Isabell Remus - Biosimilar Medicines Group, Medicines for Europe, Head of Commericial Europe, Sandoz

Isabell Remus is the Biosimilar Global Platform Head as of March 1, 2025. In this role, she is responsible for Sandoz's biosimilar business worldwide, from portfolio selection to the successful commercialization of biosimilar medicines. Prior to this, she was Head of Commercial, Europe, overseeing the Biosimilar and OTC businesses, as well as Market Access and Commercial Excellence. Under her leadership, Sandoz became the leading biosimilar company in Europe with multiple successful launches. In addition to her corporate role, Isabell is also the Chair of the Biosimilar Medicines Sector Group at Medicines for Europe. Since joining Novartis in 2005, Isabell has taken on roles of increasing responsibility across both Novartis and Sandoz, at country, regional, and global levels, such as Global Head of Product Strategy & Commercialization for Biosimilars and Oncology Injectables, and as a member of the Hexal AG board, where she led the German Specialty Business. She has a breadth of proven leadership experience across global brand management, market access, commercial excellence, new products, and portfolio management across a variety of therapeutic areas. Prior to joining Novartis/Sandoz, Isabell Remus worked for Procter & Gamble in Athens, Geneva, and Frankfurt. She studied European Business Administration in London and Reutlingen.

Fernando de Mora - Professor of Pharmacology/Consultant on Biosimilars, UAB - Universitat Autònoma de Barcelona - Spain

Fernando Fernando de Mora, PhD, MBA, is Full Professor of Pharmacology at the Universidad Autónoma de Barcelona (UAB) in Spain, where he lectures undergraduate and postgraduate students in pharmacology and biotechnology and conducts research in immunopharmacology (asthma and allergy), with international publications. Between 1988 and 1998, Dr. de Mora retained various Biomedical Research Positions in Spain, the Netherlands (University of Utrecht), the UK (University of Southampton) and USA. During this time, he completed his PhD in Immunopharmacology (1993, UAB, Spain), a Postdoc at Harvard Medical School, USA (1994-1997), and his Master of Business Administration (MBA) from the University of Chicago, USA (1999). Between 2005 and 2011 he was the Chairman of the Pharmacology Dept. at the UAB's Medical School. Since 2008, he has worked as an International Academic Speaker and Consultant in biosimilars science regulation and market. He was invited by the United Nations as an international expert and also as a speaker and chairman in major biosimilar conferences globally. Dr. de Mora has collaborated worldwide with Ministries of Health and has acted as a consultant for numerous pharma companies, in many cases as a member of their Scientific Advisory Board. Between 2009 and 2012 he was Managing Director of Salupharma Biosimilars SA, a university spin-off aimed at early-stage biosimilar development.

Elsa Mateus – CEO, Portuguese League Against Rheumatic Diseases, Portugal

Elsa Mateus was diagnosed with juvenile idiopathic arthritis in 1977. She is a PhD in Anthropology, specialising in anthropology of health. She has been a member of EULAR's Patient Research Partners Network since 2013 and a EUPATI Fellow after completing EUPATI training on patient expert in the medicines research and development process in 2015. In the same year, she became President of the Board of the Portuguese League Against Rheumatic Diseases. Elsa Mateus has been involved in EULAR (The European Alliance of Associations for Rheumatology) as a volunteer, since 2009, and between 2021 and June 2025 she has been EULAR Vice-President representing PARE (People with Arthritis/Rheumatism in Europe).

Job van Boven - Associate Professor, University Medical Center Groningen, The Netherlands

A/Prof. dr. Job FM van Boven is a health economics & real-world drug outcomes expert specialised in lung diseases. He is the founding director of the Medication Adherence Expertise Center Of the northern Netherlands (MAECON) and formerChair of the European Network to Advance Best Practices & Technology on Medication Adherence (ENABLE) COST Action 19132. He is Principal Investigator at the Groningen Research Institute for Asthma and COPD (GRIAC) and leads the research group on Cost-effective Respiratory Drug Use at the University Medical Center Groningen. He obtained his PharmD and PhD at the University of Groningen (The Netherlands), where his thesis focused on the cost-effectiveness of adherence enhancing interventions in patients with COPD. After his PhD research, he completed fellowships at the University of Colorado (USA), Monash University (Australia) and the Hospital Universitario Son Espases (Spain). He is (co)author of >200 scientific publications, current/former supervisor of 15 PhD students and received several research prices & grants (totalling>€6 million). Having interest and wide experience in both medication adherence and health economic methods, his mission is to find novel, cost-effective ways to make better use of our respiratory medications in order to maximize both patients' and societal benefits.

Malina Müller - Head of Health Economics, WifOR Institute

Dr. Malina Müller heads the research field Health Economics at WifOR Institute, specializing in statistics, health policy, and alternative economies. Her aim is to achieve health for all by making the significance of health interventions visible. She envisages a society in which the medical and socioeconomic benefits of innovations in healthcare are valued according to their true worth – by making the Social Impact of health interventions visible. Alongside her Health Economics team, Dr. Müller enables stakeholders from politics and business to recognize the value of health to society, where gaps in healthcare exist, and which measures can effectively deliver better, more resilient health.

Dr. Malina Müller holds a PhD on the determinants of healthcare utilization in German social health insurance (SHI) and is a guest lecturer at various universities across Germany. She covers topics including Health Economic Decision Modelling, Labor Market and Alternative Economics, and Institutional Economics. Since joining the Health Economics team at WifOR in 2016, Dr. Müller has lead research projects analyzing the Social Impact of medical innovations and the long-term benefits of preventative approaches for populations at a macro level. Her research models the efficacy and return on investment (ROI) of innovative medicines using advanced econometrics, statistical methodologies, and simulations.

Mourad Farouk Rezk - Vice president- Global head of medical affairs and development, Biogen-World Wide Medical Affairs

Dr Mourad Rezk joined Biogen in January 2015. He is a medical doctor who trained as a diabetologist. He brings more than 20 years of experience in the pharmaceutical industry, holding a number of leadership roles in medical affairs, R&D and marketing. Before joining Biogen, Dr Rezk was with Amgen for nearly eight years as an international medical lead for nephrology innovator biologics and the company's EU biosimilars taskforce. While there, he established an internal biosimilars medical platform and led the development and execution of a significant number of multinational studies, key publications and poster presentations. He has also spoken at a number of key international biosimilars congresses. Prior to that, Dr Rezk spent four years in Athens with Novo Nordisk Africa & Gulf as the region's medical affairs director, establishing diabetes and hematology clinical and medical educational infrastructures that supported the launch of the company's second-generation insulin analogues and hemophilia treatments. He also previously spent nearly 11 years with J&J Middle East where he was marketing & sales lead for the biotech business unit, after which he moved to head the medical affairs team.

Kate O'Regan - Head of Communications and Stakeholder Relations, Medicines for Europe

Kate is the Head of Communications and Stakeholder Relations at Medicines for Europe, the trade association representing the generic, biosimilar and value-added medicines industry. Kate joined Medicines for Europe in 2017 after a number of years at the Association of European Cancer Leagues. Having worked more than ten years in the healthcare sector from within the European Parliament, industry, civil society NGO and trade association, Kate is a firm believer in the importance of European policy in boosting access to medicines.

Luisa Avedano - CEO, European Federation of Crohn's and Ulcerative Colitis Associations

Master's Degree in Political Sciences - International Relations and Diplomatic Studies. Luisa Avedano is the Chief Executive Officer of the European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA) since 2009. She oversees the strategic, policy and daily management of the EFCCA's Secretariat as well as of the assistance and support of the Chairman and the Executive Board members in fulfilling their responsibilities and tasks. She oversees the EFCCA headquarter in Brussels and co-ordinates a team of 12 people. She has an extensive experience in international NGOs and networking. She has been managing all levels of multiple and integrated projects including budgeting and administration. She is working on project design and development, advocacy and lobbying at EU level and she is responsible for the fundraising strategy. She is co-author of several medical articles published in world-renowned scientific journals and reviews. (https://efcca.org/publications). Since 1998, she is teacher and lecturer for several organizations (Health Sector, Local Authorities, Public Bodies, Third Sector, Private Companies, international NGOs) and for the Polytechnic of Torino - Interuniversity Department of regional and urban studies and planning (DIST)

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

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.

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.

Giulia Del Brenna - Head of Unit, DG GROW, European Commission

Giulia Del Brenna (1970 - Italian / French) is Head of the Unit "Food, retail, health" In the Directorate General for Internal Market, Industry, Entrepreneurship and SMEs since May 2024. A graduate of Sciences Po Paris, she holds a Master in European Studies from ICADE Madrid, and is an Official of the European Commission since 1996. Among other functions, she was Head of the Pharmaceutical, Food and Biotechnology industries Unit (2008 to 2011), Advisor responsible for Administration and Public Health issues in the Task Force for Greece (2011 to 2014), and Deputy Head of the Cabinet of Commissioner Carlos Moedas – Research, Science and Innovation (2014 to 2019). During the COVID-19 crisis, she advised the Clearing House for Medical Devices and the Task Force for up scaling of COVID-19 Vaccines Production. From March 2021 to April 2024, she led the "Strategy and regulation: single market and industrial policy" Unit in her present Directorate General.

Karolina Nowak - Director of Innovation and Biotechnology Development Department, Medical Research Agency, Poland

Dr Karolina Nowak is director of the Department of Innovation and International Cooperation in Medical Research Agency. She was a visiting scientist at Harvard Medical School, Dana-Farber Cancer Institute. She received a prestigious scholarship at Stanford University and did an Internship at Stanford Biomaterials and Advanced Drug Delivery Laboratory. Doctor Nowak is a graduate of Executive MBA at ESG University of Quebec at Montreal and Warsaw School of Economics. She is a patent inventor of new pharmaceutical drug formulation dedicated for patients with alveolar osteitis and she was a scientist in the field of Pharmaceuticals, drug formulations and molecular biology. She has participated in numerous national and international projects. Beside her scientific activities she has experience in managing 2 commercial projects in area of drug development.

Antonella Cardone - CEO, Cancer Patients Europe

Antonella Cardone is currently the CEO of Cancer Patients Europe, the pan-European and all-cancer types patient association. She is the Patient Advocacy Expert and Advisor to the Board of Pancreatic Cancer Europe (PCE), the European Multi-Stakeholder Platform of leading and most influential groups of physicians and patients, politicians, journalists, academia, and industry on Pancreatic Cancer. She is the former Director of the European Cancer Patient Coalition (ECPC). She has 25 years of experience working for non-profits in the health, social, and employment sectors. Prior to ECPC, Antonella was the Executive Director of the Fit for Work Global Alliance, a multi-stakeholder coalition championing change in health and work policy. She has previously served as the Director of the Global Smoke-free Partnership of the American Cancer Society, leading a movement of over 100 members to coordinate the development of smoke-free laws in 40 countries. She holds a Master's in Science and one in Business Administration. She represented ECPC on the Board of All.Can and on the Board of Pancreatic Cancer Europe, in which she was vice-chair.

Maja Graf - Director Market Policy and Access, Medicines for Europe

Maja Graf is Director Market Policy and Access for Medicines for Europe, a trade association representing the pharmaceutical companies supplying the largest share of medicines across Europe and is the voice of the generic, biosimilar and value-added industries. In her role, she focuses on issues such as equitable access to affordable treatments across Europe, achieved by sustainable pharmaceutical market for off-patent medicines and innovation throughout the medicines life cycle, in the form of Value Added Medicines. She holds the Master of Sciences of Pharmacy degree obtained from Faculty of pharmacy, University of Ljubljana. Before joining Medicines for Europe, she worked in the pharmaceutical industry. Medicines for Europe is a leading partner for better healthcare aims to increase the health and wellbeing of all Europeans through better access to high-quality medicines.

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.

Robert Sauermann - Head of Department of Pharmaceutical Affairs, MD, Austrian Social Insurance, Austria

Robert Sauermann, MD, is consultant in internal medicine and clinical pharmacologist. He is head of the Department of Pharmaceutical Affairs at the Austrian Federation of Social Insurances. The department's main responsabilities include drug evaluations (comparative assessment of benefit, economic assessment) and price negotiations for reimbursement decisions in the outpatient sector in Austria.

Adam Anderson - Deputy Director Medicine Procurement & Supply Chain - Medicine Value & Access Directorate NHS England, UK

Adam is Deputy Director of Medicine Procurement & Supply Chain in NHSE. Adam's team is responsible for the horizon scanning, strategy creation, procurement and lifecycle management for the biosimilar programme across the NHSE And ICB Landscape. The aim and ambition are now operationally underpinned by NHS Planning Guidance for 2025/26 'ensure that patients are prescribed the best value biological medicine where a biosimilar medicine is available'. NHS England's aim is to be a world-leader in biosimilars adoption to achieve an ambition to realise £1bn in savings 5 years (2024-29). Adam is from a business background prior to joining the NHS and has held various senior commercial leadership roles / board level positions. Adam joined the NHS to bring business centric critical thinking and ways of working to further enhance commercial delivery.

Magnus Bodin - Head of Biosimilars, European Center of Excellence at Biogen, Co-Chair, Biosimilars Market Access Committee at Medicines for Europe

Mr. Bodin is currently heading up the Biosimilars Business in Europe for Biogen. Prior to this role, he was heading up the Market Access and Policy department for Biogen Biosimilars. He has 20 years of experience from the life sciences industry, across several therapeutic areas and geographies. He started his career in Strategy Consulting, advising both Governments and large corporations, and later held various commercial roles in the biotech and pharmaceutical industry before joining Biogen in 2017. With his role as Co-Chair of the Biosimilars Market Access Committee at Medicines for Europe, he is driving topics related to access, pricing, procurement and market sustainability. Mr. Bodin is a Swedish and Swiss dual citizen and holds a Master's Degree in Physics from Chalmers University of Technology in Gothenburg, Sweden.

Julie Maréchal-Jamil - Director Biosimilar Policy & Science, Medicines for Europe

Since October 2015, Julie has been leading the Biosimilar Medicines Group, a sector group of Medicines for Europe. Before that, Julie was part of Medicines for Europe's regulatory and scientific affairs team for 8 years, with responsibilities in the areas of Quality, Compliance, Environment, Health & Safety as well as Bioequivalence. MSc in Pharmacology by background, she previously worked for the pharmaceutical industry. Her work consists in the coordination of Biosimilar policy related activities and external liaison with policy makers, EU institutions, Medicines Agencies, International organisations, industry and professional associations as well as a broad range of stakeholders. Julie has gained experience in technical areas such as pharmaceutical development, project management, EU regulatory affairs as well as on EU pharmaceutical and health policies.

Elena Guillen - Clinical Pharmacology specialist MD, Leiden University Medical Center, The Netherlands

Elena is a Medical doctor specialized in Clinical Pharmacology with a PhD focused on the regulatory framework of biosimilars in Europe. Currently a postdoctoral researcher at Leiden University Medical Center (Netherlands). Experience in regulatory science, biologics, biosimilars, advanced therapies and innovational products. Since September 2021, actively engaged in research on biosimilar regulation, in close collaboration with EMA and national competent authorities.

Arti Rai - Professor of Law and co-Director, The Center for Innovation Policy Duke-Margolis, USA

Arti Rai, Elvin R. Latty Professor of Law and co-Director, The Center for Innovation Policy at Duke Law, is an internationally recognized expert in intellectual property (IP) law, innovation policy, administrative law, and health law. Rai has also taught at Harvard, Yale, and the University of Pennsylvania Law Schools. Rai's research on innovation law and policy in biotechnology, pharmaceuticals, and software has been funded by NIH, the Kauffman Foundation, and the Woodrow Wilson Center. Her numerous publications have appeared in both peer-reviewed journals and law reviews, including Science, the New England Journal of Medicine, the Journal of Legal Studies, Nature Biotechnology, and the Columbia, Duke, University of Pennsylvania, University of Texas, Georgetown, and Northwestern law reviews. She is the editor of Intellectual Property Law and Biotechnology: Critical Concepts (Edward Elgar, 2011) and the co-author of a 2012 Kauffman Foundation monograph on cost-effective health care innovation. Rai's current work focuses on theoretical and empirical analyses of patent eligibility doctrine and on patent institutions, including the Patent Trial and Appeals Board created by the America Invents Act of 2011.

Nivedita Roy – Global Head Regulatory Science and Policy, Alvotech

Nivedita Roy has a strong background in regulatory affairs within the pharmaceutical industry. Nivedita is currently Vice President at Alvotech, where they have held various roles, including Global Regulatory Affairs Senior Director and Director. Prior to Alvotech, Nivedita worked as an Associate Director of Regulatory Affairs at Merck Group. Before that, they were the Deputy General Manager of Regulatory Affairs at Glenmark Pharmaceuticals. Her earlier experience includes a managerial position at Biocon India Ltd. and a regulatory lead role at GlaxoSmithKline Bio, where they focused on regulatory strategy and the development of recombinant vaccines. Nivedita pursued her Doctor of Philosophy (Ph.D.) degree in Molecular Biology/ Biochemistry at the Indian Institute of Science (IISc) from 1994 to 1998.

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.

Sarah Yim - Director, Office of Therapeutic Biologics and Biosimilars, U.S. Food and Drug Administration (U.S. FDA)

Sarah Yim, M.D. is the Director of the Office of Therapeutic Biologics and Biosimilars, in CDER's Office of New Drugs (OND), since 2019. 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.

Ryosuke Kuribayashi - Ph.D – Review Director, Pharmaceuticals and Medical Devices Agency, Office of Cellular and Tissue-based Products, PMDA, Japan

Ryosuke Kuribayashi is a Review Director, Office of Cellular and Tissue-based Products at Pharmaceuticals and Medical Devices Agency (PMDA) in Japan since 2022. Currently, he is responsible for the review of biosimilars and the quality review of new biologics such as monoclonal antibodies, antibody-drug conjugates, and also bispecific antibodies. Also, he is responsible for quality of new modalities such as extracellular vesicles and microbiome of live biotherapeutic products and fecal microbial transplantation. Before that, he was in charge of the review of generics in the Office of Generic Drugs at PMDA from 2013 until 2022. Before that, he served as a researcher, Division of Biological Chemistry and Biologicals at National Institute of Health Sciences, to engage in analytical research on biopharmaceuticals from 2010 through 2012. Before that, he served as a Reviewer within the Office of New Drugs II at PMDA from 2005 - through 2010. As other activities, he is currently a member of IPRP Biosimilar WG and Biosimilar cluster. He had been involved in international activities including ICH Q4B, M9, M13, IPRP BEWG, and IGDRP BEWG.

Ali Alhomaidan - Senior Scientific Consultant, SFDA, Saudi Arabia

Dr. Ali M. Alhomaidan is a seasoned executive with extensive experience in the pharmaceutical and biotechnology sectors. He has a proven record in strategic leadership, regulatory excellence, and innovative business consultancy. As a Senior Scientific Consultant at the Saudi Food and Drug Authority, he drives transformative initiatives in pharmaceutical regulation. His expertise spans Good Manufacturing Practice, clinical research, quality assurance, and compliance with regulatory standards. He has held influential roles on international regulatory committees and working groups, including as vice-chair of IPRP Biosimilars group. His robust academic background includes a Doctorate in Biotechnology from the University of Queensland, and a Harvard Business School certificate in Management.

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.

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). He is also involved in the work of the Heads of Medicines Agencies (HMA) Biosimilar Working Group (BSWG).

Martin Schiestl - Global Head Regulatory Affairs Policy, Sandoz

Martin Schiestl received his doctoral degree in chemistry with a specialization in bioanalysis from 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 and supporting development and licensing of Sandoz' biosimilar portfolio. In his current role, he is responsible for the Global Regulatory Affairs Policy for biosimilars and generic medicines at Sandoz.

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.

Imen Ben Mansour - National Agency of Medicines and Health Products (ANMPS), Tunisia

I am pharmacist with a specialization in regulatory affairs, I began my career in the private pharmaceutical industry. I'm now Head of the Pharmacotoxicology Department at the National Agency for Medicines and Health Products in Tunisia (ANMPS), where i oversee the assesment of CMC data for biological products, biosimilars, vaccines, and blood derivatives. With over a decade of experience at ANMPS, I initially worked on the evaluation of conventional medicines before specializing in biological products and biosimilars for the past 7 years. I've been actively involved in drafting and revising national registration guidelines, particularly for biosimilars, and have been a member of the National Biosimilars Commission since 2018. I had also contributed to national and international projects and participated in biosimilar manufacturing site audits.

Gastón Morán - Director of evaluation and control of biological and radiopharmaceutical products, ANMAT, Argentina

Gastón Morán, a biochemist by Universidad de Morón (2007), holds a Specialization in Drug Quality Control (2011) and a Postgraduate Degree in Pharmacoeconomics (2016). Also he earned a Master´s Degree in Public Policies from Universidad Austral and is currently taking a Bachelor´s Degree in Philosophy Program at UCES University. Gastón started his career as an analyst at Laboratorios Rapela (20007-2008) and completed his residency at ANMAT (2008-2011), where he held various positions between 2011 and 2016, that include: microbiology analyst and commercialization inspector. He also led the departments of Foreign Commerce, Studies and Projects, and Institutional Relations, and the Technical Coordination Office of the National Institutes. He was the Vicepresident (2016-2020) and President (2020-2021) of the National Agency of Public Laboratories. From 2021 to 2022, he was the Undersecretary of Medicines and Strategic Information and Undersecretary of Primary Healthcare and Integration of Health Systems of the Ministry of Health of the Nation. Since September 2022, he has been the Director of the Office of Evaluation and Control of Biologics and Radiopharmaceuticals at ANMAT. Gastón has supplemented his education with numerous training courses specializing in Good Manufacturing Practices, Medicines Control, Quality Assurance and Pharmacology.

Radhouane Cherif - Senior International Liaison officer, European Medicines Agency (EMA)

20+ years of experience in European Regulatory Affairs both in the pharmaceutical industry and EMA. Joined EMA in 2008 as part of the Human Division. Joined the EMA International Affairs Department, as Senior International Liaison Officer in 2022. Past EMA roles include Head of Quality Assurance Department and Head of telematics office. Pharmacist by training. Post graduate degrees in European Regulatory Affairs and Health economics.

Alex Juma - Programme Officer, African Union Development Agency (AUDA NEPAD), African Medicines Regulatory Harmonisation (AMRH)

Mr. Alex Juma Ismail is a Programme Officer at AUDA-NEPAD, working under the Medicines Regulatory Harmonization (AMRH) initiative, specializing in regulatory systems strengthening and harmonization. He is focused on supporting the operationalization of the African Medicines Agency (AMA), particularly in the formation and strengthening of continental technical committees and continental regulatory work meant to support the foundation of a robust continental regulatory ecosystem. Mr. Ismail has more than 9 years of experience in the medical and pharmaceutical industries. He is a pharmacist by training and has previously worked for both private pharmaceutical companies and governmental regulatory bodies In East and Southern Africa. He was also actively engaged in the regional economic communities' medicines regulatory harmonization programmes for EAC and SADC whereas he served as the focal person assessor and regional technical officer respectively.

Reinier Schlingemann - Professor of ophthalmology, Amsterdam Medical Center & Euretina, The Netherlands

R.O. Schlingemann is a medical retina specialist and one of the AMC Principal Investigators. Focus of research: The role of angiogenic and anti-angiogenic factors in ocular angiogenesis, particularly in AMD and diabetic retinopathy. The cellular mechanisms underlying loss of the blood-retinal barrier in diabetic retinopathy. Identification of new genes and mechanisms of angiogenesis. The role of complement activation and the proteasome in retinal pigment epithelium in the early stages of age-related macular degeneration. Prospective clinical trials on the use of anti-angiogenic therapy in AMD, diabetic retinopathy and retinal vein occlusions. See also: www.ocular-angiogenesis.nl/

Alexandra Moulson - Chief eXcellence Officer and Managing director, Polpharma Biologics

Alex is an experienced leader and strategist with a broad background in drug development, portfolio management, and commercial strategy. She has over 25 years of experience in pharmaceuticals and has worked in biosimilars since 2010. Alex is British, with Biochemistry and MBA degrees. Following her MBA, Alex spent 6 years at McKinsey leaving as an Associate Principal, 2 years at Morphosys in Business Development and joined Sandoz in 2010. At Sandoz Alex was responsible for bringing a rituximab biosimilar to the EU and Japanese markets. She later led the Strategy Department for Sandoz. She joined Polpharma Biologics in 2019 and has held various positions including Chief Development Office and Chief Strategy and Portfolio Officer.

Paul Cornes - Oncologist, UK

Dr Cornes is an oncologist in Bristol. He is part of the steering group for the European School of Oncology Working Party on the Access to Innovation in Cancer Treatment, and he has run biosimilar medicine education sessions for a number of large professional organisations in Europe. In the US, Dr Cornes was part of the team that presented evidence for the first successful biosimilar medicine to the Oncology Drugs Advisory Committee of the FDA. At a local level, Dr Cornes has been an advisor to the TGA and PBS on biosimilar medicines in Australia.

Elena Elez - Medical Oncology Department Vall d'Hebron Institute of Oncology (VHIO), Spain

Dr. Elena Élez has been a Medical Oncology specialist at Vall d'Hebron Hospital in Barcelona since 2007 and is principal investigator of the clinical and translational research program for colon at the Vall d'Hebron Institute of Oncology (VHIO). She leads the Colorectal Cancer Group and works within the Gastrointestinal and Neuroendocrine Tumors Unit, directed by Dr. Josep Tabernero. Dr. Élez has contributed as both principal and sub-investigator in various clinical studies, particularly focused on new therapies and biomarker identification in colon cancer. Her work on molecular typing and classification of colorectal cancer through gene expression and mutational profiling has been key in establishing VHIO's gastrointestinal tumor group as a leader in colorectal cancer research. She is recognized internationally for her research on colorectal cancer with the BRAFV600E mutation and microsatellite instability, a subtype with poor prognosis and high molecular complexity, affecting approximately 10% of colorectal cancer patients. Her work has led to the development of new targeted therapies and a better understanding of resistance factors for this tumor type. Dr. Élez's research has resulted in significant scientific contributions, including different publications in The New England Journal of Medicine between 2015 and 2025. Additionally, she has pioneered an extensive liquid biopsy program, analyzing circulating free DNA (cfDNA) in blood samples to study its predictive and prognostic value, as well as potential biomarkers. This research has positioned VHIO as a reference center for colorectal cancer with BRAFV600E mutation and microsatellite instability, driving scientific advancements in the field.

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

Zorana Maravic is the CEO of Digestive Cancers Europe (DiCE), a leading patient advocacy organisation dedicated to improving the lives of those affected by digestive cancers. With over 12 years of experience in the NGO sector, she has been instrumental in shaping patient-centric policies and initiatives across Europe. She has spearheaded large-scale research projects on unmet patient needs, influencing cancer care and policy at the European level. Zorana is passionate about integrating patient voices into decision-making, ensuring equitable access to care.

She holds a Bachelor's degree in Molecular Biology from the University of Belgrade and an MBA from the University of Sheffield. In 2025, she was appointed Chair of the ESMO Patient Advocates Working Group, further advancing patient engagement in oncology. Under her leadership, DiCE actively participates in several EU-funded projects, contributing to research, policy, and awareness initiatives. A strong and inspiring team leader, she excels in bringing diverse stakeholders together to drive impactful change in cancer care.

Susana Millán Ruiz - Chief Medical Officer, mAbxience

Susana Millán Ruiz is an expert in life sciences and clinical research, bringing over 30 years of experience in the field. She holds a degree in Biology & Biochemistry and a PhD in Medicine (Human Physiology) from the Universidad Complutense de Madrid. Currently serving as Chief Medical Officer (CMO) at mAbxience, she leads the clinical development strategy and execution for the company's pipeline, ensuring innovation and excellence in global clinical programs. Prior to her role at mAbxience, she held senior leadership positions at PharmaMar, Aventis, and Rhone Poulenc Rorer, specializing in the clinical development of groundbreaking oncology molecules. She also holds an MBA from IESE and possesses extensive expertise in biosimilars, pediatric drug development, and global regulatory submissions, with a proven track record in EMA, FDA, MENA, LATAM, and Asia regions.
She is also passionate about sailing

Joseph Dunford - Vice-President Speciality Brands, Accord Healthcare

Joe has over 25 years' experience in the pharmaceutical industry. After graduating with a Pharmacology Degree and a brief role in Quality at GSK, he worked in a number of Commercial Sales & Marketing roles at 3M Healthcare, IVAX and Teva, and is currently at Accord Healthcare (for the last 10 years). Joe joined Accord Healthcare in 2015, initially as EMENA Biosimilars Franchise Director, launching their first biosimilar filgrastim in 2016, across Europe & MENA. This was followed by 1st to market Pegfilgrastim 2 years later, and since then 3 more biosimilars in trastuzumab, teriparatide and Ustekinumab, alongside numerous Value- Added Medicines and New Chemical Entities, with rapid franchise growth from conception in 2015 to managing a branded division of over €250M Net Sales. In 2022, Joe was appointed Vice President of the Speciality Brands Division (including the biosimilar portfolio, in addition to managing the Market Access function for EMENA). He is a member of the Accord EMENA Executive Committee, and sits on the Global Intas Biosimilar Steering Committee, discussing development of biosimilars and biologic products from clone development to commercialisation, and with ambitious plans to launch 20 biosimilars in the next decade.