launching coordination.
Previously, Carlos held a variety of positions in several local and regional roles in Spain, Germany, and The USA.
Carlos holds a BSc in Biology, a BSc in Biochemistry, a Ph.D. in Molecular Cell Biology from the University of Navarra. Lastly, he pursued an MBA at Hult International Business School – San Francisco campus.

Francisco Javier Domingo
Adamed Pharmaceutical, Spain

Member of the Spanish Steering Committee.
FJ received an Executive MBA in IESE Business School and a Msc in Chemical Engineering (Universidad Complutense

de Madrid) and Msc in Industrial Management Engineer (Universidad Pontificia de Salamanca). In addition, he is PhD Candidate in Healthcare Science from Universidad de Alcalá de Henares.

Mayra Pérez
UDIBI, Mexico

Dr. Sonia Mayra Pérez-Tapia is a Full Professor at the Department of Immunology of the National School of Biological Sciences (ENCB) of the IPN and Professor of Immunology at the Faculty of Chemistry at National Autonomous University of Mexico (UNAM). Has a PhD in Immunological Sciences from the IPN and specializes in innovation, development, evaluation, and regulation of biological and biotechnological products. Has published 104 articles in peer-reviewed journals and 7 book chapters. Has supervised more than 60 theses at the BSc, MSc and PhD levels. Dr. Perez-Tapia currently participates as an Expert Member of the COFEPRIS (equivalent to FDA in Mexico) for Biotechnological Products, as well as is a member of the Consortium of Innovative Scientists in Vaccines led by the Mexican Foreign Ministry.

Rui Seabra Ferreira Jr.
CEVAP-UNESP, Brazil

Senior Researcher CEVAP-UNESP. Full Lecturer in Venomous Animals: Accidents and Toxins. Graduated in Veterinary Medicine (UNESP), Master and PhD in Tropical Diseases (School of Medicine – UNESP), Post-doctorate in Immunochemistry at Butantan Institute. Professor of the Postgraduate – 1) Course in Tropical Diseases and 2) Course in Clinical Research. Director of CEVAP/UNESP (actual). Editor-in-Chief of JOURNAL OF VENOMOUS ANIMALS AND TOXINS INCLUDING TROPICAL DISEASES. President (2016-2020) of the Brazilian Association of Scientific Editors. Scientific Director of the Botucatu Technological Park. Member of the BRAZILIAN ACADEMY OF PHARMACEUTICAL SCIENCE. Experience in Bioprospecting, Drug development and Clinical Trials (Translational Science).

Mauricio Rubio
Suanfarma, Colombia

Bilingual Life Sciences and Pharmaceutical Business Development, Sales & Marketing Executive in Latin America, with extensive experience performing Business Development and Sales to boost the Life Science and pharmaceutical product development & commercialization lifecycle. Supported skills in pharmaceutical and health care sector analysis and abilities of negotiation with key accounts, government, customers, licensors, and suppliers for products and services.

Stephan Jarpa Cuadra, Chile
inHouse Agency, Chile

Pharmaceutical Chemist (Chile)
General Director Regulatory Agency inHouse.
Advisor and Consultant to private and public companies and institutions in Chile and Latin America.
Counselor of foundations and associations.
Academic in National and International Universities in matters of PV, Regulation, Health and Business Management. (post degree and pre degree)
Public Hospital Management Advisor.
COVID19 Vaccine Coordinator POSTA CENTRAL (Emergency Hospital Public Assistance of Chile), (First LATAM vaccines)

- Vice President of the Chilean Pharmacovigilance Society.
- Director of the Chilean Patient Safety Foundation.
- Member of the Latin American Network of Human Factors / Ergonomics in health systems (RELAESA).
- Vice President of ALO Prociencia (LATAM association of regulatory agents)
- Member of Pro Salud Chile (health innovation guild).
- Member of the Colombian Association of Pharmacovigilance.
- Cooperated with and advisor to the Mexican Pharmaceutical Professional Associations. (AMEPRES)