Adrian van den Hoven - Director General, Medicines for Europe

Adrian van den Hoven joined Medicines for Europe as a Director General in September 2013. His priorities at Medicines for Europe are to stimulate competition in off-patent medicine markets, foster access to medicine, support policy measures for sustainable pricing, promote efficient regulatory standards and develop a coherent EU industrial strategy to support the long-term viability of the generic, biosimilar and value added medicines industries. Adrian is the former President (and current Member of the Board) of the European Medicines Verification Organisation (EMVO) for the implementation of serialisation against falsified medicines. Prior to joining Medicines for Europe, Adrian van den Hoven was Deputy-Director General of BUSINESSEUROPE where he was responsible for the International Relations Industry departments.
He previously worked as a researcher in Italy (EUI), France (Nice) and Canada (Windsor). He obtained his doctorate in Political Science from the University of Nice, France in 2000.

Gerald Beuerle - Chair of the Bioequivalence WG Medicines for Europe, Teva

Dr. Gerald Beuerle studied pharmacy at the Julius-Maximilians-University in Würzburg, Germany and got his PhD at the Eberhard-Karls-University of Tübingen. He has been working for ratiopharm GmbH since 1996. Once ratiopharm was acquired by Teva in 2010 he became responsible for Teva Europe as Regional Manager in the Generics Global Biopharmaceutics group. After two years working in early clinical development for New Therapeutic Entities, he is now Senior Director Pharmacokinetics Europe / International Markets in the Teva Global Generics Clinical R&D organisation. Being the chair of the Bioequivalence and Clinical Development Working Group of Medicines for Europe and a member of the Steering Committee of the European Federation for Pharmaceutical Sciences (EUFEPS) Network "Bioavailability and Biopharmaceutics" he is involved considerably in discussions related to pharmacokinetic aspects and on new bioequivalence guidelines. He was speaker at several Medicines for Europe / EGA, EUFEPS and Informa meetings and a member of Organising Committees, e.g. in all four conferences related to the Global Bioequivalence Harmonization Initiative.

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

Sarah Ibrahim is the Associate Director for Stakeholder and Global Engagement in the Office of Generic Drugs (OGD)/ Center of Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). In this role, Dr. Ibrahim develops OGD strategies to address identified and emerging regulatory challenges in relation to the international nature of the generic drug industry. In collaboration with other CDER and FDA offices, she supports stakeholder engagement concerning issues related to globalization of the generic pharmaceutical supply and harmonization of regulatory approaches for generic drugs. Dr. Ibrahim received her PhD in Biopharmaceutics/Pharmaceutics from the School of Pharmacy, University of Cincinnati and a B.S. in Pharmacy and Pharmaceutical Sciences from Cairo University, Egypt. Dr. Ibrahim started her career at the FDA in 2014 as a scientific reviewer in the Office of Pharmaceutical Quality. Prior to her FDA career, she has years of experience in the US pharmaceutical industry in the area of pharmaceutical development. As an assistant professor, along with the founding faculty, Dr. Ibrahim established the pharmaceutical sciences department for the second school of pharmacy in the state of New Jersey.

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 has been Scientific Secretariat for the Pharmacokinetics Working Party (PKWP) since 2015. 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 as an Australian NHMRC scholar on the topic of fetal growth and cardiovascular disease risk in later life (the 'fetal origins' hypothesis). 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 is also EMA lead in the development of product-specific bioequivalence guidelines with the PKWP. 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/extrapolation in drug approval.

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Peter Bachmann - Head International Liaison Office and Conferences, European Union and International Affairs, BfArM (DE), Chair of IPRP

Peter Bachmann has joint in 1999 the Federal Institute for Drugs and Medical Devices (BfArM, Germany), Department of 'Drug Approval'. He was in the following years the head of several subunits and units responsible for the variation and authorisation of medicinal product in the framework of MRP, including the task of the German representative to the MRFG (Mutual Recognition Facilitation Group). Following the reorganisation of the BfArM in July 2005, Peter Bachmann was appointed as Senior Expert for 'European Drug Regulatory Affairs' at Department 'European and International Affairs'. He was the appointed German CMDh member until November 2011 and served as elected CMDh Chair from November 2011 till November 2017. His current position is the Head of 'International Liason Office and Conferences at BfArM. He is acting as Co-Chair of the European Union Network Data Board (EU NDB), is a member of the EU Big Data Steering Group (BDSG) (since 2020) and is for the BfArM-Scientific Coordinator of the Horizon 2020-Projekt UNICOM (2019 – 2024) and the Deputy-Lead of UNICOM WP 3. Peter Bachmann is since 2018 on behalf of the European Commission a Management Committee Member of the International Pharmaceutical Regulators Programme (IPRP) and serve since 2020 as the elected IPRP Vice-Chair and currently as re-elected Chair. He is also a member of the EU ICH MC Team (since 2018) and the European Lead to the ICH GDG (Generic Discussion Group). He is a lecturer for 'Drug Regulatory Affairs' at the Universities of Bonn, Duisburg-Essen, Basel and Copenhagen, a honorary member of the 'Middle-European Society for Regulatory Affairs' (MEGRA), a honorary life-time TOPRA-member, a former member and Vice-Chair of the DIA Advisory Committee Europe (2007 – 2013), DIA Board of Directors (2013 – 2016), a DIA Fellow (2021) and is currently serving as Member of the DIA Council of Regulators.

Susana Almeida - Clinical Development and Safety Director, Medicines for Europe, Brussels, Belgium

Dr. Susana Almeida is Clinical Development and Safety Director at Medicines for Europe (formerly EGA). Before joining Medicines for Europe, Susana was the Chair of the Association's Bioequivalence Working Group for almost 15 years. She has worked in clinical trials and pharmacovigilance in Europe and in North America, and her experience includes the pharmaceutical industry and clinical research organizations. She has overseen the conduction of dozens of clinical trials carried out in Europe, North and South America and Asia. At Medicines for Europe, Susana is responsible for the coordination of multiple working groups, working on different aspects involving policy and regulatory science: Susana coordinates the activities related to clinical development, pharmacovigilance/drug safety, and medical devices (single integral products, Medical Device Regulation article 117).

She has represented the International Generic and Biosimilar Medicines Association (IGBA) in multiple Expert Working Groups at the International Council for Harmonisation (ICH): M13, Generic Discussion Group and M9. She is also involved in the Therapeutics Pillar of the Access to COVID-19 Tools (ACT) Accelerator partnership, launched by WHO and partners. She holds a PhD in Clinical Pharmacology from the Faculty of Medicine, Universidad Autònoma de Barcelona (UAB), Spain and has authored several scientific papers and patents.

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.

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.

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 this group. 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, an approval procedure for products (mainly generics) within areas such as HIV/AIDS, tuberculosis and malaria. He is 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 ICH M13 on Bioequivalence for immediate-release solid oral dosage forms as Regulatory Chair and Topic Leader.

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

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.

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 Laboratory Information Management System certified according to the rules of GALP, helding 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 Institute of Medical Statistics of the Medical University of Vienna. He has extensive experience with GCP/GLP, bioanalytics, pharmacokinetics, and biostatistics. His professional career spans 43 years and more than six hundred bioavailability studies. He participated in the BioInternational conferences (1989–2005), GBHI workshops (2015–2022), 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’.

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

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 following a career in the field of basic pharmacological and endocrinological research and has been working in the area of clinical development of generic products for over 30 years. He joined PLIVA in 2004 with responsibilities and experience covering pharmacokinetic, bioequivalence and other clinical studies for generic products, conducted mostly for EU, US and other major global regulatory submissions. Pavel Farkas is currently responsible for PLIVA/TEVA's R&D Global Clinical Operations as a Senior Director, acting as a member of the Clinical Development Working Group of Medicines for Europe, also representing IGBA as a member of ICH M15 (Model Informed Drug Development) EWG.

Kristin Karlsson - Swedish Medical Products and Vice chair of the EMA MWP

Kristin Karlsson has been part of the pharmacometric community for almost 20 years and has experience with modelling and simulation within regulatory agencies, academic research and within the pharmaceutical industry. Kristin Karlsson has an MSc in Chemical Engineering and earned a PhD in Pharmacometrics at Uppsala University, Sweden. Kristin Karlsson is currently employed as a senior assessor of pharmacometrics at the Swedish Medical Products Agency. Since June 2022, Kristin is a member of the EMA Pediatric Committee (PDCO). Furthermore, Kristin is the vice-chair of the newly formed EMA Methodology Working Party. Kristin is also the regulatory chair of the ICH M15 informal working group (Model Informed Drug Development), and a previous member of the ICH E11A expert working group (Paediatric extrapolation).

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Pradeep Rawat - Bioanalytical Expert, Clinical Development, Sandoz Hyderabad, India

Pradeep Rawat is a bioanalytical expert at Clinical Development division of Sandoz Development center Hyderabad, India. Before joining Sandoz in Dec. 2019, Pradeep was bioanalytical lead at Drug metabolism & Pharmacokinetic division at Dr. Reddy's laboratories for almost 8 years where he has extensively worked in regulated bioanalysis for development of 5 differentiated products in neurology, pain and dermatology for 505(b)(2) NDA submissions. He also worked as a bioanalytical scientist at clinical Pharmacology and pharmacokinetic division of Ranbaxy (now Sun Pharma) and developed various challenging LC-MS/MS assay methods. He has overseen conduction of more than 150 BA/BE studies in Europe, North America, middle East, Australia, and Asia. At Sandoz, Pradeep is responsible for bioanalytical strategy and oversight of outsourced global clinical studies for standard generics, complex injectables/ inhalational and first to file products.
He is currently pursuing his PhD in Pharmaceutical Sciences from Birla Institute of Technology and Science Hyderabad and has authored 2 scientific papers in ocular drug delivery for treatment of Glaucoma.

Indravadan Bhoir - Senior Director-Bioanalytical Operations, Teva

Indravadan Bhoir is the Senior Director for Bioanalytical Operations in the Internal Clinic of Teva Global Generics Clinical R&D organization since 2006. In this role Indravadan is responsible for bioanalytical method development, validation and analysis of study samples involving small molecules employing LC-MS/MS methods for submissions to various regulatory regions. He has successfully led several regulatory bioanalytical inspections from USFDA and UKMHRA. Indravadan has overall experience of 28 years in the field of analytical chemistry, bioavailability and bioequivalence. He has reach experience of regulated bioanalysis and guided team for development of innovative methods. Before joining Teva, Indravadan served as head of bioanalytical of a CRO and head of department of a Research Center affiliated to Mumbai University for conducting applied research and successfully guided students for Ph.D. program as a research guide. Indravadan holds a Ph.D. in Analytical chemistry from the University of Mumbai. He is the recipient of "Young Scientist Research Award-2000" by the Department of Atomic Energy (DAE), Government of India. He has over 25 scientific publications on pharmaceutical analysis and bioanalysis involving high performance liquid and super critical fluid chromatographic techniques.

Janja Luksa - Head Global Clinical QA, Product Development QA, Sandoz Int., GmbH Holzkirchen, Germany

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 departments 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 Austria in Kundl, 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, which is also her current role, Janja is responsible for GCP compliance of clinical studies either sponsored by Sandoz or acquired from license partners, for compliance of 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 is responsible for respective clinical External Service Providers used in Sandoz studies. Janja is vice-chair of the Bioequivalence and Clinical Development Working Group of Medicines for Europe.

Peter Twomey, 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 and wholesaling (responsible person). He holds a BSc and Masters degrees in pharmacy, and two Bachelor of Laws degrees.

Nilufer Tampal - Associate Director for Scientific Quality in OB within OGD FDA

Dr. Nilufer Tampal is the Associate Director for Scientific Quality in OB within OGD. In this role, Dr. Tampal develops strategies and oversees implementation of data quality and the scientific integrity of bioequivalence data submitted in Abbreviated New Drug Applications (ANDAs). She provides leadership and expertise in utilization of advanced analytic data tools in the assessment of bioequivalence studies submitted in ANDAs. Dr. Tampal serves as the FDA Topic Lead for the ICH Expert Working Group on M13: Bioequivalence for Immediate Release Solid Oral Dosage Forms. She also served as the Rapporteur for the ICH Generic Drug Discussion Group. Dr. Tampal received her Ph.D. in Toxicology from the University of Kentucky and an M.S. in Chemistry from Bombay University, India. She started her career at the FDA in 2002, as an investigator in the Office of Study Integrity and Surveillance and has held various leadership positions in OB for the last 12 years. Prior to her FDA career, she gained years of experience in synthesis and analysis of small molecules working as chemist at a multinational pharmaceutical company in India.

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