Susana Almeida - PhD Secretary General, IGBA

Dr. Susana Almeida was nominated Secretary General of the International Generic and Biosimilar medicines Association (IGBA) in January 2024. With over 20 years of substantial contribution to the role of the European and international generic and biosimilar medicines industry's trade bodies and companies, Susana also brings significant experience in the process of international harmonisation of standards through the International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Before joining the IGBA, Susana was Clinical Development and Safety Director at Medicines for Europe. She has also worked in clinical trials and pharmacovigilance in Europe and in North America, and her experience includes the pharmaceutical industry and clinical research organizations. Susana is a firm believer that the generic and biosimilar medicines industries play a vital role in fostering worldwide patient access to quality-assured medicines and that a strong off patent sector is essential to a healthy medicines ecosystem. She holds a PhD in Clinical Pharmacology from the Faculty of Medicine, Universidad Autònoma de Barcelona (UAB), Spain (2011) & has authored several scientific papers and patents.

Jan Welink - (Senior) Clinical Assessor, MEB/EMA

Drs. Jan Welink works since 1997 as a (senior) clinical assessor at the Dutch Medicines Evaluation Board (MEB). He was chair of Pharmacokinetic Working Party of the European Medicines Agency (EMA) till September 2019 and thereafter as an expert member of the Operational expert group on pharmacokinetic/bioequivalence product specific guidelines. Specialist areas of interest are bioavailability, bioequivalence and the BCS. Joined the EUFEPS Steering Committee on Bioavailability and Biopharmaceutics in 2012. He is involved in the WHO Prequalification program, a qualification procedure for products (mainly generics) within areas such as HIV/AIDS, tuberculosis and malaria. He has been participating in the ICH Generics Discussion Group (IGDG) as Regulatory Chair and has been involved in the ICH harmonization process M09 on BCS-based biowaivers as Rapporteur and in ICH M10 on Bioanalytical method validation as Deputy Topic Leader. Currently he is involved in the ICH M13 on Bioequivalence for immediate-release solid oral dosage forms as Regulatory Chair and Topic Leader.

Russ Rackley - Global Head, Clinical Pharmacology, Viatris

Experienced Global Head with a demonstrated history of working in the pharmaceuticals industry. Strong drug development professional skilled in Life Sciences, Clinical Trials, GCP, and Regulatory Affairs, with understanding of global health authority expectations. Areas of expertise include assisting in formulation development with respect to in vitro screening and relevance to in vivo performance, as well as design and reporting of clinical pharmacokinetics and bioequivalency studies. Experience includes development of small to complex molecules, in simple to complex formulations, for oral, topical, transdermal and injectable routes of delivery. Current responsibilities include serving as a global resource for the development of products to be registered world-wide. Russ has also served as IGBA Topic Lead to ICH M13 Expert Working Group & for Generic Discussion Group, 2020 – Present.

Lei Zhang - Deputy Director of the Office of Research and Standards (ORS), Office of Generic Drugs at the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA)

Lei Zhang serves as the Deputy Director of the Office of Research and Standards (ORS), Office of Generic Drugs at the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). ORS implements the Generic Drug User Fee Amendments (GDUFA) science and research commitments to ensure the therapeutic equivalence of generic drug products. Dr. Zhang was previously Senior Advisor for Regulatory Programs and Policy in the Office of Clinical Pharmacology at CDER, FDA. She is an accomplished professional with more than 24 years of combined experiences in the areas of drug research, development and regulatory review and approval. She has contributed to numerous guidance development and research projects focused on the science-based regulatory decision-making. Before joining FDA in 2002, she worked at Bristol-Meyers Squibb Company as a Research Investigator and Preclinical Candidate Optimization Team Leader. Dr. Zhang is an Adjunct Professor in the Department of Bioengineering and Therapeutic Sciences, University of California at San Francisco, Schools of Pharmacy and Medicine. She has authored and co-authored numerous papers, book chapters, abstracts, and invited presentations in the area of clinical pharmacology and regulatory science. Dr. Zhang received her Ph.D. in Biopharmaceutical Sciences from UCSF. She is currently the Rapporteur of ICH M13 Expert Working Group that is developing harmonized guidelines on bioequivalence (BE) for immediate-release oral dosage forms. She was a member of the ICH Generic Drug Discussion Group (GDG), serving as the U.S. FDA Topic Leader. Dr. Zhang was named American Association of Pharmaceutical Scientists (AAPS) Fellow in 2013.

Kevin Blake - Scientific Officer Clinical Pharmacology Scientific Evidence Generation Department, EMA

Kevin Blake is the Scientific Specialist Clinical Pharmacology in the Translational Science Office at EMA and provides the Scientific Secretariat function for the Product-specific Bioequivalence Guideline (PSBGL) Drafting Group of the CHMP Methodology Working Party. He is also an EMA Scientific Coordinator in the Scientific Advice Office with a focus on procedures relating to generics/hybrids. Prior to joining EMA in 2010 he was a Clinical Assessor at the then Irish Medicines Board (now HPRA) since 2006. Dr. Blake received his primary medical degree (MB. BCh. BAO) at University College Dublin in 1989 and a Ph.D. in Epidemiology at the University of Western Australia in 2003.
While at EMA he has been involved in a number of guidelines including those on post-authorisation efficacy studies (2016), first-in-human clinical trials (2017) and on the reporting of physiologically based pharmacokinetic (PBPK) modelling and simulation (2018). He has over 30 scientific publications including recent overviews of the EMA experience with PBPK models, product specific guidelines and biowaivers. His interests include the regulatory approval of generics, including complex generics; sharing regulator's experience with submitted applications; and the use of modelling and simulation in drug approval.

Irmela Gabriel - Associate Director Global Clinical Operations – Generics, Teva

Dr. Irmela Gabriel studied pharmacy at the University of Tuebingen, Germany, including one year at the University of Washington in Seattle, USA. She specialized in drug information and earned her PhD in natural sciences at the University of Tuebingen, Germany. She has been working in clinical research in various functions within Teva for more than 20 years. Apart from two years working in early clinical development for new therapeutic entities, her main focus has been on generic products. She managed a large number of bioequivalence studies for different markets and was also involved in therapeutic endpoint studies for various indications. Dr. Irmela Gabriel is a member of the Medicines for Europe Bioequivalence and Clinical Development Working Group. She is representing IGBA as topic lead in the ICH expert working group on the Guideline for Good Clinical Practice ICH E6(R3).

Helmut Schütz – University of Vienna

Helmut Schütz is a chemical engineer by training and worked in the pharmaceutical industry as well as for 20 years in a contract research organization, where he established a GALP-certified Laboratory Information Management System and held senior management positions, most recently as head of the biostatistical department. Since 2004 he is an independent consultant in the domain of comparative bioavailability studies and since 2022 he is a lecturer at the Center for Medical Data Science of the Medical University of Vienna.

He has extensive experience with GCP/GLP, bioanalytics, pharmacokinetics, and biostatistics. His professional career spans 44 years and more than six hundred bioavailability studies. He participated in the BioInternational conferences (1989–2005), GBHI workshops (2015–2024), is a co-organizer of the BioBridges conferences (since 2016) and maintains the global BEBA Internet Forum since 2004. He gave more than 300 presentations on topics related to bioequivalence. Amongst others, he is a member of the European Federation for Pharmaceutical Sciences (EUFEPS), the International Pharmaceutical Federation (FIP), the American Association of Pharmaceutical Scientists (AAPS), the International Biometric Society (IBS), the International Society for Clinical Biostatistics (ISCB), and the Association for Applied Human Pharmacology (AGAH). Since 2015 he is a member of the editorial board of 'Drugs in R&D'.

Paulo Paixão - University of Lisbon Faculty of Pharmacy

Paulo Paixão has been an Assistant Professor of Pharmacokinetics and Biopharmaceutics at the Faculty of Pharmacy, University of Lisbon, since 2012. He has also served as a Clinical Pharmacology Assessor at INFARMED (the Portuguese Regulatory Agency) since 2003. Additionally, he was a member of the former PKWP and is currently a member of the MWP at EMA. He was recently appointed as the Portuguese Alternate Member for CHMP. In his regulatory work, he has been actively involved in assessing bioequivalence and clinical pharmacokinetics within Centralized, Decentralized, Mutual Recognition, and National Procedures. He has also participated in Scientific Advice Procedures at both the national and European levels. His research primarily focuses on pharmacokinetics and Therapeutic Drug Monitoring. Specifically, he has contributed to the development and optimization of drug development tools, including the application of QSAR and data integration techniques with PBPK models. His work has been particularly centered on modeling and simulating oral drug absorption, with numerous publications influencing regulatory sciences related to bioavailability and bioequivalence. Notably, his research has played a role in defining pharmacokinetic metrics for bioequivalence in modified-release formulations, evaluating similarity metrics for dissolution profiles and BE criteria for NTI drugs.

Pavel Farkas - Senior Director, Global Clinical Operations, Teva R&D

Pavel Farkas graduated and earned a Doctor of Pharmacy degree from J.A. Comenius University and Institute of Experimental Endocrinology of Slovak Academy of Sciences in Bratislava, Slovakia, completed a specialization degree in Clinical Pharmacy at the National Institute of Oncology in Bratislava, Slovakia and Pharmaceutical Medicine at the Charles University in Prague, Czech Republic. He joined the generic pharmaceutical industry after a career in basic pharmacological and endocrinological research and has been working in clinical development of generic pharmaceutical products for over 30 years. He became part of PLIVA, now part of Teva group, in 2004. His responsibilities and experience primarily cover pharmacokinetic, bioequivalence, therapeutic equivalence and other clinical studies for generic drug products, conducted mostly for EU, US and other major global regulatory submissions.

Pavel Farkas is currently responsible for Teva's R&D Global Clinical Operations as a Senior Director, acting as a chairman of the Clinical Development Working Group of Medicines for Europe, also representing IGBA as a topic leader and member of ICH M15 (Model Informed Drug Development) Expert Working Group.

Flora Musuamba Tshinanu, FAMHP- UNamur

Flora Musuamba holds a Ph.D. in Pharmacy and biomedical sciences from Université Catholique de Louvain, in Belgium. She is a Pharmacometrics and Pharmacovigilance internal expert at the Belgian federal medicines agency (FAMHP). Flora Musuamba is the Chair of the European Medicines Agency Modelling and Simulation European Specialised Expert Community (ESEC) and the Modelling and Simulation Operational Expert Group (OEG) and a member of the the methodology (MWP), the scientific advice working parties (SAWP) and the network data steering group (NDSG) at the European medicines agency (EMA). She is also Professor of Clinical Pharmacology and Pharmacotherapy at University of Namur and University of Lubumbashi.

James E. Polli - Professor of Pharmaceutical Sciences, University of Maryland

Dr. James E. Polli is Professor of Pharmaceutical Sciences and Ralph F. Shangraw/Noxell Endowed Professor in Industrial Pharmacy and Pharmaceutics at University of Maryland. His research interest is oral drug absorption. He has served as advisor to 25 Ph.D. graduates. He is co-Director of the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI; www.cersi.umd.edu) and the Center for Research on Complex Generics (CRCG; www.complexgenerics.org), each an FDA-funded collaborative agreement with the Agency. He is Director of the online MS in Regulatory Science program (www.pharmacy.umaryland.edu/regulatoryscience).

He is a fellow of the American Association for Pharmaceutical Scientists. He is a member of the University of Maryland General Clinical Research Center Advisory Committee and the University of Maryland institutional review board (IRB).

Carlos Bertoncini, PhD – Clinical Science and Biopharmaceutical Manager, CHEMO – INSUD PHARMA

Carlos Bertoncini specializes in the field of biophysical sciences and biopharmaceutics, with a robust academic and professional background. He holds a PhD in Biophysical Sciences from the University of Gottingen, Germany, where he conducted research at the prestigious Max Planck Institute. His academic journey also includes a postdoctoral research stint at the Department of Chemistry, University of Cambridge, UK, funded by an EMBO fellowship, and a Marie Curie Research fellowship at the Barcelona Institute for Research in Biomedicine. Carlos Bertoncini is also a published author with over 40 original research articles, reviews, and book chapters. His work has been focused on structure-based drug discovery in CNS and Oncology, as well as analytical methods, including NMR and fluorescence spectroscopy, ITC, DLS, CD, and HPLC-MS. Within the pharmaceutical industry, Carlos Bertoncini has held pivotal roles such as Clinical Science and Biopharmaceutical Manager at CHEMO - INSUD PHARMA in Spain since early 2022. Prior to this, he served as Clinical Development Manager and Biosimilar Analytics Manager at different CROs. He has made significant contributions to the development of complex generic and biosimilar medicines.
He has extensive experience in designing pharmacokinetic and pharmacodynamic trials for various pharmaceutical forms, including solids, long-acting injectables, and inhalers. His expertise extends to navigating FDA, EMA, LATAM, and RoW regulations for ANDAs, 505(b)2, and bioequivalence and biosimilarity clinical trials.

Talia Flanagan - Head of Product Design and Performance, Pharmaceutical Sciences, UCB Pharma SA

Talia is currently Head of Product Design and Performance at UCB Pharma in Belgium. She is accountable for the design, development and manufacture of drug products from preclinical and clinical development through to the commercial phase, and leads a multi-skilled department including biopharmaceutics, formulation, manufacturing, materials science and solid state experts. Her previous roles at UCB include Head of Biopharmaceutics, where she was accountable for biopharmaceutics strategies on projects across the portfolio, and Principal Scientist, with a focus on strengthening collaboration between the Pharma Sciences, Clinical Pharmacology and DMPK functions to drive integrated risk assessment and cross-functional product development strategies. Before joining UCB in 2019, Talia worked at AstraZeneca in the UK for 12 years, most recently as an Associate Principal Scientist in Biopharmaceutics. She has extensive and diverse experience of developing and overseeing biopharmaceutics and clinically relevant dissolution strategies on drug projects, with particular focus on oral products Phase 2 to post-launch. Her research interests include clinically relevant dissolution tests and specifications, IVIVC/IVIVR, biowaivers, and biopharmaceutics in patients and special populations. Talia is active in several cross-industry collaborations and consortia, including EFPIA and IQ working groups. Talia was EFPIA Deputy Topic Lead on the ICH M9 (BCS-based biowaivers) Expert Working Group, and is currently representing EFPIA as Deputy Topic Lead on the ICH M13 (bioequivalence studies) Expert Working Group. She has been an invited speaker at several national and international conferences/workshops in the field of biopharmaceutics and clinically relevant specifications, and has authored/co-authored more than 40 manuscripts and 3 book chapters in these fields. Talia received a Master of Pharmacy with honours (2002) and Doctor of Philosophy (2007) degrees from the Welsh School of Pharmacy, Cardiff University.

Janja Luksa – Head Preclinical and Clinical Development Quality, Sandoz

Dr. Janja Luksa brings over 30 years of experience in generic pharmaceutical industry. She studied chemistry at the University, Ljubljana, Slovenia, where she got also her PhD in biochemistry. She started her career in Lek Pharmaceuticals in Ljubljana, Slovenia, as analyst in Quality Control product release lab, moving then to Research & Development for Analytical and Stability testing, followed by establishing and heading new GCP Bioanalytical lab for bioequivalence study samples analysis in early nineties. She expanded this role to become Head of Clinical Development including Clinical department and Bioanalytical lab at the beginning of new millennium. After Novartis/Sandoz acquisition of Lek Janja was heading vertically integrated Sandoz Development Center (SDC) in Kundl, Austria, and later Sandoz Development Center in US in East Hanover, NJ. She returned to roots of Quality as well as roots of Clinical in 2015 as Sandoz Head Global Clinical QA in Holzkirchen, Germany.

In this role Janja was responsible for GCP compliance of generic clinical studies either sponsored by Sandoz or acquired from license partners, for compliance of Generic Clinical Operations in all Sandoz Development Centers as well as for local Country`s Clinical Operations all around the globe where locally required clinical studies have to be executed and last but not least she was responsible for qualifications of respective clinical External Service Providers used in Sandoz generic studies. In year 2023 when Sandoz Generic clinical development and Biosimilars clinical developments merged, she took over the role of quality head for merged Global Clinical development as Head Preclinical and Clinical Development Quality, which is also her present position. In Medicines of Europe association Janja acts as vice-chair of the Bioequivalence and Clinical Development Working Group.

Peter Twomey - Head of Inspections, EMA

Peter Twomey is currently the Head of Inspections at EMA, with responsibility for the Office tasked with supervising compliance with GMDP, GCP, GLP, GVP and BE practices for human and veterinary medicines, market surveillance, quality defects and recalls and harmonisation and policy development in the inspections area. He is the current Regulatory Chair of the Expert Working Group drafting the revision of ICH GCP E6 (revision 3). He previously worked at the Irish Health Products Regulatory Authority, where he held the position of senior GCP/Pharmacovigilance inspector and GCP/PV Inspection manager, and representative at the GCP/Pharmacovigilance EMA inspector working groups (IWGs) and the CMDh GCP IWG working party. He also held the role of Pharmacovigilance inspector with the UK-MHRA, and positions in various areas of industry, including PV (QPPV and PV manager), medical affairs & wholesaling (responsible person). He holds a BSc and Masters degrees in pharmacy and two Bachelor of Laws degrees.

Aurora Rojo, AEMPS

Aurora Rojo has been Technical Advisor and Head of the GCP and GVP inspectorate in the Pharmaceutical Inspection and Enforcement Department of the Spanish Agency of Medicines and Medical Devices from 2021. She is also member of the respective inspection working groups (GCP and PhV IWG) of the European Medicines Agency (EMA). She holds a PhD in Pharmacy from the Complutense University of Madrid and she is Specialist in Hospital Pharmacy. Before assuming her current position, she was a GMP inspector in the Spanish Agency of Medicines and Medical Devices.

Nilufer Tampal, PhD - Associate Director for Scientific Quality, Office of Bioequivalence (OB), Office of Generic Drugs (OGD), Center for Drug Evaluation & Research (CDER) | FDA

Dr. Nilufer Tampal is the Associate Director for Scientific Quality in the Office of Bioequivalence, Office of Generic Drugs, at the FDA. In this role, she provides key leadership in developing strategies and oversees implementation of data quality and the scientific integrity of bioequivalence data submitted in Abbreviated New Drug Applications (ANDAs). She provides expertise in utilization of advanced analytic data tools supporting ANDA reviews. Dr. Tampal represents the FDA as the Topic Leader on the ICH M13A, M13B, and M13C Expert Working Groups for developing the harmonized M13 guideline in series, for bioequivalence of immediate release (IR) solid oral dosage forms. As the Rapporteur for the ICH Generic Drug Discussion Group she facilitated the identification and scoping of bioequivalence topic areas for harmonization through consensus building and presented the proposals for developing the IR and MR guidelines, to the ICH Management Committee. She received her PhD in Toxicology from University of Kentucky and an M.S. in Chemistry from Bombay University, India. Her multi-disciplinary knowledge and training in pharmacology, toxicology, chemistry, bioanalysis, site inspections and regulatory science have positioned her to contribute towards a multitude of FDA's strategic efforts to advance regulatory science and policies in areas of on-going importance to the Agency.

Sarah Ibrahim - Associate Director for Stakeholder and Global Engagement in the Office of Generic Drugs (OGD)/ Center of Drug Evaluation and Research (CDER), FDA

Dr. Sarah Ibrahim serves as the Associate Director for Stakeholder and Global Engagement at the Office of Generic Drugs (OGD) within the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). In this role, Dr. Ibrahim formulates strategies to address both current and emerging regulatory challenges related to the global generic drug industry. She founded OGD's Global Affairs Program and the FDA Global Generic Drug Cluster, the first forum to bring together leading regulatory agencies worldwide. Additionally, Dr. Ibrahim initiated OGD's Patient Engagement Program and launched its first Patient Listening Session series. Collaborating with other CDER and FDA offices, she facilitates stakeholder engagement on issues pertaining to the globalization of the generic pharmaceutical supply chain and the harmonization of regulatory standards for generic drugs.
Dr. Ibrahim earned her Ph.D. in Biopharmaceutics/Pharmaceutics from the University of Cincinnati's College of Pharmacy and holds a B.S. in Pharmacy and Pharmaceutical Sciences from Cairo University, Egypt. She joined the FDA in 2014 as a scientific reviewer in the Office of Pharmaceutical Quality. Before her tenure at the FDA, Dr. Ibrahim accrued extensive experience in the U.S. pharmaceutical industry, focusing on pharmaceutical development. As an assistant professor, she was instrumental in establishing the pharmaceutical sciences department at New Jersey's second pharmacy school, working alongside the founding faculty.

Matthias Roost - Clinical Pharmacology Assessor, Division Clinical Assessment, Swissmedic

Dr. Matthias Roost joined the Division Clinical Assessment at Swissmedic as Clinical Pharmacology Assessor in 2016. In his current position, he also acts as deputy unit head. He represents Swissmedic in the Access Consortium (Australia-Canada-Singapore-Switzerland-United Kingdom) Generic Medicines Working Group (GMWG). In addition, he is the co-chair of the International Pharmaceutical Regulators Programme (IPRP) Bioequivalence Working Group for Generics (BEWGG). He was the Swissmedic topic leader in the International Council of Harmonisation (ICH) M12 working group on drug interaction studies. He holds a Master's degree from the University of Geneva, Switzerland, and a PhD in Biomedical Sciences from the Leiden University Medical Center, Netherlands.

Dr. Luther Gwaza - Team Lead for Norms and Standards, WHO

Dr. Luther Gwaza is the Team Lead for Norms and Standards for Pharmaceuticals in the Health Products Policy and Standards Department at the World Health Organization (WHO) headquarters in Geneva, Switzerland. In this role, he manages the technical standards for pharmaceuticals and serves as the Secretary of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. Previously, he was a technical officer in WHO's Regulation and Prequalification Department, facilitating regulatory approvals for priority medical products and supporting regional marketing authorization approaches. With over 17 years of experience in pharmaceutical regulation and systems strengthening, he has also worked as a WHO prequalification bioequivalence assessor and consulted for organizations such as Management Sciences for Health and the World Bank Group. Dr. Gwaza holds a Bachelor of Pharmacy and an MPhil in Pharmacology from the University of Zimbabwe, as well as a PhD in Pharmaceutical Policy and Regulation from Utrecht University.

Aaron Josephson - Senior Director of Global Regulatory Policy , Teva Pharmaceuticals

Aaron Josephson is Senior Director of Global Regulatory Policy at Teva Pharmaceuticals where he develops and advocates for global policies that enable more efficient and predictable regulatory systems aligned with Teva's development programs, business objectives, and patient needs. Aaron's work includes representing Teva at global trade associations, including as chair of the IGBA Single Global Development Task Force, and through which he promotes globally aligned approaches that balance regulatory requirements with patient access to medicines. Aaron's prior professional experience includes 10 years at the US FDA; consulting for drug, vaccine, and medical device companies; and working for a Member of the United States Congress.

Lucas Sigman, Chair, IGBA´s CEO Advisory Committee, Member of the M4E's Executive Committee and Chief Executive Officer, Insud Pharma S.L.

Lucas Sigman has a degree in Biology from the University of Buenos Aires and an MBA from the IESE business school. With more than 20 years of experience, he directs an international group with a presence in more than 50 countries, 20 production plants and more than 9,000 professionals. Between 2014 and 2020 he was Managing Director of the Chemo business unit within the Insud group, developing significant experience in various areas of the industry: R&D; Production, Commercial and Portfolio. From 2020 he is Insud Pharma CEO. In addition, Lucas is a speaker and collaborator in different industry forums.

He is IGBA's CEO Advisory Committee, member of the Medicines for Europe's Executive Committee, member of the board of AESEG, the Spanish Association of Generic Medicines and is a patron of the Mundo Sano Foundation, dedicated to neglected diseases, in which he actively collaborates.