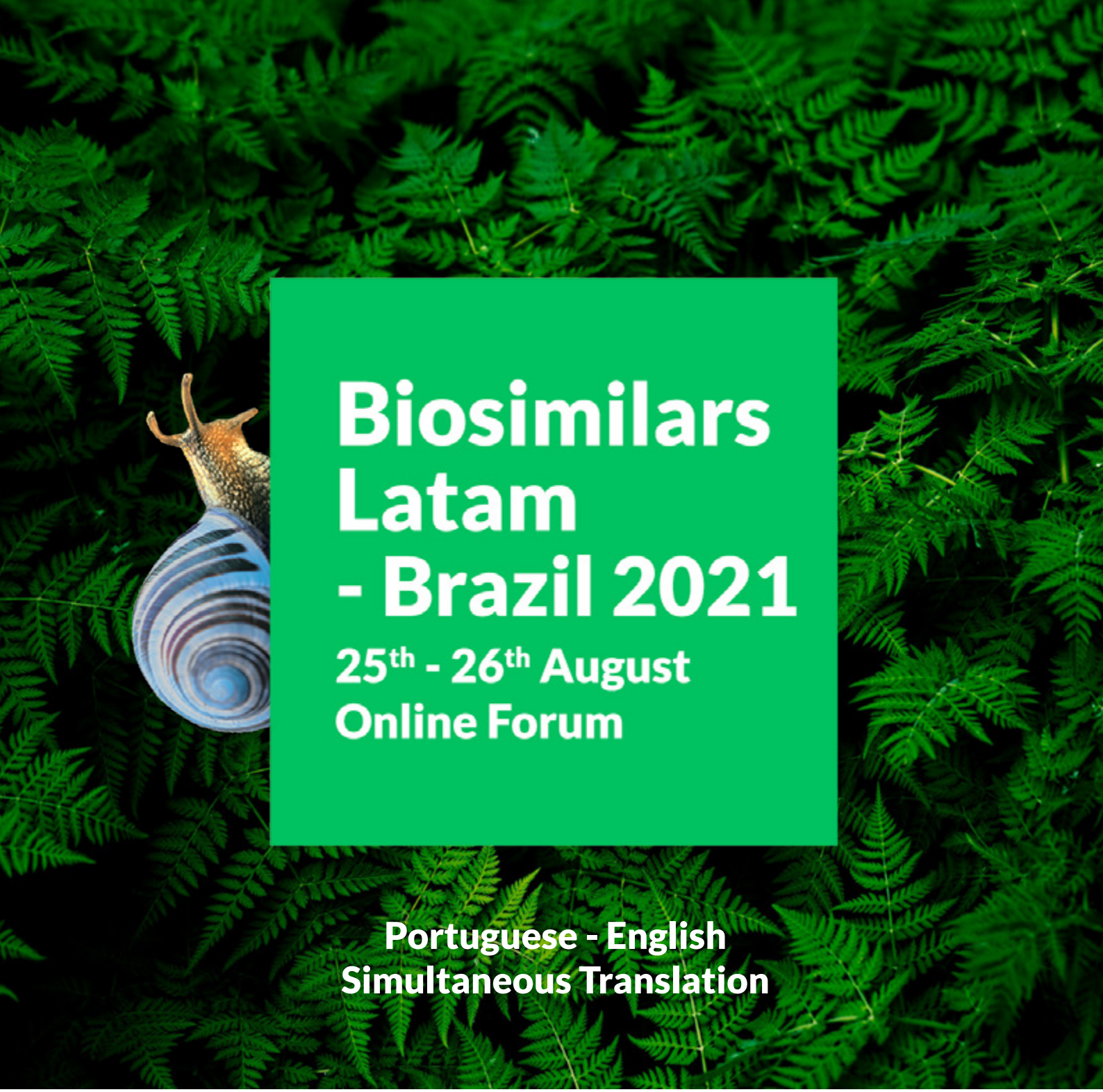

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25th - 26th August
Online Forum

Portuguese - English Simultaneous Translation

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

Elkiane Macedo Rama
ANVISA, Brazil
Health Regulation Expert

Andrea Padovani
ANMAT, Argentina
Head of the Pharmacological Clinical Evaluation Service of the Directorate of Evaluation and Control of Biological Products and Radiopharmaceuticals

Roberto Frontini
EMA, Germany
Pharmacovigilance Risk Assessment Committee (PRAC) alternate member

Gustavo Mendes Lima Santos
ICH / ANVISA, Brazil
ICH MC Member, General Manager of Medicines and Biological Products

Shahin Kauser
MHRA, United Kingdom
Leading Senior Scientific Assessor

Luciana Rahal Abrahão
Brazil
Independent Medical Affairs Professional

Cristina Ausin
FDA, USA
Scientific Reviewer

Thiago Mares Guia
Bionovis, Brazil
Scientific & Business Executive Director

Philippe Lauwers
Terumo, Belgium
Director Technology Development

Julie Marechal-Jamil
Medicines for Europe, Belgium
Director Biosimilars Policy & Science

Gloria Giraldo
Health Canada, Canada
Senior Scientific Evaluator

Edilson Uiechi
Bionovis, Brazil
Institutional Affairs & Business Development Manager

Mauricio Ede-Filho
Sandoz, Canada
Chief Medical & Scientific Officer

Learn More

Speaker Panel

Dorthe Bartels
AMGROS, Denmark
Senior Strategic Advisor, Negotiator
and Head of the Biosimilar task force

Nicolas Estrada
Merck, Mexico
Single-Use customer applications

Marcos Roman Calgaro
Thermo Fisher Scientific, Brazil
Sr. Manager – LATAM, Bioproduction Group

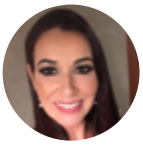
Monique Samaan
Cristalia, Brazil
Senior Biotechnology R&D Scientist

Kattia Milena Riaño
Sandoz, Colombia
Regulatory Affairs Manager

Tore K. Kvien
University of Oslo, Norway
Diakonhjemmet Hospital, Oslo, Norway
Professor em/Senior Research Advisor

Fernando Carmona
Cytiva, Argentina
Upstream Technical Sales Specialist

Natalia Sousa Freitas Queiroz
University of Sao Paulo School of Medicine, Brazil
Gastroenterology Sciences
Postgraduate Program Professor



Mariana Peixoto
Sociedade Mineira de Reumatologia, Brazil
President Sociedade Mineira
de Reumatologia

Rodrigo Oliveira
bioMérieux, Brazil
Field Application Specialist, Healthcare

Daniel Morales
University of Dundee, United Kingdom
Epidemiologist and Academic GP

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

Learn More

Program

Day 1

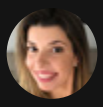
25th August

Chairman

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

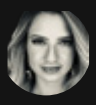
Br 09:00 Opening Ceremony

Br 09:10 Regulatory Update



Elkiane Macedo Rama
ANVISA, Brazil
Health Regulation Expert

Br 09:50 Quality Control Challenges for Biologics Production



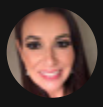
Monique Samaan
Cristalia, Brazil
Senior Biotechnology R&D Scientist

Br 10:25 Pathway to Overcome Primary Packaging and Drug Product Manufacturing Challenges - Case Study of Ophthalmic Drug

Philippe Lauwers
Terumo, Belgium
Director Technology Development

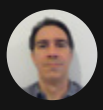
Br 10:55 Networking Break

Br 11:25 Biosimilars Prescription for Rheumatic Diseases



Mariana Peixoto
Sociedade Mineira de Reumatologia, Brazil
President Sociedade Mineira de Reumatologia

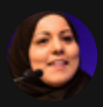
Br 11:55 Scalability in mAb´s Production



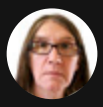
Fernando Carmona
Cytiva, Argentina
Upstream Technical Sales Specialist

Br 12:25 Pharmacovigilance Challenges for Biosimilars

Roberto Frontini
EMA, Germany
Pharmacovigilance Risk Assessment Committee (PRAC) alternate member

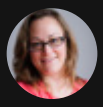


Shahin Kauser
MHRA, United Kingdom
Leading Senior Scientific Assessor

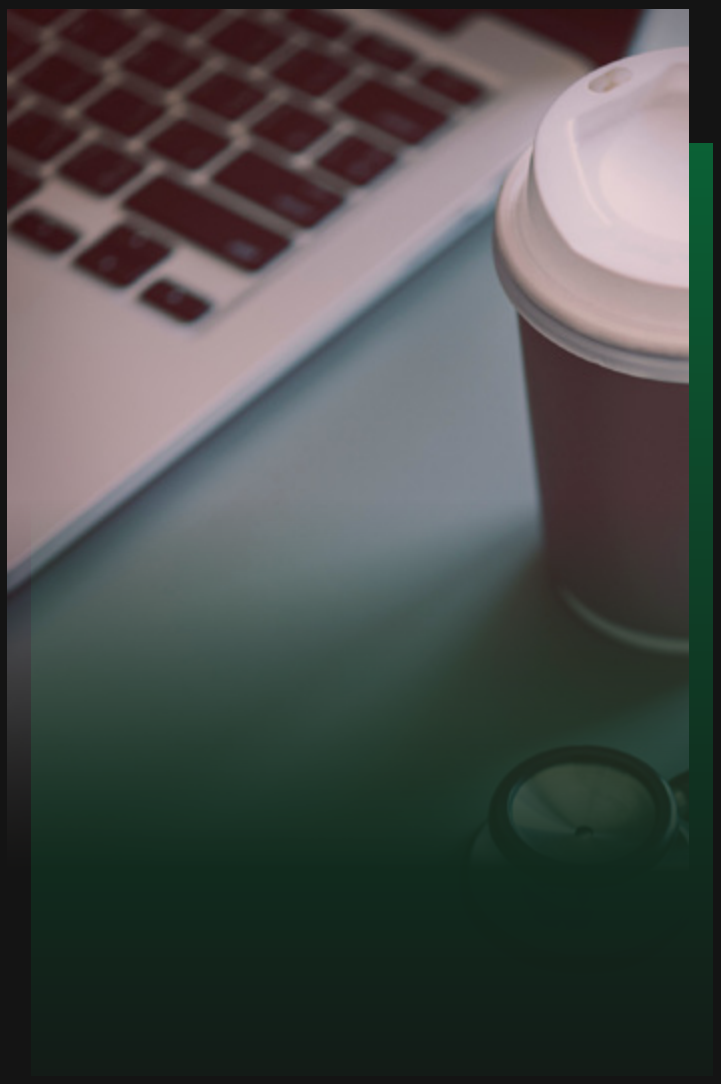


Andrea Padovani
ANMAT, Argentina
Head of the Pharmacological Clinical Evaluation Service of the Directorate of Evaluation and Control of Biological Products and Radiopharmaceuticals

Moderator



Julie Marechal-Jamil
Medicines for Europe, Belgium
Director Biosimilars Policy & Science



Br 13:10 Lunch Break

Br 14:10 Challenges in Tech Transfer for Biosimilars in Brazil

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

Br 14:40 Biosimilars International Regulatory Framework: Canada's Review

Gloria Giraldo
Health Canada, Canada
Senior Scientific Evaluator

Br 15:10 Q&A/Open Mic and Wrap up

Program

Day 2

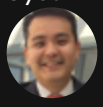
26th August

Br 09:00 Summary 1st Day

Br 09:10 Biosimilars Safety

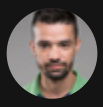
Daniel Morales
University of Dundee, United Kingdom
Epidemiologist and Academic GP

Br 09:40 Partnerships for Productive Development and their Contribution to Brazil's Health Care System



Edilson Uiechi
Bionovis, Brazil
Institutional Affairs & Business Development Manager

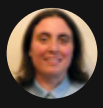
Br 10:10 Rapid Sterility Testing to Ensure Patient Safety



Rodrigo Oliveira
bioMérieux, Brazil
Field Application Specialist, Healthcare

Br 10:40 Networking Break

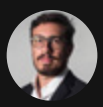
Br 11:10 Biosimilars Regulatory Licensing Framework



Cristina Ausin
FDA, USA
Scientific Reviewer

Mauricio Ede-Filho
Sandoz, Canada
Chief Medical & Scientific Officer

Moderator



Gustavo Mendes Lima Santos
ICH / ANVISA, Brazil
ICH MC Member, General Manager of Medicines and Biological Products

Br 11:55 Modern Technical Solutions for Biosimilars

Marcos Roman Calgaro
Thermo Fisher Scientific, Brazil
Sr. Manager – LATAM, Bioproduction Group

Nicolas Estrada
Merck, Mexico
Single-Use customer applications

Moderator

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

Chairman

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

Br 12:40 Success Stories Surrounding Biosimilars

Dorthe Bartels
AMGROS, Denmark
Senior Strategic Advisor, Negotiator and Head of the Biosimilar task force

Thiago Mares Guia
Bionovis, Brazil
Scientific & Business Executive Director

Moderator

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

Br 13:25 Lunch Break

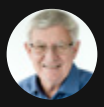
Br 14:25 Originator and Biosimilar Market Dynamics

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

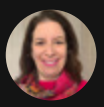
Br 14:55 Manufacturing Biosimilars: Production Process Improvement and Hurdles to be Faced

Kattia Milena Riaño
Sandoz, Colombia
Regulatory Affairs Manager

Br 15:25 Upcoming Considerations for Biosimilars

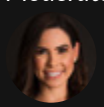


Tore K. Kvien
University of Oslo, Norway
Diakonhjemmet Hospital, Oslo, Norway
Professor em/Senior Research Advisor



Luciana Rahal Abrahão
Brazil
Independent Medical Affairs Professional

Moderator



Natalia Sousa Freitas Queiroz
University of Sao Paulo School of Medicine, Brazil
Gastroenterology Sciences Postgraduate Program Professor

Br 16:10 Closing Words by the Chairman

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Xcellerex XDUO mixers

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Xcellerex XDUO 100 to 2500 L mixers
HyClone buffers and process liquids

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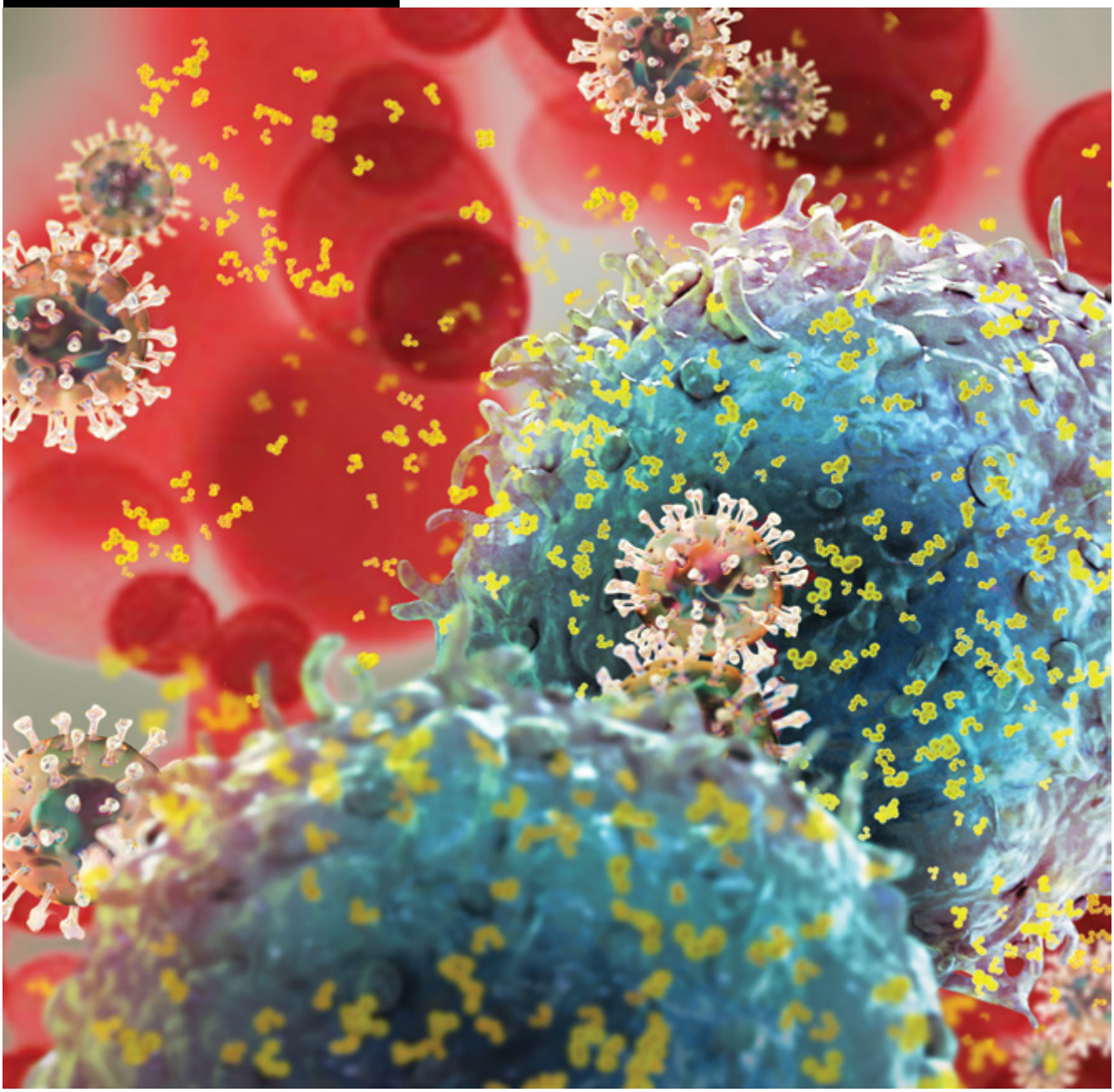

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Biographies

Tiago Rocca
Instituto Butantan, Brazil

Mr. Rocca serves as Strategic Partnerships & Business Development Manager at Instituto Butantan. Rocca has been working at Butantan for over 14 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).

Elkiane Macedo Rama
ANVISA, Brazil

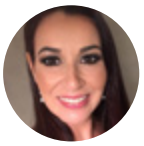
Elkiane is a Health Regulation Expert at the Biological Products Office of the Brazilian Health Regulatory Agency - ANVISA. She has been working for 16 years as a reviewer of Anvisa, and the last 7 years reviewing both CMC and clinical trials dossiers of biological and biotechnological products, including biosimilars. She has been a member of ICH Q12 Expert Working Group. She holds a Pharmacy and Biochemistry Degree with specialty in Pharmaceutical Industry (2004), a Master's degree in Toxicology (2013), a Postgraduate certificate in Toxicology (2009), and a Postgraduate certificate in Health Regulation (2007).

Monique Samaan
Cristalia, Brazil

Monique is a Senior Biotechnology R&D Scientist at Cristália Prod. Químicos Farmacêuticos in Brazil. She has a cross-functional experience from API to drug product, focusing on development, optimization and scale-up for both early and late-stage biologics. She has been part of Cristalia's team for 10 years and participated intensively in preparing CMC Module 3 and Comparability Exercise for Criscy® register in ANVISA, the first biosimilar growth hormone 100% developed and manufactured in Brazil.

Philippe Lauwers
Terumo, Belgium

Philippe Lauwers is Director Technology Development at Terumo Pharmaceutical Solutions (TPS). Philippe graduated in Biotechnology from Ghent University, Belgium, and worked as a scientific researcher at the Catholic University of Leuven, Belgium. Upon obtaining an additional degree in Biomedical Engineering, he moved from an academic to an industrial environment. He has been active in the medical device and pharmaceutical packaging sector for the last ten years.



Mariana Peixoto
Sociedade Mineira de Reumatologia, Brazil

President Sociedade Mineira de Reumatologia

Fernando Carmona
Cytiva, Argentina

I´m a Biotechnologist who made his studies at the University of San Martin in Argentina and my thesis was based on cell adhesion
I began my professional career serving as a scientific assessor. Then my career followed in the human and animal pharmaceutical industry in cell culture area, protein purification and process development. I was able to acquire knowledge about equipment and application techniques. This previous works allowed me to understand the whole biotechnology flow path which now I´m using in my daily work on Cytiva

Roberto Frontini
EMA, Germany

Roberto Frontini was born in Milan (Italy) 1950. He moved to Germany 1969 and studied music in Frankfurt/Main. He was from 1976 to 1981 resident conductor at the theatre of Lübeck and 1978 to 2002 chief conductor of the Youth Symphony Orchestra Lübeck.

He studied Pharmacy in Hamburg from 1983 to 1988 and he obtained the PhD 1993. After working as hospital pharmacist in Lübeck and Cologne he was 2001 to 2017 Director of Pharmacy, Qualified Person and lecturer on Pharmacoepidemiology at the University Hospital of Leipzig as well as Director for Patient Care at the Centre for Patient Safety. From 2015 to 2017 he was board member and 2009 to 2015 president of the European Association of Hospital Pharmacists (EAHP). Since June 2019 is alternate member of the Pharmacovigilance Risk Assessment Committee (PRAC) at the European Medicine Agency (EMA) in Amsterdam.

Shahin Kauser
MHRA, United Kingdom

Shahin is a Leading Senior Scientific Assessor and joined the Medicines and Healthcare products regulatory (MHRA) Agency (former MCA) in 2001. She has extensive experience of the 'life-cycle' of pharmacovigilance both nationally and in Europe.
Her current portfolio includes monitoring the post-marketing safety of medicines in various therapeutic areas including biosimilars (such as epoetins), G-CSFs, blood disorders, multiple myeloma and malignant melanoma. Shahin has expertise in assessing risk management plans, additional risk minimisation measures and assessing their effectiveness. She also has experience of conducting benefit-risk assessment, EAMS, PSURs, safety variations and renewal procedures.

Andrea Padovani
ANMAT, Argentina

Head of the Pharmacological Clinical Evaluation Service of the Directorate of Evaluation and Control of Biological Products and Radiopharmaceuticals Doctor graduated from the University of Buenos Aires, adjunct professor of the Department of Medicine Orientation Infectology, U.D.H Hospital de Clínicas. She completed the basic residency in the Medical Clinic at the Penna General Hospital of Agudos and her post-basic residency in Infectology at the Hospital de Infectious F.J. Muñiz. She is technical-scientific evaluator of ANMAT Clinical Trials since 1999.

Julie Marechal-Jamil
Medicines for Europe, Belgium

Leading the 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 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. Since January 2019 on, she has been co-chair of the Biosimilars committee of the International Generic and Biosimilar medicines Association (IGBA) focusing on convergence of global policies and standards.

Gloria Giraldo
Health Canada, Canada

Dr. Gloria Giraldo is a Microbiologist, Master in Epidemiology from the University of Antioquia, Colombia; a Nurse Specialist in Oncology, from the University of Buffalo, U.S.A; Specialist in Burden of the Disease from the University of Harvard, U.S.A. Dr. Giraldo has international experience in oncology research, epidemiology of infectious diseases, pharmacoepidemiology and pharmacovigilance. Currently, she is a Senior Scientific Evaluator at the Marketed Health Products Directorate of Health Canada in Ottawa, Canada.
Dr. Giraldo has experience coordinating and conducting clinical trials, including analysis of quality of life; in pharmacoepidemiology, and in pharmacovigilance of commercialized products, including the evaluation of risk management plans; the application of methodologies for risk-benefit assessment and in the application of methods for health research and risk communication. Currently, Dr. Giraldo works mainly in the pharmacovigilance of vaccines, rare diseases, and vaccines/therapies related to COVID-19, and provides technical support to the Pharmacovigilance Network of the Pan American Health Organization, the Uppsala Monitoring Center (UMC) and the International Society of Pharmacovigilance (ISoP) and serves as a member of the WHO's Expert Advisory Panel on Medicine Safety.

Daniel Morales
University of Dundee, UK

Dr Morales is an Academic GP and Epidemiologist holding a Wellcome Trust Clinical Research Career Development Fellowship. He is based at the University of Dundee and has a second affiliation with

the University of Southern Denmark. His interests lie in chronic disease epidemiology, drug safety and medicines regulation. He is a current member of the European Medicine Agency Pharmacovigilance Risk Assessment Committee and Emergency Pandemic Task Force.

Edilson Uiechi
Bionovis, Brazil

Institutional Affairs & Business Development Manager
Experienced Government Affairs with a demonstrated history of working in the pharmaceuticals industry. Skilled in Pharmaceutics, Governmental Affairs, Vaccines, Oncology, and Haematology. Strong professional with a PhD scholarship focused on Human Reproduction Science from Universidade Federal de São Paulo.

Rodrigo Oliveira
bioMérieux, Brazil

As Pharmacist and Biochemist with a Master's Degree in Microbiology.
He has 14 years of experience in quality in the pharmaceutical industry in the segments of bioproduction, sterile and non-sterile products. Volunteer and speaker at PDA Brazil and other institutions, always addressing quality issues and new technologies harmonized with international regulatory standards. He is currently an Application Specialist at bioMérieux Brazil.

Cristina Ausin
FDA, USA

Cristina Ausin received her Bachelor's in chemistry and her Masters in chemical engineering from University Ramon Llull in Spain and her Ph.D. in chemistry from the University of Barcelona in Spain
She arrived to the Office of Biotechnology Products in the Food and Drug Administration (FDA) as a post-doctoral fellow in 2004 and spent four years doing research in the oligonucleotide synthesis field. In 2008 she became a researcher reviewer, a full-time reviewer in 2013, and a team lead in 2015. Dr. Ausin joined the Office of Therapeutic Biologics and Biosimilars (OTBB) in FDA in 2018 as a scientific reviewer.

Mauricio Ede-Filho
Sandoz, Canada

Industry professional with nearly 20 years of experience in Clinical Development and Scientific Support to technology, drug and device development at a Global level. I have formal training in Cardiovascular Surgery and Physiology and have worked for large and small organizations. Currently I lead the Scientific Affairs Team at Sandoz Canada, where I have oversight of Regulatory Affairs and the Regulatory Compliance Centre, Medical Affairs, Government Relations & Policy, Patient Support Programs and Medical Information.

Gustavo Mendes Lima Santos
ICH / ANVISA, Brazil

Gustavo Mendes Lima Santos. General Manager of Medicines and Biological Products. Graduated in Industrial Pharmacy from the University of São Paulo (2001), Specialization in Sanitary Surveillance from FIOCRUZ (2007) and Master's Degree in Toxicology Applied to Sanitary Surveillance from the State University of Londrina (2013). Experience of 18 years at Anvisa working in bioequivalence, marketing authorization and clinical research of medicines.

Marcos Roman Calgaro
Thermo Fisher Scientific, Brazil

Education: Ph.D. in Sciences – University of São Paulo, (IFSC), São Carlos, SP-Brazil. (2002-2007)

Master Degree in Genetics and Evolution- Federal University of São Carlos, São Carlos, SP-Brazil. (2000-2002)

B.S. in Genetics – University of Misiones, Posadas, Misiones-Argentina. (1993-1999)

Professional Experience: 2005-2008 Manufacturing Supervisor - Invitrogen do Brasil. São Paulo, SP, Brasil

2008-2015 Bioprocess Product Specialist LATAM - GE Healthcare Life Sciences do Brasil, SP, Brasil

2015 - 2019 Bioproduction Business Development Manager – Brasil - Thermo Fisher Scientific

2019 - now Sr. Commercial Manager LATAM, Bioproduction Group - Thermo Fisher Scientific

Main goal is to develop the Upstream/Downstream Market in LATAM

Focus on Single Use Technology, SU Bioreactors, SUB Mixers, Cell Culture Media GIBCO, Chromatography Media POROS, Analytical Systems

Nicolas Estrada

Merck, Mexico

Nicolás Estrada joined Merck Millipore in 2016 as a Single-Use Sales Development Specialist LATAM. He has worked for more than 15 years in the pharmaceutical industry and has extensive experience in the management of injection product manufacturing areas (aseptic processes). In the commercial and technical approach, he has more than 15 years of experience in filtration and Single-Use technologies.
Nicolás received his bachelor's degree as a Bachelor of Pharmaceutical Chemical Biologist from the Autonomous Metropolitan University in Mexico City. He is currently one of the main references of the application, use and implementation of Single-Use technologies in the industry.

Dorthe Bartels

AMGROS, Denmark

Senior Strategic Advisor, Negotiator and Head of the Biosimilar task force

Thiago Mares Guia

Bionovis, Brazil

Current position: Scientific & Business Executive Director @ Bionovis, a company 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.

Brian Godman

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

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.

Kattia Milena Riaño

Sandoz, Colombia

Student of Msc – EU Regulatory Affairs, Marketing Management Specialist Pharmacist. With more than ten (10) years of professional experience, in areas such as: Regulatory Affairs, Quality Assurance and R&D; eight (8) out of ten (10) fully dedicated to the Regulatory Affairs´ field. With experience within the Pharmaceutical Industry and in Regulatory Affairs counselling for companies that belong to different sectors.
Currently working for the Regulatory Affairs department in a company that belong to Biopharmaceutical sector and recognized as a leader in the commercialization of Biosimilars.

Tore K. Kvien

University of Oslo, Norway Diakonhjemmet Hospital, Oslo, Norway

Tore K. Kvien has been Professor of Rheumatology at the University of Oslo since 1997 (now professor em) and Head of the Department of Rheumatology at Diakonhjemmet Hospital, Oslo from 1994 to 2019. He was the principal investigator of the Norwegian government-funded NOR-SWITCH trial, which was published in Lancet 2017. He has published more than 600 original research articles, was President of EULAR 2005-2007, Editor-in-Chief of the Annals of the Rheumatic Diseases 2008-2017. He has received several international awards and the Norwegian King in 2019 appointed professor Kvien as Officer First Class of the Royal Order of St Olav.

Luciana Rahal Abrahão

Sandoz, Brazil

Physician, specialist in Internal Medicine and Critical Care, PhD in Health Sciences By USP Medical School. Medical manager in Sandoz Brazil, responsible for Biosimilars.

Natalia Sousa Freitas Queiroz

University of Sao Paulo School of Medicine, Brazil

Natália Sousa Freitas Queiroz is Associate Professor of the Gastroenterology Postgraduate Program of the University of Sao Paulo. She completed her Fellowship in Gastroenterology at the Clinics Hospital from the University of Sao Paulo (2012) and achieved her PhD degree in the University of Sao Paulo in 2018. Dr. Queiroz actively participates as a member of the board of coordinators of the Brazilian IBD study group (GEDIIB) and is currently associate editor of Crohn's and Colitis 360 Journal.