

Biosimilars LatAm - Brazil 2022

August 24th & 25th Hybrid Forum

Renaissance Sao Paulo Hotel

Evaluation Form





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Speaker Panel



Meiruze Freitas ANVISA, Brazil Director





Marcelo Holanda Biocon Biologics, Brazil Head of Latam



Cinthya Galicia AMFV / Pfizer, Mexico President / Country Safety Lead



Prasad S. Deshpande
Biocon, India
Senior Vice President & Global Head Procurement, Supply Chain Management, Contract
Manufacturing and Central Engineering

Chairman



Daniel Freire Sandoz, Brazil Regional Medical Director - LatAm



Tiago Rocca Butantan Institute, Brazil Strategic Partnerships and Business Development Manager



Martin Cruz Leucotec, Mexico Executive Director



Ana Carolina Ferreira Cardoso Libbs Farmacêutica, Brazil Scientific Relationship Coordinator



Matias Fassolari Merck KGA, Argentina Upstream Technical Application Specialist



Alecio Pimenta Cytiva, Brazil Product Manager for Bioprocess



Manish Kumar Singh Wockhardt, Brazil Senior General Manager



Diego Rodríguez Baquero Innovación estratégica, Colombia Consultant, ex Brand, Launch and Project Manager



Mariana Duarte de Cerqueira PALL, Brazil Biotech Specialist

Speaker Panel



Rosane Cuber Bio-Manguinhos / Fiocruz, Brazil Deputy Director of Quality



Thiago Mares Guia Bionovis, Brazil Executive Vice President



Albert Kim Samsung Bioepis, Republic of Korea Vice President, Commercial Strategy Team Leader



Brian Godman University of Strathclyde, UK and Sefako Makgatho Health Sciences University, South Africa Professor



Maripaz Márquez Quiroz Utrecht University, Netherlands / CINVESTAV, Mexico Researcher



David Honba UNIZIMA, Belgium Head of Business Development



Laura Arce Mora Pfizer, Costa Rica Country Safety Lead



Bianca Schiavetti Américas Vitória Santos, Brazil Gastroenterologist



José Antonio Maza Larrea Asociación Farmacéutica Mexicana, Mexico Director of the Pharmacovigilance section



Jorge Revilla Probiomed, Mexico Medical Director



Alma Aidé Fernández Herrera Probiomed, Mexico Pharmacovigilance Manager



Chairman



Marcelo Holanda Biocon Biologics, Brazil <u>Head of Latam</u>

Br 08:30 Registration and Coffee

Br 09:00 Opening Ceremony

Br 09:10 Latest News on Regulatory Processes



Meiruze Freitas ANVISA, Brazil Director



In-person

Br 09:50 Greater Access to Safe and Effective Lifesaving Medications



Daniel Freire In-person Sandoz, Brazil Regional Medical Director - LatAm

Br 10:20 Strategies and Technologies Enabling Upstream Process Intensification



Matias Fassolari In-person Merck KGA, Argentina Upstream Technical Application Specialist

Br 10:50 Coffee Break



Br 11:20 Technology Innovation: From Production Processes to Packaging and Administration of Biosimilars



Martin Cruz Leucotec, Mexico Executive Director In-person



Mariana Duarte de Cerqueira In-person PALL, Brazil Biotech Special<u>ist</u>

Moderator



Tiago Rocca In-person
Butantan Institute, Brazil
Strategic Partnerships and Business
Development Manager

Br 12:05 Tendering Procedures: Healthy Competition and Public Health



Manish Kumar Singh Wockhardt, Brazil Senior General Manager

In-person

Moderator



Prasad S. Deshpande Virtual
Biocon, India
Senior Vice President & Global Head - Procurement,
Supply Chain Management, Contract Manufacturing
and Central Engineering

Br 12:50 Biosimilars and the Extrapolation of Indications



Ana Carolina Ferreira Cardoso In-person Libbs Farmacêutica, Brazil Scientific Relationship Coordinator

Br 13:20 Lunch



Br 14:20 Biosimilars Interchangeability



Cinthya Galicia Vi AMFV / Pfizer, Mexico President / Country Safety Lead

Br 14:50 Development of New Antibody Purification Platforms



Alecio Pimenta In-person Cytiva, Brazil Product Manager for Downstream

Br 15:20 Biosimilars Market Innovation: from Developing a Mindset for Global Competitiveness to Business Strategies



Diego Rodríguez Baquero Virtual Innovación estratégica, Colombia Consultant, ex Brand, Launch and Project Manager

Br 15:50 Daily Closing Summary Chairman



Br 15:55 Networking

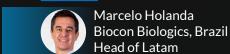






Renaissance Sao Paulo Hotel, Brazil

Chairman



Br 08:30 Registration and Coffee

Br 09:00 First Day Summary

Br 09:10 PDP's Success Stories



Virtual Albert Kim Samsung Bioepis, Republic of Korea Vice President, Commercial Strategy Team Leader

Moderator



Thiago Mares Guia Bionovis, Brazil **Executive Vice President**

In-person

Br 09:50 Protecting Patients: Minimization and Communication of the Risk of Adverse Reactions Focused on the Clinical Practice



Laura Arce Mora Pfizer, Costa Rica Country Safety Lead

Virtual

Br 10:20 Good Distribution Practices: Stakeholders Perspective



Jorge Revilla Probiomed, Mexico **Medical Director**



Alma Aidé Fernández Herrera Probiomed, Mexico Pharmacovigilance Manager

Br 11:05 Coffee Break



Br 11:35 GVP Case Study



Bianca Schiavetti In-person Américas Vitória Santos, Brazil Gastroenter<u>ologist</u>

Br 12:05 How Do Quality Considerations Impact Clinical Immunogenicity?

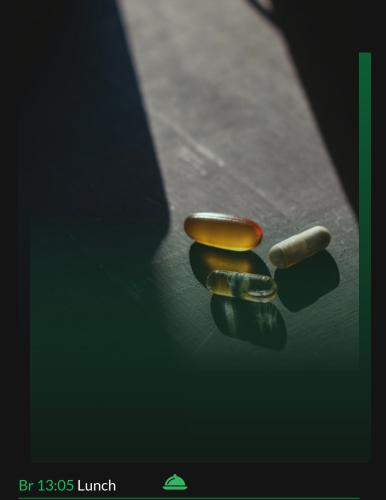


Maripaz Márquez Quiroz Virtual Utrecht University, Netherlands CINVESTAV, Mexico Researcher

Br 12:35 Sterility within Production Processes



Rosane Cuber Virtual Bio-Manguinhos / Fiocruz, Brazil **Deputy Director of Quality**



Br 14:20 Clinical Focus on Pharmacovigilance



Systems

José Antonio Maza Larrea Asociación Farmacéutica Mexicana, Mx Director of the Pharmacovigilance section

Br 14:50 Making Local Biomanufacturing and Effective Healthcare Systems a Reality



David Honba In-person UNIZIMA, Belgium Head of Business Development

Br 15:20 Case Study: European Market Dynamics



Brian Godman University of Strathclyde, UK and Sefako Makgatho Health Sciences University, South Africa Professor

Br 16:05 Closing Words by the Chairman

MabSelect PrismA

AFFINITY CHROMATOGRAPHY

MabSelect™ PrismA is a next-generation Protein A chromatography resin that offers significantly enhanced alkaline stability and binding capacity for improved process economy in monoclonal antibody (mAb) processing. The resin builds on the proven track record of MabSelect and MabSelect SuRe™ resins in commercial mAb production. In comparison with its predecessors, however, MabSelect PrismA has been improved with an optimized highflow agarose base matrix and a genetically engineered Protein A-derived ligand, allowing future demands in mAb processing to be met (Fig 1).

Key features of MabSelect PrismA include:

- Enhanced dynamic binding capacity (DBC) allows high mass throughput of processed mAb per resin volume unit.
- Excellent alkaline stability enables efficient cleaning and sanitization using 0.5–1.0 M NaOH for improved process economy and robustness.
- Covered by a comprehensive security of supply program, including dual sources of the agarose base matrix and Protein A ligand.

Since the first commercially approved mAb in 1980s, this class of therapeutic molecules has grown to represent a large part of biopharmaceutical sales. Today, mAbs represent the largest and fastest growing segment of biopharmaceuticals. Over the past 30 years, Protein A chromatography resins and mAbs have followed a highly synergistic evolutionary path, with annual productivity gains in the Protein A step of above 4.5% and increases in Protein A binding capacity of more than 5.5% (1).

With their high affinity for the antibody Fc region, Protein A resins provide an efficient mAb purification platform. The homology of the Fc region allows most of all mAbs to be purified using essentially the same standard approach, thereby significantly reducing process development time. This is an important factor, explaining why nearly all commercially approved mAb manufacturing processes utilize Protein A capture as the initial step in downstream purification. The main characteristics of MabSelect PrismA resin are summarized in Table 1.



Fig 1. MabSelect PrismA is developed to meet future demands in large-scale mAb processing.

Designed for high productivity in mAb capture

Recent advances in upstream procedures are driving up the mass of mAb being sent to downstream purification, thus putting pressure on the Protein A step. With the increasing mAb titers, cell culture feed also contains increased levels of impurities. Concurrently, the high nutrient load present in the cell culture harvest, combined with a low alkaline resistance of the Protein A resin, results in an elevated risk of resin fouling and bioburden issues. For efficient purification of the upstream batch, the resin capacity needs to match the mass of produced mAb. Historically, binding capacity of Protein A resins has lagged behind ion exchange chromatography resins, resulting in the need for larger resin volumes and chromatography column sizes.

Read more

cytiva.com







WHO WE ARE

At Unizima, we provide access to the people, the skills, and the technology needed to set up and operate local bioproduction facilities.

Our approach replaces conventional, centralized manufacturing with a flexible model that brings facilities, services, and people to where they are needed most. By doing this, we can deliver lifechanging biologics to deliver better health and prosperity.

SERVICES AND PRODUCTS

INTEGRATED SERVICES

Feasibility studies (market landscape analysis, business case development), inlicensing support and conceptual design

TECHNOLOGY TRANSFER

Full tech transfer support for drug substance and drug product, including analytics

WORKFORCE DEVELOPMENT

Specialized training to increase the proficiency of the local biomanufacturing ecosystem

MODULAR SOLUTIONS

Rapidly deployed, modularized facilities for drug substance and drug product manufacture



Unizima is an affiliate of the Univercells group, a global life sciences company enabling and expanding the biotech industry to deliver biologics to all. To reach this vision, Univercells has built an different affiliates, ecosystem of each focussing on a different area of bioprocessing.

BIOMANUFACTURING TECHNOLOGY

Cutting-edge technology portfolio to enable partners to achieve low cost, low footprint, high quality RNA, DNA and viral production from research to industrial scales





CDMO

Designing and delivering bespoke bioproduction with state-of-the-art technology (including proprietary biomanufacturing technologies), GMP capabilities and expertise for therapy innovators in the C>, RNA, Vaccines.





GLOBAL ACCESS, TURNKEY SOLUTIONS

Turnkey services to support nascent bio industries in low-and-middle income countriesfrom design to operation of bioproduction sites, incl. tech transfer, training, and regulatory affairs. Making local bioproduction a reality!





CONTACT US FOR MORE INFO

hello@unizima.com

unizima.com



Biographies



Marcelo Holanda **Biocon Biologics, Brazil**

Experienced Hospital Manager with a demonstrated history of working in the pharmaceuticals industry. Skilled in Negotiation, Marketing Management, Business Planning, Medical Devices, and Oncology. Strong business development professional with a CAEG focused on Marketing and Finance from Fundação Getulio Vargas.

Anvisa

Meiruze Sousa Freitas ANVISA, Brazil

Director of the Second Board

Term: 11/04/2020 to 12/12/2024

Serving Anvisa, she served as deputy director, general manager of Toxicology and manager of the medication area.

Academic graduation / title

2013 - Specialist in Pharmaceutical Technology -

Faculdade Federal Fluminense;

2003- Improvement in clinical analysis - Faculty of Pharmacy, Federal University of Minas de Gerais; 2000 - PHARMACY - Qualification in Clinical Analysis -Faculty of Pharmacy, Federal University of Minas de Gerais Professional performance:

National Health Surveillance Agency (Anvisa)

Dec/2020 - Current - Director - Second Board of Anvisa Apr/2020 - Dec/2020 - Deputy Director - Fourth Board of

Dec/2018 - Apr/2020- Deputy Director - Fourth Board of Anvisa

Jul/2018 - Dec/2018 - Deputy Director - Board of the National Health Surveillance System

Apr/2017 - Jul/2018 - Deputy Director - Authorization and **Registration Board**

Feb/2016 - Apr/2017 - General Manager of Toxicology Aug/2016 - Dec/2016 - Deputy Director - Authorization and Registration Board

Jun/2014 - Feb/2016- Superintendent of Medicines and Biological Products - Substitute

Jun/2014 - Oct/2014- Drug Post-Registration Manager May/2012 - Jun/2014 - Pharmaceutical Technology

Manager - Substitute

Mar/2009 - Jun/2014 - Coordinator of the Post-Registration of Medicines Coordination

Mar/2007 - Mar/2009- Specialist in Regulation and Sanitary Surveillance at the General Management of Medicines

Centificalab Laboratory - Santa Casa de Misericórdia Hospital (2006 - 2007)

Function: Clinical analysis laboratory manager Main responsibilities: People management; Cost and quality management

Drogaria Araújo S/A (2000 - 2003)

Function: Pharmacist - Technical Responsible productions Bibliographic production:

2013- Evaluation of stability studies of carbamazepine drugs registered until June 2013. (Improvement/ Specialization in Specialization Course in Pharmaceutical Technology) - Universidade Federal Fluminense - UFF.

COLLABORATION IN PUBLICATION

2007 - Clinical Protocol FHEMIG - Hospital management of tuberculosis - https://studylibpt.com/doc/1543647/ caderno-de-protocolos-cl%C3%ADnicos-da-fhemig. Page 229 - 240

PARTICIPATION IN EVALUATION OF A SPECIALIZATION COURSE MONOGRAPH 6/6 - Discarding Medicines for Domestic Use -2011- Specialization Course in Health Surveillance - ANVISA/FIOCRUZ; - Microbiological quality control of non-sterile medicines- 2010- Specialization Course in Health Surveillance - ANVISA/FIOCRUZ;

Daniel Freire Sandoz, Brazil

Medical degree from Universidade de Sao Paulo, with specialization in Endocrinology and Metabolism and a Ph.D. in endocrine oncology at the same institution. Working in the pharmaceutical industry for 15 years, with special focus in endocrinology, oncology, immunology, biologics and biosimilars. In the last 3 years, supporting the launch of Rituximab, Adalimumab and Etanercept biosimilars from Sandoz over 15 countries in Latin America.

Matias Fassolari Merck KGA, Argentina

Dr. Matias Fassolari has more than 12 years of hands-on experience in cell culture technologies. He has a vast technical and scientific background in molecular biology, cell culture techniques and Upstream Process Development. He holds a Ph.D. in Molecular and Cell Biology from the University of Buenos Aires, obtained after studying the cell cycle regulation of protozoan parasites. Afterward, he worked for 6 years as an R&D scientist in the biopharmaceutical industry. During that time, he led projects of CHO cell lines development and cell culture optimization for rProteins production.

Mariana Duarte de Cerqueira PALL, Brazil

Mariana is currently a Biotech Specialist with broad expertise across the pharmaceutical and Biotech Industries. She has a PhD in Microbiology from the Federal University of Rio de Janeiro (UFRJ), with several publications in prestigious journals. She has got six years of experience helping customers with the development of biosimilar products and improving processes through Pall solutions.

Martin Cruz Leucotec, Mexico

Electronics and Communications Engineer at the Monterrey Institute of Technology and Higher Studies 1997, Master of Business Administration at the Monterrey Institute of Technology and Higher Studies 2010, Executive Coaching at the Monterrey Institute of Technology and Higher Studies 2012, Pharmaceutical Marketing at ANAHUAC University 2013, Corporate Finance at the Autonomous Technological Institute of Mexico 2016, Senior Management Program at IPADE Business School (Pan-American Institute of Senior Business Management) 2022.

He started in voice and data network engineering in transnational companies such as Nortel Networks, Cisco Systems and Huawei Technologies, participating and executing projects at a national level. He started business activities in 2005 and later, in 2010, dedicated himself fully to the commercialization of vaccines and managed to obtain a health license as a warehouse for the storage and distribution of biological medicines and blood products regulated by COFEPRIS Mexico. Subsequently, he started a partnership for the development of food supplements and cosmetics, managing to market a product based on Hydrolyzed Collagen, positioning the Colagenart brand, with an extension of the cosmetic line. Currently in the process of obtaining a second sanitary license for a distribution warehouse for biologicals and blood products regulated by COFEPRIS Mexico.

Tiago Rocca Butantan Institute, Brazil

Mr. Rocca serves as Strategic Partnerships & Business Development Manager at Instituto Butantan. Rocca has been working at Butantan for over 15 years and has assumed responsibilities in several other areas related to vaccines and biopharmaceuticals production, Technology Transfer, Validation, Quality Assurance and Compliance. Pharmacist and post-graduated in Health Law at Public Health School of University of São Paulo and in Pharma Business Management at Higher School of Advertising and Marketing (ESPM). Currently is the Secretary of Emerging Biopharmaceuticals Manufacturers Network (EBPMN) and a member of Executive Committee of Developing Countries Vaccine Manufacturers (DCVMN).

Manish Kumar Singh Wockhardt, Brazil

Working with Wockhardt Ltd based at Sao Paulo Brazil and have done MBA in International Business from one of the top management institute of India. INDIAN INSTITUTE OF FOREIGN TRADE, New Delhi.

Prasad S. Deshpande Biocon, India

Prasad has 27 years of global and diversified experience in the field of Supply Chain Management and Contract Manufacturing with a dynamic and transformational approach.

A key member of Biocon's Executive Leadership Team, Prasad leads the Strategic & Operation of Supply Chain, CMO, and spearheads Central Engineering projects and Manages Environment, Health & Safety. Building renewable energy driven organisation is one of his dream projects at Biocon.

Prior to Biocon, Prasad worked in Pfizer, spanning different countries including USA, Belgium, Singapore and India. He has a BE (Mechanical Engineering) degree and MS in Manufacturing Management.

Ana Carolina Ferreira Cardoso Libbs Farmacêutica, Brazil

Ana Carolina is graduated in Biology by Federal University of São Carlos, with master and doctor in Oncology by School of Medicine of University of São Paulo (FMUSP), with part of the doctorate done in MD Anderson Cancer Center. Nowadays, she works as Scientific Relationship Coordinator in Libbs Farmacêutica. She has experience in conducting and managing basic research and clinical research projects, focused on the areas of oncology, hematology and gynecology.

Cinthya Galicia AMFV / Pfizer, Mexico

President of the Mexican Pharmacovigilance Association / Country safety lead at Pfizer

Alecio Pimenta Cytiva, Brazil

Alecio holds a bachelor's degree in
Technological Chemistry from the Institute of Chemistry
of São Carlos - USP and a PhD in Science - Biomolecular
Applied Physics from the Institute of Physics of São Carlos
- USP. He worked as a researcher at Recepta Biopharma
in partnership with Butantan Institute in the development
of Monoclonal Antibodies against Cancer. He is currently
Product Manager for Downstream at Cytiva, focusing on
production and purification of biomolecules.

Diego Rodríguez Baquero Innovación estratégica, Colombia

Degree in engineering, in addition to a specialization and two master's degrees in marketing, sales and innovation, certificate in project management (PMP) with more than 14 years of experience in the pharmaceutical industry in transnational and multinational companies, Diego has held positions such as brand manager, launch manager and project manager focused on incorporating innovation techniques, he has worked with innovators, biosimilars and bioequivalent products, now Diego works as a consultant.

Albert Kim Samsung Bioepis, Republic of Korea

Albert Kim is Vice President and Commercial Strategy Team Leader at Samsung Bioepis, overseeing commercialization of biosimilar products under partnership with Organon. He joined Samsung Bioepis in September 2020 as Vice President and Commercial Strategy Team Leader to head its commercial operations, which covers the global oncology business and immunology businesses outside Europe.

Throughout his 20-year global pharmaceutical career, Albert Kim has held leadership roles across commercial, operation, and finance sectors in Asia-Pacific including South Korea, as well as in Europe, the Middle East and North Africa.

Thiago Mares Guia Bionovis, Brazil

Current position: Scientific &
Business Executive Director @ Bionovis, a company
focused in developing, manufacturing and marketing

focused in developing, manufacturing and marketing biopharmaceuticals, including Biosimilars and innovative Biologics.

Physician with 20+ years' experience in Biotechnology RD&I (Academia / Industry) and Translational Medicine/ Research.

PhD in Biochemistry and Immunology, Postdoc in Biotechnology and Cell Therapy.

Laura Arce Mora Pfizer, Costa Rica

Graduated in Pharmacy from the Universidad de Iberoamérica (UNIBE), in San José, Costa Rica, and has a Master's degree in Pharmacy and Medication Management from OBS Business School and the International University of Catalonia Barcelona. He has over 10 years of experience in Retail Pharmacy. More than 8 years working at Pfizer, where in 2013 he started as a Medical Representative, and in 2017 he joined the Drug Safety Pharmacovigilance Unit, appointed in October 2020 as Country Safety Lead for Central America and the Caribbean and QPPV for Panama and Guatemala.

Alma Aidé Fernández Herrera Probiomed, Mexico

Medical Doctor, Master in Clinical Research, specialist in Pharmaceutical Medicine, 13 years experience in the area of clinical research, pharmacovigilance and technovigilance. Currently Pharmacovigilance Manager at Probiomed.

Bianca Schiavetti Américas Vitória Santos, Brazil

Specialist by the Brazilian Federation of Gastroenterology. Member of ECCO, PANCCO and GEDIIB. Coordinator of the IBD outpatient clinic in Santos City Hall.

Maripaz Márquez Quiroz Utrecht University, Netherlands / CINVESTAV, Mexico

Maripaz Márquez is a Doctor of Pharmacology with experience as a researcher and health consultant, mainly in biologic and biosimilar medicines. She worked for Philips Healthcare Amsterdam, Pfizer Biosimilars Mexico and the University of Utrecht (the Netherlands) where she conducted analytical comparison of biosimilars of filgrastim and erythropoietin. She obtained the MBA (Master in Business Administration) degree from the University of Tilburg Business School, the Netherlands. Additionally, Maripaz is member of the National System of Researchers (SNI), Conacyt, Mexico

Rosane Cuber Bio-Manguinhos / Fiocruz, Brazil

Rosane Cuber has a PhD in Health Surveillance from the National Institute for Quality Control in Health (INCQS / Fiocruz) and a master's degree in Biochemistry from the Federal University of Rio de Janeiro (UFRJ). She has experience in Public Health, working mainly with quality, good practices, vaccine development, regulation and biosafety. She is the deputy director of Quality of Bio-Manguinhos and has part in the actions against the pandemic by implementing and managing the Testing Support Units for COVID-19. She is also responsible for coordinating the transfer process of AstraZeneca's analytical methodology to carry out the Quality Control of the Oxford vaccine that will be produced at the Institute.

José Antonio Maza Larrea Asociación Farmacéutica Mexicana

Part of a health organization, working to promote and strengthen health services making use of Jose's skills as an EMT, Pharmacist and Physician to improve and monitor treatments, the compliance of quality standards within the framework of health services, assuring a benefit for the patient. And a profitable growth of the organization in which he collaborates.

David Honba UNIZIMA, Belgium

David holds a Master in Bioingeneering from the Laval University in Canada, Gembloux Agro-BioTech (ULg) in Belgium and Shandong University in P.R. China. His core qualifications are projects, stakeholders and team's management, as well as GMP, QMS, industrial processes, performance optimization, lean/risks management and Ease of understanding, researching, drafting and communicating applied sciences. David is a reliable individual with demonstrated experience in both project management and pharmaceutical manufacturing, keen to contribute in strategic roles to enable business growth as well as continuous medicine access. Undertook several assignments in both West and Central Africa.

Making Local Biomanufacturing and Effective Healthcare Systems a Reality.



Since 2006, Brian has been working with health authorities, their advisors, and academics across countries to enhance the rational use of medicines and prescribing efficiency. Initially this was across Europe, but now expanded to all continents including South America. This includes both new and established medicines including biosimilars. This has resulted in over 350 papers in peer-reviewed journals since 2008 including multiple papers in South America including both infectious and non-infectious diseases as well as exploring managed entry agreements, access to pharmaceuticals, drug shortages and disinvestment processes. He has also published extensively on biosimilars across countries.

Upcoming Events



Biosimilars LatAm

- Mexico 2022 November 10th & 11th

Hybrid Forum

♥ Haven Riviera Cancún







Upcoming Events - Brazil 2023

Biosimilars LatAm - Brazil 2023

April 18th & 19th

Tech Pharma LatAm

- Brazil 2023

September 13th & 14th

