biosimilar medicines
better access. better health.

Biosimilar Medicines CONFERENCE

HILTON AMSTERDAM AIRPORT SCHIPHOL

7–8 MAY 2026

Christine Berndt - Chair for the Biosimilar medicines group, Vice President Global Specialty Development Stada

Dr Christine Berndt, Vice President Global Specialty Development at STADA, is a senior pharmaceutical executive with extensive global experience in biosimilar and specialty medicines development. She has led international cross functional teams and managed biosimilar portfolios from strategy through regulatory approval, launch and lifecycle management in major markets. As Chair of the Biosimilar Working Group at Medicines for Europe, she brings hands on experience to representing the biosimilar industry as well as her passion for increasing patient access to life-changing drugs. Her expertise is grounded in a robust scientific background, with a PhD in cellular biology and a Master's degree in biochemistry/molecular biology, complemented by executive education in leadership and business as well as a decade's experience in strategy management consulting.

Javier Padilla Bernáldez - Secretary of State for Health, National Ministry of Health, Spain

Born in 1983 in Madrid. Degree in Medicine (Universidad Autónoma de Madrid). Masters in:
- Public Health and Health Management (Andalusian School of Public Health, 2013-2014)
- Health Economics and Medicine (Universitat Pompeu Fabra, 2012)
- Philosophy for Contemporary Challenges (Universitat Oberta de Catalunya, 2021).

Resident Medical Intern at the Andalusian Health Service (2008-2012)
Family and Community Physician in the Madrid Health Service (2015-2021)
Regional Deputy of Más Madrid (2021-2023).
Currently, and since November 2023, he holds the position of Secretary of State for Health of Spain. He is co-author of Malestamos (2022) & Epidemiocracia (2020) and author of ¿A quién vamos a dejar morir? (2019), as well as co-coordinator of Salubrismo o barbarie (2017). He enjoys reading and traveling, and has a daughter with whom she likes to spend as much time as possible (as often as work allows).

Adrian van den Hoven - Director General, Medicines for Europe

Adrian van den Hoven has been director general of Medicines for Europe since September 2013. In his role he focuses on stimulating competition in off-patent medicine markets, fostering access to medicine, reducing medicine shortages and addressing major health crises, supporting policy measures for sustainable pricing, promoting efficient regulatory standards, and developing a coherent EU industrial strategy to support the long-term viability of the generic, biosimilar and value-added medicines industries. He is also member, and former president, of the European Medicines Verification Organization (EMVO) board for the implementation of serialization against falsified medicines, the former Chair of the International Generic and Biosimilar medicines Association (IGBA) and a member of the joint industry advisory council of the Health Emergency and Response Authority (HERA) and the Vice-Chair of the Critical Medicines Alliance.

Joanna Udo de Haes, Directorate for Medicines and Medical Technology, Ministry of Health, Welfare and Sport, Netherlands

Solène Jouan - Policy Officer, European Patients'Forum

Solène Jouan joined EPF in January 2025 as a Policy Officer. In her role, she is responsible for EPF's policy and advocacy work on the topic of access to treatments and EU healthcare budget. She is also leading the EPF Universal Access Working Group (UAWG). Before joining EPF, she worked for EURORDIS-Rare Diseases Europe, contributing to European and international policy development for people living with rare diseases. She started her career working at the Human Rights Action Unit of the European Parliament monitoring the situation of former Sakharov Prize Laureates and following developments in the area of human rights. She then joined a health policy consultancy in Brussels, where she was involved on a variety of EU health policy files, including cancers, rare diseases, digital health and non-communicable diseases. Solène is a jurist and holds a double Bachelor's degree in Law and Languages (English-Chinese) from the University of Grenoble and a Master's degree in EU law from the ULB University of Brussels and the Faculty of Law of Strasbourg.

Benedetta Baldini, European Social Insurance Platform (ESIP)

Benedetta Baldini is Senior Health Policy Advisor at the European Social Insurance Platform (ESIP), the umbrella organisation bringing together national statutory social security institutions from 19 EU Member States and Switzerland. Since 2020, Benedetta Baldini is in charge of European health policies at ESIP and represents healthcare payers and pricing and reimbursement authorities in Brussels. She leads ESIP's work on several policy files, such as the EU general pharmaceutical legislation, the Critical Medicines Act, the Biotech Act, the review of the Medical Devices Regulation, with a strong advocacy-oriented focus. She also supports the coordination of the Medicine Evaluation Committee (MEDEV), an informal network bringing together all the relevant institutions responsible for the assessment, pricing and reimbursement of medicines in Europe. Benedetta is an active member of several health policy networks, including the European Commission's Beating Cancer Stakeholder Group, the HTA Stakeholder Network and the WHO/Europe Novel Medicines Platform. From 2026, she is also part of the Young Forum Gastein Taskforce.

Rainer Becker - Director D "Medical Products and Innovation", European Commission, DG SANTE (inv)

Rainer Becker is Director for Medical Products and Innovation at the European Commission's DG for Health and Food Safety. He is responsible for legislation and policies on human and veterinary medicines, medical devices and innovation. His directorate, amongst others, leads the Commission's work on the revision of the EU pharmaceutical legislation, the availability of medicines, the targeted evaluation of the medical devices regulations and clinical trials. Prior to his current position, Rainer, amongst others, was in charge of antitrust enforcement in the area of pharmaceuticals and health in the Commission's DG Competition.

Nathalie Berger, European Commission DG GROW (INV)

Elisabeth Hustert, Formycon

Eugenio Rossi, Vice Chair Biosimilar medicine group and Sandoz

Raluca Radu - Associate Director Pharmaceutical Policy, Medicines for Europe

Raluca works currently as Associate Director Pharmaceutical Policy at Medicines for Europe. In her current role she combines her scientific background from her training as a pharmacist, with her passion for health and regulatory policy. In her daily work Raluca focuses on advocating for policies which create a supportive environment for innovation in the off-patent space, allowing us to capitalise on the full potential of existing medicines, and shift to a more sustainable drug development pathway.

Sabine Vogler - Austrian National Public Health Institute | Gesundheit Österreich GmbH

Synne Ildahl Svendsen - Scientific advisor, The Norwegian Hospital Procurement Trust

Synne Ildahl Svendsen is a Scientific advisor at The Norwegian Hospital Procurement Trust, where she works with procurement of pharmaceuticals on a national level. Synne holds a Master's Degree in Biotechnology from Imperial College London and has prior experience from the consulting industry with a focus on the development, structuring, and financing of research and development projects. In addition, she has experience from the pharmaceutical industry as a Medical advisor, specialising in inflammatory diseases. In this role she has contributed with scientific expertise and cross-functional collaboration. In her current position as a Scientific advisor at The Norwegian Hospital Procurement Trust she is responsible for eight national tenders, including tenders involving biological medicines used in rheumatology, gastroenterology and dermatology, both with and without biosimilar competition. An important part of her procurement responsibilities is to act as a key liaison between clinicians (expert groups connected to the tenders) and the wider project team, ensuring meaningful clinical involvement in procurement processes and robust contract implementation and follow-up.

Christopher Adlung, Alliance for Procurement Impact – API

As Expert Advisor on Innovation Adoption for Health Proc Europe, Christopher Adlung contributes to advancing the transformation of healthcare procurement into a strategic, innovation-driving function. Health Proc Europe is a digital-first, cross-sector community connecting healthcare institutions with industry stakeholders, particularly in the fields of medical devices and pharmaceuticals. By facilitating collaboration within industry-driven initiatives, Health Proc Europe empowers its members to drive meaningful change through digital engagement, strategic networking, and active participation in procurement transformation across Europe. Within this ecosystem, the Alliance for Procurement Impact (API) serves as a transformative initiative, promoting the security and sustainability of pharmaceutical supply through more effective procurement practices. By providing an open platform, API supports the adoption and implementation of best practices in a rapidly evolving global environment. Christopher is engaged in advancing a procurement framework designed to better align market incentives with health system goals. The framework promotes (i) sustainability-oriented supply procurement, (ii) encourages more efficient resource utilisation, and (iii) incentivises green industrial practices through measurable tender criteria. Operationally, this work seeks to expand adoption of the Most Economically Advantageous Tender (MEAT) methodology, integrate environmental performance criteria into contracting processes, and strengthen early multi-stakeholder dialogue across value chains. With over twelve years of international experience across Europe, Africa, Asia, and the United States, Christopher brings a practitioner-scholar perspective to healthcare transformation. He is Founder and CEO of TAIRIS Medical B.V. and an external PhD researcher at Delft University of Technology. His work focuses on how health innovations transition from unrealised adoption potential to real-world implementation, particularly in low-resource and complex healthcare settings. Drawing on implementation science and frugal innovation theory, he examines how factors such as affordability, simplicity, and system readiness influence adoption pathways across organisational, market, and policy levels.

Niamh Furey, Chair, Biosimilar Market Access Committee (BMAC), Biosimilar medicines Group and Senior Vice President, Head of Commercial EU & RoW, Fresenius Kabi Biopharma

Niamh Furey has been working with Fresenius Kabi since 2005. She is currently the Senior Vice President, Head of Commercial for EU and Rest of World for the Biopharma business of Fresenius Kabi working in Eysins, Switzerland. Previously she was Managing Director for Fresenius Kabi UK and Ireland from 2017 to 2022 and has wide experience working across much of the Fresenius Kabi portfolio including generic medicines, clinical nutrition, medical devices, homecare and compounding. She has held many international commercial roles across her career. She is currently the Chair of the Biosimilar Market Access Group (BMAG) of Medicines for Europe and has previously held board positions at the British Specialist Nutrition Association (BSNA), the Irish Nutrition & Dietetic Institute (INDI), the British Generic Manufacturing Association (BGMA) and has also worked with the British Biosimilars Association (BBA).

Andrew Lotery, Professor of Ophthalmology, University of Southampton, UK

Andrew Lotery is Professor of Ophthalmology at the University of Southampton. He has published over 400 papers and led more than 100 retinal clinical trials. His research focuses on retinal diseases. He has received prestigious research awards including the Nettleship Award from the Royal College of Ophthalmologists and the Henkind Medal from the Macula Society. He was named one of the UK's top 100 doctors by The Times. He served as Editor-in-chief of Eye for 10 years and is Honorary Secretary of the Royal College of Ophthalmologists. He currently leads major studies funded by the Wellcome Trust and the National Institute of Health Research.

Luc Licari, Retina France

Kalveer Flora, Oxford University Hospital NHS, UK

Marcus Guardian - General Manager, International Horizon Scanning Initiative (IHSI)

Since 2019, Marcus is the General Manager of the International Horizon Scanning Initiative (IHSI). He led the organisation from initial concept to the successful development and implementation of a fully operational, internationally recognised horizon scanning database. Marcus has build a collaborative international framework, bringing together experts in HTA, policy makers, negotiators and other professionals. In 2024, Marcus established The Brussels Centre for Collaboration in Health (BCCH), a non-profit organisation that provides specialised administrative and project management support for the implementation of joint activities by European Health Technology Assessment (HTA) bodies under the EU HTA Regulation. Previously he held the position as COO of EUnetHTA since 2015 and is considered as one of the key architects of the European HTA system. Based on an educational background in international law (Technische Universität Dresden), business administration (Qingdao University), and diplomatic studies (University of Leicester) Marcus has forged a career in network development, strategic guidance, and policy management. In 2015, he embarked on a significant challenge by taking on the role of Chief Operating Officer (COO) for EUnetHTA, where he made substantial contributions until 2023. Parallel to his tenure at EUnetHTA, in 2018 Marcus spearheaded the launch of the International Horizon Scanning Initiative (IHSI) as its General Manager. Under his direction, IHSI established a comprehensive global database of pharmaceutical products in the development phase, coupled with state-of-the-art data modelling tools. These advancements have been critical in bolstering healthcare systems' preparedness and enhancing the member state healthcare product negotiation potential. In 2017 Marcus created the “Heads of Agency Meeting” which in 2021, transformed under his leadership led to the formation of the Heads of HTA Agencies Group. Where he served as General Manager until 2023. This initiative unites key European HTA decision-makers, creating a forum to discuss and align on major strategic questions relevant to EU HTA agencies.

Alex Filicevas, Executive Director, World Bladder Cancer Patient Coalition (WBCPC), Chair, WECAN Foundation, Co-Chair, Global Cancer Coalitions Network (GCCN)

Alex Filicevas is the Executive Director of the World Bladder Cancer Patient Coalition – an international umbrella organization representing people affected by bladder cancer globally. Alex leads the efforts to foster an international community of strong bladder cancer patient advocates and organisations around the world, empowering patient voices across the research and care continuum. Alex currently Chairs the WECAN Foundation, is Co-Chair of the Global Cancer Coalitions Network, Vice-Chair of the Patient Advisory Committee of the European Cancer Organisation and Member of the EAU Patient Office Board. Passionate about high-quality, equitable cancer care for all, and the role of efficiency in achieving it, he champions evidence generation and sharing and multi-stakeholder collaboration in urology and oncology.Prior to his current roles, he was the Head of EU Affairs at Europe's largest cancer patient umbrella organisation, where he focused on advocacy activities, capacity building and policy initiatives with a particular focus on overarching issues faced by cancer patients and their carers in Europe. As a healthcare consultant, Alex has supported a number of private and non-governmental organisations in successful advocacy efforts at the EU level on a range of disease areas and issue-specific public health challenges.

Aurelio Arias - Director, Thought Leadership, IQVIA

Aurelio creates topical and forward-looking strategic content relevant to pharma executives worldwide and publishes articles, blogs, and white papers on a regular basis. Aurelio's predominant focus is on off-patent markets where he generates evidence-led insights with a view to spark high-level discourse on biosimilars, generics and value added medicines.

Isabel del Río Álvarez - Deputy Director, BioSim, Spain

Isabel del Río Álvarez is the Deputy Director of BioSim (the Spanish Association of Biosimilar Medicines) since January 2020. Having joined the association in 2016 as a project manager, she has since been involved in coordinating technical reports and driving the association's strategic initiatives. She expanded her expertise in market access by completing a Master's degree in Health Economics and Pharmacoeconomics at the Universidad Carlos III de Madrid. She also holds an MBA in the pharmaceutical and biotechnology industry. She has co-authored publications on the economic impact of biosimilars medicines in the Spanish NHS and comprehensive reviews of individual prescribing incentives for biosimilars in Europe and the USA. She holds a PhD in Biotechnology from the Universidad Politécnica de Madrid, and her career includes extensive research experience at the Center for Plant Biotechnology and Genomics and the Karlsruhe Institute of Technology in Germany.

Eric Low - Eric Low Consulting UK

Eric Low is the Founder of Eric Low Consulting, specialising in health technology assessment, market access, patient engagement, and life sciences and healthcare policy. Before this, Eric established and served for 20 years as CEO of Myeloma UK. Eric is committed to improving patient outcomes and puts patients at the centre of everything he does. He holds several Board, honorary, advisory and voluntary positions and advises numerous medical, research and health-focused charities on a pro bono basis. He was awarded an OBE for services to charity in the Queen's Birthday Honours 2012.

Xenofon Baraliakos MD, EULAR President

Prof. Dr. Dr. h.c. Xenofon Baraliakos is the Head of Rheumatology at the Rheumazentrum Ruhrgebiet Herne and Professor for Internal Medicine and Rheumatology at the Ruhr-University Bochum, Germany. He studied Human Medicine at the universities of Magdeburg and Berlin, Germany and received his PhD degree in 2005 with the first study on the MRI outcomes of patients with ankylosing spondylitis before and after therapy with monoclonal antibodies against TNFa. Prof. Baraliakos received his official Board Degrees in orthopaedic surgery in 2007 and in Internal Medicine and Rheumatology in 2014. His research interests include clinical and academic research in the field of spondyloarthritides, with special emphasis on imaging outcomes and treatment of the disease. Among others, Dr Baraliakos won the EWRR Award, in 2005, the EULAR Young Investigator Award, in 2006 and 2008, the German patient's AS Society Award in 2010 and the 2014 Award for Excellence in Clinical Research from the European Society for Clinical Investigations. Dr. Baraliakos has also received a honorary doctorate degree from the University of Athens, Greece and is a Visiting Professor at the Sichuan University, China. Dr Baraliakos is the elected President of EULAR (European Alliance of Associations for Rheumatology) for the period 2025 - 2027. He has served as President of ASAS (Assessment of Spondyloarthritis International Society) and Chair of the EULAR standing committee for musculoskeletal imaging. He holds a honorary membership of the Hungarian Society of Rheumatology, a honorary doctorate from the University of Athens and is a visiting Professor at the University of Chengdu, China. Dr. Baraliakos is member of the American College of Rheumatology (ACR), the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) and the German Society of Rheumatology. He also acts as a reviewer and is an Associate Editor in a number of major rheumatological journals.

Souzi Makri – Vice President PARE, EULAR

Souzi Makri has been a patient advocate since 2008 when she was diagnosed with enteropathic spondylarthritis and Fibormyalgia. Souzi has been trained as a patient research partner by EULAR in 2013 (The European Alliance of Associations for Rheumatology) and became a EUPATI Fellow in 2015, after following a 14-month course on the research and development of medicines. Since then, she has participated in various projects with Academia, Industry, and other European consortia as a patient research partner. Souzi has led two European Organizations as Chair, namely AGORA (Southern European Platform for people with Rheumatic diseases) from 2011-2017, and ENFA (European Network of Fibromyalgia Associations) from 2014-2019. From 2020 -20204 Souzi held the position of Chair Elect , Chair and Past Chair of the EULAR PARE committee . Currently she holds the position of EULAR VP PARE. At present, Souzi holds the position of Vice- President of the Cyprus League of People with Rheumatism (CYLPER).

Johan Pontén - Senior Adviser International Affairs, TVL Sweden

Johan Pontén is Senior Adviser International Affairs at the Swedish pricing and reimbursement authority, the Dental and Pharmaceuticals Benefits Agency (TLV). Johan is also elected Head of the Management group in the European network National Competent Authorities on Pricing and Reimbursement (NCAPR) since 2024, and Co-chairs the MEDEV network of 25 national authorities from 20 Member States responsible for the assessment, pricing and reimbursement of medicines in Europe. Johan has a broad experience of the Swedish civil service and work in international organisations (Bank of Sweden, Ministry of Finance, National Board of Trade, EU Commission, amongst others). Prior to his post at TLV he was Trade Policy Advisor at the National Board of Trade and in that capacity chaired the UN International Trade Procedures Working Group.

Dr. Joachim Kiefer - Head of Clinical Development of Biologics at Gedeon Richter.

Dr. Kiefer brings more than 25 years of experience in clinical development, spanning global programs across multiple therapeutic areas. Before joining Gedeon Richter, Dr. Kiefer held senior roles in the development of biosimilars, innovative biologics, and small molecule therapies. His work has covered a broad range of indications, including osteoporosis, rheumatology, oncology, hematology, dermatology, and ophthalmology, within both major pharmaceutical companies and smaller biotechnology organizations. He holds a doctoral degree in biochemistry from the University of Kaiserslautern in Germany.

Zorana Maravic - Chief Executive Officer, Digestive Cancers Europe (DiCE)

Zorana Maravic is a passionate patient advocate and experienced healthcare leader with almost 15 years of experience driving meaningful change across the European cancer landscape. As CEO of Digestive Cancers Europe (DiCE), she leads one of Europe's most prominent cancer umbrella organisations, working to improve outcomes and quality of life for people affected by digestive cancers through policy engagement, awareness, and patient-centred research. Zorana began her advocacy career at EuropaColon, supporting its expansion across more than 30 countries and strengthening national advocacy capacity. She played a key role in the organisation's transition to Digestive Cancers Europe (DiCE) in 2018, contributing to its broader strategic focus across all digestive cancers. She became Director of Operations in 2019, leading patient-centred research, education, and awareness initiatives, including impactful projects such as the metastatic colorectal cancer (mCRC) patient survey. Appointed CEO in 2021, Zorana has since driven DiCE's growth expanding its policy influence, strengthening partnerships, and increasing its role in EU-funded programmes that embed patient perspectives into research, policy, and healthcare transformation. Zorana brings a unique blend of scientific expertise and strategic leadership to her work. She holds an MBA from the University of Sheffield, a degree in Molecular Biology from the University of Belgrade, and has a decade of experience in the pharmaceutical industry. This multidisciplinary background enables her to connect scientific understanding with lived patient experience, ensuring that advocacy remains evidence-based, inclusive, and impactful. A strong believer in the power of listening to patients, Zorana is committed to transforming patient insights into better systems and services. Her work is grounded in empathy, evidence, and equity - driving her mission to make cancer care across Europe more responsive, inclusive, and effective.

Mina Grguri - Biosimilar Policy & Science Officer, Medicines for Europe

Mina is the Biosimilar Science and Policy Officer at Medicines for Europe, the trade association representing the generic, biosimilar, and value-added medicines industry. After graduating from university in her home country, Serbia, and becoming a pharmacist, Mina began her professional career in the sphere of clinical trials in a global CRO company. Joining Medicines for Europe and the healthcare policy sector at the beginning of 2023 gave her the opportunity to merge her pharmaceutical knowledge and her passion for improving healthcare outcomes with a patient centric approach. In her role, Mina has been involved in advocating for a strong EU biosimilar industry and the evolution of biosimilar regulatory framework, aiming to increase access to off-patent biologic therapies across Europe.

Sarah Yim – Director, Office of Therapeutic Biologics and Biosimilars, U.S. Food and Drug Administration (FDA)
Sarah Yim, M.D. is the Director of the Office of Therapeutic Biologics and Biosimilars, in CDER's Office of New Drugs (OND). She has been with FDA since 2005 in various roles, including 2 years as Director of the Division of Clinical Review in the Office of Generic Drugs, and 11 years in various roles in rheumatology regulatory review. She received her undergraduate degree from Stanford University, her Doctor of Medicine degree from the Uniformed Services University of Health Sciences and completed a postdoctoral fellowship in rheumatology at the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), at the National Institutes of Health.

René Anour - Chair EMA BMWP and Senior Clinical Expert/Head of National Scientific Advice, AGES, Austria
René Anour is working as a senior clinical expert for the Austrian Federal Office for Safety in Health Care, where he is involved in centralised Marketing Authorisations and EMA Scientific Advice. He is furthermore Process Lead of National Scientific Advice at his agency. He has been a member of the EMA's Biosimilar Medicinal Products Working Party since 2020 and has been elected the Working Party's chair in 2023. He is furthermore a member of the HMA Biosimilar Working Group.

Dr. Francisco de Matos Afonso Pereira, MHRA, UK

Ali Alsamil, SFDA, Saudi Arabia

Dr. Martin Schiestl - Global Head Regulatory Affairs Policy, Sandoz

Martin Schiestl received his doctoral degree in chemistry with focus on bioanalysis at the University of Innsbruck in Austria in 1996. In the same year, he started his work on Biosimilar medicines at Sandoz where he built up the analytical and pharmaceutical development departments in charge of the biosimilar portfolio and other biological medicines of Sandoz. He moved into the regulatory and policy field in 2009, further fostering regulatory sciences for biosimilar medicines. He also authored several influential peer-reviewed articles on the science of biosimilars. In his current role, he is responsible for the Global Regulatory Affairs Policy for generic and biosimilar medicines at Sandoz.

Joerg Windisch, PhD, Vice Chairman - Polpharma Biologics Group

Dr. Windisch is a highly experienced biopharma executive, board member, and advisor with 30 years of experience in the field of biosimilars and innovative biopharmaceuticals. He is the current Vice Chairman and former CEO of Polpharma Biologics Group, a privately-owned company with longstanding experience in developing and manufacturing biosimilars. The company's products are sold globally via commercialization partners. In addition to his work for Polpharma Biologics, Dr. Windisch also serves on the boards of innovative biotech companies. Before joining Polpharma Biologics, he was the Chief Operating Officer (COO) at Affimed NV, a NASDAQ-traded biotech company which developed innovative bi- and trispecific antibodies as immune cell engagers to treat various kinds of cancer. Prior to this, Dr. Windisch spent almost 20 years at Novartis/Sandoz where he most recently served as Chief Scientific Officer (CSO) for Sandoz Biopharmaceuticals. He was a key figure in developing the first biosimilars approved in Europe and the US.

Luis Correira Pinheiro, Data Analytics Workstream, Data Analytics and Methods Taskforce, EMA

Luis Correia Pinheiro, PharmD, MEPI, has a background in epidemiology and data science. He works in the Data Analytics and Methods Taskforce at the European Medicines Agency. He is a rapporteur for the AI workstream of the NDSG Data and AI workplan. He coordinates a Health Data Lab at EMA and is a member of the leadership team of the Special Interest Area on AI and Data Science.

Thomas Kirchlechner, IGBA Biosimilars Committee Co-Chair and Sandoz

Dr. Thomas Kirchlechner holds a PhD in chemistry and is Senior Director of Regulatory Policy in Sandoz Global Regulatory Affairs and has worked in pharmaceutical industry for 25 years. Based in Austria, he has served in his current role for 7 years, which entails regulatory policy areas such as global harmonization of regulatory requirements for biosimilars, by means of providing expert comments to biosimilar draft guidelines from around the world, in particular from Asia, Africa, Middle East and Latin America, and by running biosimilar workshops with health authorities or speaking at biosimilar conferences in these regions. Apart from his language proficiency in English and German (native) he is fluent in Spanish and Portuguese.

Dr. Ariana Pamela Ruiz Ruiz - Medical Doctor, Health Law Specialist, Regulatory Affairs Expert, COFEPRIS, Mexico

Dr. Ariana Pamela Ruiz Ruiz is a Medical Doctor and Health Law Specialist with over 10 years of experience in regulatory affairs, clinical research, and pharmacovigilance. She currently serves as a Specialized Regulatory Reviewer at COFEPRIS, Mexico's National Regulatory Authority, where she is responsible for the scientific evaluation of technical documentation supporting the approval of medicines, including generics, biosimilars, innovative drugs, vaccines, and orphan products. Her expertise includes CTD dossier assessment, benefit–risk evaluation, and compliance with international regulatory standards, including ICH and WHO guidelines. She also has solid experience in the conduct of bioequivalence studies under regulatory standards, including protocol development and adverse event monitoring.

She has participated in international regulatory collaboration initiatives, including the COFEPRIS–DKMA Strategic Sector Cooperation Project (Mexico–Denmark) focused on pharmaceuticals and biosimilars (2025). Dr. Ruiz has completed advanced training in pharmacovigilance, medical devices regulation, and global health through institutions such as UNAM, the World Health Organization, and the University of Copenhagen. Her professional interests focus on strengthening regulatory systems, improving access to safe and effective medicines, and fostering international collaboration in public health.

Asmaa Fouad, Egyptian Drug Agency (EDA)

Dr. Asmaa Fouad heads the Central Administration of Biological & Innovative Products and Clinical Trials at EDA, Egypt responsible for regulatory functions of marketing authorization, laboratory testing & lot release of biological products including vaccines and marketing authorization of innovative/ new biotherapeutics as well. She is also responsible for regulating clinical trials at EDA. She is also a member of Supreme Council for Clinical Research Ethics oversight in Egypt. She serves as a temporary advisor on the Experts Advisory Panel on Biological Standardisation with the WHO- ECBS since September, 2023 for four years and member of Technical Advisory Group on Local Production and Technology Transfer with WHO since January 2025 for two years term. Dr. Fouad is EDA representative in ICH since beginning of observer ship journey in November 2021 untill now and responsible for managing EDA activities in ICH https://www.ich.org/page/members. She is also representing EDA in International Program for Regulators of Pharmaceuticals-IPRP- management committee since May 2022 & has been elected as IPRP vice chair of management committee since June 2024 for two years term (Co-chairing with EDQM). Dr. Fouad is a member of EDA Egypt's Emergency Committee, head of scientific committee for biological products in EDA. She is playing a key role in formulating national guidelines and has actively collaborated with the WHO's COVID-19 vaccines global review team. With more than 20 years of biologics regulatory experience, Dr. Fouad leads international cooperation efforts between EDA & many international regulatory authorities. Dr. Asmaa is a part-time instructor at The American University in Cairo, AUC for clinical research diploma.

Gillian Woollett - VP, Head Regulatory Strategy and Policy, Samsung Bioepis, Biosimilars Committee Chair, IGBA

Dr. Gillian Woollett joined Samsung Bioepis in November 2021 as VP, Head Regulatory Strategy and Policy, US (SBUS), to stand up a US presence for science-based regulatory strategy and policy in the leading global market for biologics, including but not limited to biosimilars. Prior she was SVP and Principal Regulatory Scientist at Avalere Health where she led the FDA Policy and Regulatory Strategy Practice, providing the “prequel” of scientific and technical expertise to support drugs, biologics and devices gaining approval at the FDA in a manner that allows them to be commercially successful. Previously, Dr. Woollett was Chief Scientist, and Administrator, at the law firm of Engel & Novitt, LLP. She was VP, Science and Regulatory Affairs at BIO, after serving as AVP at PhRMA, where her group led on the negotiation and creation with FDA of the comparability protocol in support of manufacturing changes to already licensed biologics (that became the conceptual basis of biosimilarity). In her PhRMA capacity, she testified before Congress and represented the biopharma industry in the media as the industries’ voice on international, as well as US, regulatory and scientific issues. She has served on Federal Advisory Committees; for example, as the industry representative on CDC’s Board of Scientific Counsellors to the National Center for Infectious Disease. She is an appointee to the Nomenclature and Labelling Expert Committee of the United States Pharmacopeia (USP), was on the Board for the Foundation for The Accreditation of Cellular Therapy (FACT), and served on the Science Board of the Pharmaceutical Education Research Institute (PERI). Dr. Woollett earned her B.A., M.A. in Biochemistry from the University of Cambridge, and her D.Phil. in Immunology from the University of Oxford in the UK.

Niklas Ekman – Vice-Chair EMA BMWP and Head of Biological Section, Senior Researcher, Finnish Medicines Agency (FIMEA)

Dr Niklas Ekman has a background in molecular cell and cancer biology. After joining the Finnish Medicines Agency in late 2006, he worked the next 11 years as a quality assessor for biological medicinal products with focus on biosimilars. His main activities and responsibilities included assessments of European Medicines Agency (EMA) centralized marketing authorization applications, scientific advices, as well as clinical trial applications. Currently, Dr Ekman is the head of the biological section at the Finnish Medicines Agency. At EMA, Dr Ekman is the vice-chair of the Biosimilar Medicinal Products Working Party (BMWP) and a member of the Biologics Working Party (BWP).

Steffen Thirstrup - Chief Medical Officer, EMA

Steffen Thirstrup is a medical doctor and board-certified specialist in clinical pharmacology and therapeutics. He holds a PhD in pharmacology and has a long background in clinical internal medicine with special emphasis on adult respiratory medicine. Additionally, Dr. Thirstrup was appointed adjunct professor in pharmacotherapy at the Faculty of Health Sciences, University of Copenhagen, in 2012. From 2004-09 Steffen Thirstrup worked at Danish Medicines Agency first as the Danish member of CHMP at the European Medicines Agency (EMA) for five years including 10 months as joint CHMP- and CAT-member, followed by a short period as head of Danish Institute for Rational Pharmacotherapy dealing with HTA and best practice guidelines for primary care. In 2011 Prof. Thirstrup rejoined the licensing division at the Danish Medicines Agency acting as Head of Division for Medicines Assessment and Clinical Trials. During this period Prof Thirstrup co-chaired the European Commission's working group on market access for biosimilars medicinal products and acted as key scientific contact for the managing entity of the IMI beneficiaries for the PROTECT collaboration (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium). In March 2013, Prof Thirstrup joined the pharmaceutical consultancy company NDA Group AB as a full-time medical advisor on NDA's regulatory advisory board. In April 2014 Prof Thirstrup was appointed as director for the Regulatory Advisory Board at NDA Regulatory Services Ltd. Since June 2022 Prof Thirstrup has been the Chief Medical Officer at the European Medicines Agency, Amsterdam, The Netherlands. Prof Thirstrup is author of more than 30 scientific papers, guidelines and text-book chapters as well as co-editor of 5th edition of Basal og Klinisk Farmakologi (Medical school pharmacology textbook in Danish). Prof Thirstrup shares his life between Amsterdam and with his family in a small community (Værløse) just outside Copenhagen, Denmark**.**