12-15 & 18 SEPTEMBER 2023
23 OCTOBER 2023

5TH AFRICA REGULATORY CONFERENCE

SPEAKER BIOGRAPHIES

ORGANIZED BY IFPMA

IN PARTNERSHIP WITH arePI, IPASA, apki Kenya Association of Pharmaceutical Industry, leem les entreprises du médicament, LIPA

2023 AFRICA REGULATORY CONFERENCE

Speaker biographies

(in alphabetical order by first name)

Adela ASHIE

Principal Regulatory Officer,
Food and Drugs Authority, Ghana

Adela Ashie is a pharmacist with over 15 years of experience in Pharmacovigilance. She holds a master's in international health (MPH IH) from the University of Nottingham, United Kingdom and is currently Head of the Vigilance Unit under the Safety Monitoring Department of the Food and Drugs Authority.

Adela is involved in the strengthening of the pharmacovigilance system in Ghana through education of stakeholders including healthcare professionals and the general public.

Adela's recent works have been in assisting pharmaceutical companies in Ghana to establish efficient Pharmacovigilance systems through the training of Qualified Persons for Pharmacovigilance and the conduct of Good Pharmacovigilance Practice Inspections since 2016.

Akhona Tshangela

Program coordinator for PAVM, Africa CDC

Akhona Tshangela has more than 13 years of experience in public health in the laboratory, implementation of public health programs, surveillance and data management. She is currently the program coordinator for Partnerships for African Vaccine Manufacturing at the Africa Centres for Disease Control and Prevention (Africa CDC). She joined the Africa CDC in 2016 as one of the first staff members and played a critical role in pioneering the Africa CDC and supporting the development of its first programs. During the COVID-19 response, she co-chaired the Science, regulations and standards technical working group under the COVID-19 continental joint strategy for Africa, supporting Member States with making science-based policy decisions. She also led the knowledge management platforms for the COVID-19 response and was part of the Steering Committee for the COVID-19 Clinical Research Coalition. Prior to working for the Africa CDC, she worked for the National Institute for Communicable Diseases in South Africa with a focus on respiratory pathogens.

Alex ADUSEI

Executive Director, Women's Hope Foundation

Alex Adusei is Executive Director of Women's Hope Foundation, an NGO advancing patient safety, women and girls human rights and gender equality in Ghana. He is a World Health Organization Patient for Patients Safety Advisory Group Member and Patient Safety Champion in Ghana. He is a member of the Global Patient for

Patients Safety Network, as well as a member of the WHO Guidelines Developing Group (GDG) for the new WHO guidelines on the prevention of bloodstream infections (BSI) and other infections associated with intravascular catheters (IVCs). I'm a Council member of the World Patient Alliance. He is a Human Right Advocate and Community Health Promoter and works as a researcher, facilitator, trainer and consultant on Patient Safety issues in Ghana.

Angelika Joos

Executive Director Global Regulatory Policy, MSD

Angelika Joos is a trained pharmacist. She is responsible for Regulatory Policy issues within MSD's Global Regulatory Affairs and Clinical Safety department. This role includes identifying regulatory policy priorities that align with MSD's business priorities, leading cross-functional networks to define policy positions, and informing MSD's regulatory strategy development. Angelika represents MSD in the IFPMA Regulatory Science Committee and is one of IFPMA's delegates to the ICH Management Committee. She is also involved in international policy activities through EFPIA as well as the BIO and the PhRMA International Committees.

Benita Morar

MEA PV Partnership Lead, AbbVie, South Africa

Benita Morar is MEA PV Partnership Lead for AbbVie. She is a highly skilled professional with 16 years of Pharmaceutical Industry experience. Before devoting her time to Pharmacovigilance, she worked in Quality Assurance for Reckitt Benckiser and Ranbaxy.

Chimwemwe Chamdimba

Head of the African Medicines Regulatory Harmonisation, African Union Development Agency (AUDA-NEPAD)

Chimwemwe Chamdimba is the Head of African Medicines Regulatory Harmonization Initiative at the African Union Development Agency (AUDA-NEPAD). She responsible for the management of the African Medicines Regulatory Harmonization (AMRH) Programme and technical support to the operationalization of the African Medicines Agency (AMA). She is leading policy reforms linking regulatory systems strengthening to procurement in support of local manufacturing of medical products and technologies. As a health policy specialist, she has spearheaded health policy and regulatory reforms, regional harmonization and partner coordination. She has contributed to key continental policies including the AU Model Law on Medical Product Regulation; the Treaty for the establishment of the African Medicines Agency (AMA); and the AU Private Sector Engagement in Health Framework.

Christelna Reynecke

Chief Operations Officer,
South African Health Products Regulatory Authority

Christelna Reynecke is the COO of South African Health Products Regulatory Authority (SAHPRA). She holds a Master of Business Administration (MBA) from the Edinburgh Business School (Heriot Watt University). She also has a BPharm Degree from the University of the North West. Before joining SAHPRA in Jan 2021, Christelna spent 13 years in the Pharma Logistics sector in both Quality Assurance/Regulatory Compliance and Logistics Operations roles and developed an appreciation for Lean Six Sigma approaches, tools and process improvement. The first 8 years of her career in the Retail and Courier Pharmacy sector cemented her passion for prioritizing patient well-being and out-of-the box thinking – to find different, new and innovative approaches to problems that frontline healthcare workers are confronted with.

Dianliang Lei

Scientist, WHO

Dr Dianliang Lei received his doctor degree in medical science from Medical School of Osaka University Japan in 1996. He joined World Health Organization in 2003 as a scientist working in Technical Specifications and Standards unit of Health Product Policy and Standards department, responsible for development of WHO international standards including measurement standards and written standards for vaccines and biological products.

He has been in charge of development of WHO Guidelines for lot release of vaccines, GMP for biological products, Guidelines for post-approval changes to vaccines, Guidelines for marketing authorization of pandemic vaccines in importing countries, Recommendations for acellular pertussis vaccines, DT-based combined vaccines, Hepatitis E vaccines, Enterovirus vaccines, yellow fever vaccines and Manual for calibration of secondary standards etc.

Dirk Gillé

Vice President, J&J,
Head Capacity Development J&J Global Public Health R&D

Dirk Gillé has a background of 35 years in drug development with strong expertise in clinical operations, and quality management. Before taking up his current role in 2017 as Head Capacity Development – Global Public Health R&D, he has taken senior positions in Janssen and Tibotec as Head Clinical Operations Central and Eastern Europe, Global Head Clinical Operations and Quality

Management at Tibotec, Global Head Quality Management & Training at GCO and Global Head Quality Assurance BRQC.

During his career he applied strong data driven risk-based approaches that resulted in significant increase in efficiencies and compliance for the applicable organizations. In his current function, Dirk is responsible to mitigate the increased risk and challenges linked to the execution of clinical trials and other clinical data generation activities in low- and middle-income countries. He drives different projects that will result in the execution of cost-effective and compliant clinical trials in resource limited settings. These initiatives include both Janssen-internal and consortium projects such as CTCAN, involving other pharma companies through the cross-pharma capacity development initiatives that aim to bring more clinical trials to Africa and ensure earlier access to medical innovations for African patients.

His team also drives the Ebola vaccine projects and supports the Dengue, TB and Leprosy development programs.

Edwin Nkansah

Director, Vaccine, Vigilance and Clinical Trials Directorate, Food and Drugs Authority Ghana

Edwin Nkansah (PhD) is a 44-year-old Ghanaian Director, and Head of the Vaccines, Vigilance and Clinical Trials Directorate at the Food and Drugs Authority (FDA), Ghana. Prior to his current role, he was the founding Head of the Vaccines and Biological Products Department, the Department responsible for the regulatory oversight for Biological Products, including vaccines. His current scope of regulatory oversight includes the clinical trials, vaccine and biological products and safety monitoring regulatory functional areas. Edwin has been a regulatory officer since November 2012, He led the establishment of the Department and oversaw its progression from a Unit to a Department with the responsibility of establishment the basic regulatory framework for authorizing the use of biological products, including vaccines in Ghana. Edwin's PhD was in Pharmaceutical and Biological Chemistry, specializing in molecular biology techniques and protein engineering, and a master's degree in Drug Discovery, all degrees from the University College London School of Pharmacy. He has been involved in 11 publications and abstracts. Prior to joining the FDA, Edwin was a full-time lecturer at the School of Pharmacy, University of Ghana. He retains a part-time role at the school with the Department of Pharmacology and Toxicology.

On the global front, Edwin has consulted for the World Health Organization (WHO) and has participated in the drafting of WHO guidelines, including the revision of the WHO Biosimilar guidelines, which was developed to provide guidance to manufacturers and regulators. Further, he was one of the primary drafters for the

Marketing Authorization and Clinical Trials Oversight fact-sheets of the WHO Global Benchmarking tool (GBT), the tool used to evaluate the maturity of National Regulatory Authorities.

Emmanuel Owusu

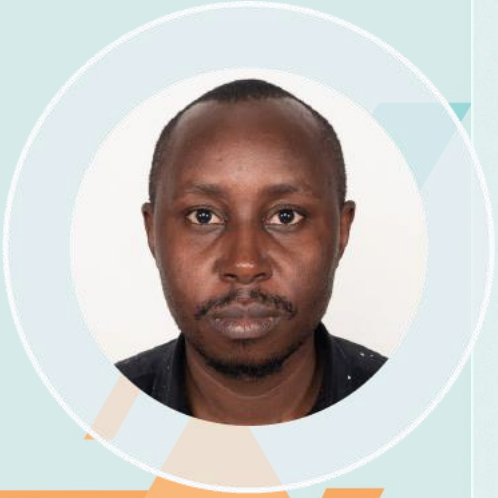
ICT Officer, Food and Drugs Authority Ghana

Emmanuel Owusu Adasi is an Information Technology Officer with the Information Management & Technology Solutions Department of the Food and Drugs Authority Ghana. He holds a Bachelor of Science (Hons) degree in Information Technology from Pentecost University, Accra, Ghana and currently pursuing a Master of Science in Digital Forensics and Cybersecurity at the Ghana Institute of Management and Public Administration. Emmanuel has worked with the Food and Drugs Authority for ten years, where he brings his knowledge, skills, and experience to bear.

He is currently a member of the Information Management System Technical Committee for African Medicines Regulatory Harmonization (AMRH).

Farida El Maouhab

Director of Registration of Pharmaceutical Products, ANPP



Felix Mochache

Country Patient Safety Head, Novartis

Felix Mochache is a Country Patient Safety Head at Novartis, responsible for East and Southern Africa countries. At Novartis, he is responsible for ensuring the local compliance to both internal and external Pharmacovigilance requirements. He is a Pharmacist by training, and currently pursuing a Masters in Public Health. He has 7 years of professional experience, 5 of which is in Pharmacovigilance. He has also worked briefly in Quality Assurance and Regulatory Affairs. Felix is an active member of the local Industry Association (KAPI), where he has contributed to advocating for stronger Pharmacovigilance Systems in Africa through various platforms and collaborations.

Flavia Kyomukama

Executive Director, Action Group for Health,
Human Rights and HIV/AIDS (AGHA), Uganda

Flavia Kyomukama is the Executive Director at Action Group for Health, Human Rights and HIV/AIDS (AGHA) Uganda and the coordinator for women@40 campaign National Coordinator; Global Coalition of Women Against AIDS In Uganda (GCOWAU) 2006 - 2013, She served as HIV Adviser; at the United National Fund for International Partnerships (UNFIP) HIV Advisor/ Provincial Youth Council Coordinator (Zambezia Province and Sofala Province); UNESCO Mozambique: Project Manager, Support on Aids and Life through Telephone Helpline (SALT) 2003-2004 and an educationist

Flavia represents Patients Organisation (NGO) on the Uganda GFATM CCM BOARD, She sits on the following committees at ministry of health – Condom Coordination committee, ADH TWG, PMTCT TWG, Community Health Task Force, the following on Uganda AIDS Commission – HIV Prevention Steering committee, National HIV Equity Plan Implementation Committee, Nation HIV Stigma and Discrimination Prevention Committee, etc. She has participated in advocating for patients' rights to access essential medicine. Participating in community led pharmacovigilance and supporting patients with adverse medicine events to specialised services.

She has in the past participated in advocacy processes and discussions relating to medicine regulation especially related to the TRIPS agreements and East African Legislative Assembly Harmonisation of policies to enhance cross boarder PLHIV access to ART and other STI treatment.

Francesca Mangia

International Operations Regulatory Manager, Roche

Francesca Mangia is an International Regulatory Affairs Manager. She joined the Regulatory Affairs department at F. Hoffmann-La Roche in 2020 after completing her Doctoral Degree in Structural Biology and Biophysics at the University of Basel. Currently she works in the CMC Regulatory International Operations group at F. Hoffmann-La Roche where she focuses on filings to the International Markets and is actively involved and passionate about Policy topics, especially convergence and harmonization. Francesca is also a strong advocate for reliance and its global implementation.

Gabriela Zenhäusern

Deputy Head Stakeholder Engagement, Swissmedic

Gabriela Zenhäusern, a pharmacist with a PhD in biomedical research, joined the Stakeholder Engagement Division at Swissmedic, Switzerland in 2019. In her current position, she is responsible for the coordination of international collaboration, acts as Vice-Chair of the Assembly of the International Council of Harmonisation (ICH) and represents Swissmedic at the Management Committee of the International Pharmaceutical Regulators Programme (IPRP) and the Access Consortium (Australia-Canada-Singapore-Switzerland-United Kingdom). In addition, she is leading the patient organisation working party at Swissmedic. Gabriela Zenhäusern used to work in the sector authorization at Swissmedic from 2010 to 2015 before joining the Regulatory System Strengthening Team in Regulation and Safety at the World Health Organisation (WHO) from 2015 to 2019.

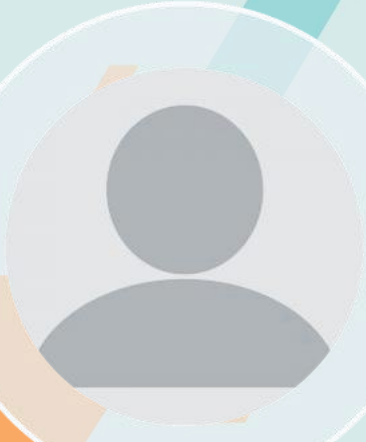
Hebatalla Ibrahim

Head of Marketing Authorization Administration
of biological products, Egyptian Drug Authority

Hebatalla Ibrahim is the Head of Biological Products Marketing Authorization Administration at Egyptian Drug Authority. She has a bachelor's degree in pharmaceutical science, and a Master's degree in business administration in project management.

She is EDA representative as a member in the African Medicine Regulatory Harmonization (AMRH) Technical Committee on Regulatory Capacity Development (RCD-TC).

She is EDA representative as Chairperson of RCD-TC Subcommittee on Vaccines Regulatory Oversight. She was a member in the team of updating registration guideline of biosimilar product in Egypt. She was also a member in the WHO team for assessing COVID-19 vaccines submitted for EUL.



Helen Byomire Ndagije

Director Product Safety, National Drug Authority of Uganda

Dr. Helen Byomire Ndagije is a Pharmacist who holds a PhD from the Université Catholique de Louvain, Belgium. She is the Director Product Safety at the National Drug Authority and the Head of the National Pharrmacovigilance Centre in Uganda. She is a patient safety advocate and serves on the patient engagement special interest group on the ISoP. She is the current President of the African Chapter of the International Society of Pharmacovigilance (ISoP).

She has actively contributed to drug regulation and guidance for Pharmacovigilance, Clinical Trials and Drug Promotion in Uganda.

She heads the accreditation Pharmacovigilance Continuous Professional Development (CPD) Course for Nurses, Midwives and Dispensers.

At the East African Community level, she is a member of the Pharmacovigilance and Post Market Surveillance expert working Group. She has been an assessor using the WHO Global Benchmarking Tool of the national regulatory systems for two African countries. She has served as an expert, WHO in pharmacovigilance, to determine the minimum requirements for pharmacovigilance in countries applying for a Global Fund to fight AIDS, TB and Malaria. She has over 20 peer reviewed publications on Pharmacovigilance.

Hyena Kang

Access to medicines and health products (MHP) division, World Health Organization

Dr HyeNa Kang is a Scientist in the Norms and Standards for Biological Products (NSB) team of the division of Access to Medicines and Health Products in the World Health Organization (WHO), Switzerland.

Dr Kang joined WHO HQ in January 2009 and has been in charge of development/implementation of WHO guidelines for regulatory evaluation of biologicals, particularly biotherapeutics including biosimilars. She has coordinated the works to provide regulatory principles in biotherapeutic area, e.g., evaluation of quality, safety and efficacy of biotherapeutics; biosimilarity evaluation; regulatory assessment and manufacturing changes of approved biotherapeutics. She has organized many workshops and coordinated works to develop case studies to implement the evaluation principles of WHO guidelines into regulatory practices in countries. She is a member of Biosimilar Working Group of the International Pharmaceutical Regulators Programme. She also works in the vaccine area.

Prior to joining WHO, Dr Kang was a scientific officer for twelve years at Korea Ministry of Food and Drug Safety (formerly Korean Food and Drug Administration) who was responsible for reviewing license applications, quality control test, and facility inspection of bacterial vaccines, blood products, plasma-derived products, and tissue transplant products. In 2004, she worked on the project to develop HCV DNA vaccines at the Vaccine and Infectious Disease Organization-International Vaccine Center in the University of Saskatchewan in Canada.

Isabelle Colmagne-Poulard

Head of International Global Regulatory Affairs
& Scientific Policy, Merck Group

Isabelle Colmagne-Poulard is a Regulatory/QA executive with over 20 years of progressively responsible experience and accomplishments in the areas of drug and medical device development.

Isabelle has joined Merck since 2008 where she held growing managerial roles in Reg. Affairs and Reg. CMC as Head of Department, based in Switzerland. She therefore has a solid practice of regulatory CMC requirements pre- and post-approval for small and large molecules and is used to represent Merck towards Health Authorities.

She is actively involved in regulatory policy as member of EFPIA, EuropaBio, and IFPMA RSC since 2015. In this respect, she represented IFPMA at various conferences in Asia, Europe, Middle East and Africa, has been a WHO ECSPP observer and is currently IFPMA representative at ICH Training Sub-Committee. In her current capacity as Head of International Global Regulatory Affairs & Scientific Policy, she leads the development of Merck International regulatory policy priorities, supporting the strategic development of Merck R&D portfolio. Prior to joining Merck, she worked for several companies in several areas including in Clinical Development for Servier and assumed various site managerial responsibilities within Sanofi QA/RA for 7 years. Isabelleholds a Master degree in Biology & Sciences and a Pharm. D as Industrial Pharmacist, coupled with a Master in Quality Management from ESCP Paris.

Jacqueline Acquah

Associate Director, Global Public Health
Vaccines Regulatory Affairs (EMEA), J&J

Jacqueline Acquah is a registered pharmacist in Ghana and currently works with Johnson & Johnson as an associate director responsible for vaccines regulatory affairs in emerging markets in Europe, Middle East, and Africa (EMEA).

She also currently serves as the Co-Chair for the Africa Regulatory Network (ARN) of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). The association works in partnership with regulatory authorities and the pharmaceutical industry in Africa to encourage greater harmonization of regulatory requirements on the African continent and strengthening of the regulatory ecosystem.

Jacqueline has also previously worked with Pfizer, the 37 Military Hospital and the Pharmaceutical Society of Ghana.

Jacqueline Rodgers

Consultant, Regulation of Vaccines, Project Management

Jacqueline Rodgers is a pharmacist and a pharmaceutical biotechnologist with over 15 years' cumulative experience in regulation of medicines, biopharmaceuticals, vaccines, blood and blood products, and tobacco products.

Her current role at WHO, supports regulatory capacity in review of clinical trial applications via the African Vaccines Regulatory Forum (AVAREF) multi-country joint review procedure, regulatory and ethics training, development of guidelines and training courses aimed at regulatory systems strengthening mainly in Africa.

Jayesh Pandit

PVCH and QPPV at Bayer for East and North-West Africa countries

Dr. Jayesh M. Pandit is the Pharmacovigilance Country Head (PVCH) and the Qualified Person for Pharmacovigilance (QPPV) for Bayer Pharmaceuticals and Consumer Health in East Africa, based in Kenya and coordinates pharmacovigilance activities across North-West Africa (NWA) country cluster. Before joining Bayer, Jayesh was the Head of the Medicines Information and Pharmacovigilance Division at the Pharmacy and Poisons Board- Kenya's National Medicines Regulatory Authority, where he served for 10 years. Jayesh initiated and developed the National Pharmacovigilance System to ensure the quality, safety, and efficacy of medicines used in Kenya. Jayesh has also served as the Secretary to the Expert Committee on Clinical Trials, has been a member of the Africa Vaccines Regulatory Forum (AVAREF), a member of various public health program- technical working groups (TWGs) as well as WHO's team of consultants on Pharmacovigilance in Africa (Pharmacovigilante-Sans-Frontier). Currently Jayesh is an active member of the Pharmaceutical Society of Kenya (PSK), International Society of Pharmacovigilance (ISoP) and its Africa chapter and ISoP's Special Interest Group on Eco Pharmacovigilance (EcoPV), among other professional groups.

At the Kenya Association of Pharmaceutical Industries (KAPI), Jayesh, until recently, also Chaired the Pharmacovigilance and Medical Affairs Committee.

Jo Ann De Crescenzo

Senior Director, Head of Regulatory Affairs, EMEA Emerging Markets & GPH, J&J, Italy

Jo Ann De Crescenzo holds the role of Senior Director, Head of Regulatory Affairs, EMEA Emerging Markets & Global Public Health (GPH). She is responsible for leading Regulatory Affairs activities in the Emerging Markets region, including Africa, Middle East, Turkey

and Russia/CIS, driving the strategic agenda for Regulatory Affairs function in the region, supporting the business and Global Public Health, as well as securing compliance.

Jo Ann is a passionate and accomplished Regulatory Affairs leader with over 19 years of experience in Regulatory Affairs roles spanning across the pharma value chain from CMC to launch. Jo Ann joined J&J Consumer in 2015 as Director of Regulatory Affairs responsible for leading various internal and external growth Initiatives and cross category projects in EMEA and emerging markets.

Prior to joining J&J, she worked in worked in Regulatory Affairs leadership roles at Takeda Pharmaceuticals and Actavis Pharmaceuticals across EU and global Emerging Markets. As a Director for Regulatory Affairs in global emerging markets she has a led submission strategies ex US, EU markets bridging the two and shaping emerging regulatory environments.

Jo Ann holds a bachelor's degree in pharmacy from the University of Malta and an MBA form Henley Business School (University of Reading, United Kingdom).

John M Mwangi

Head, Regulatory Affairs – East & West Central Africa,
Bayer Pharmaceuticals

John Mwangi currently works at Bayer as Head of Regulatory Affairs responsible for East & West Central Africa Region based in Kenya, responsible for Pharmaceuticals and Consumer Health divisions and doubling up as Regulatory Policy & Intelligence Lead for EEMEA Region. He has previously held different roles in Pharmacovigilance and Quality Control within the Pharmaceutical Industry. He has been an active member of several industry associations including KAPI (Kenya Association of Pharmaceutical Industry) where he has served as member since 2013 including as past executive secretary and continues to serve in in various committees within KAPI and as Board Member.

John is passionate about supporting the streamline of Pharmaceutical Regulatory Systems & Policy and is currently a member of the Africa Regulatory Network (ARN) within the IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) where he is the immediate past co-chair. Additionally, John represents Bayer in the Africa Engagement Committee of the IFPMA and is currently a member of the Africa Strategy for the Global Self Care Federation (GSCF).

Joseph Anthony Hotton

Asst. Director/GBT-Coordinator, National Agency for Food & Drug Administration & Control, Nigeria

Dr Hotton Joseph Anthony is a Chemist, Quality Auditor, Assistant Director, and a regulatory Inspector with over 20 years' experience with National Agency for Food and Drug Administration and Control [NAFDAC] Nigeria.

He is the Nigerian GBT national focal person that derived and championed the coordination and supervision of the Nigeria NRA WHO-GBT Program across all regulatory functions to the successful attainment of maturity level three (ML3).

He contributed to several initiatives in terms of development of policy, guidance documents for good Regulatory Practice in Nigeria.

A resource person in system strengthening programs, capacity building, training including mentoring of other NRAs on GBT Program in Nigeria and other NRAs for the attainment of ML3.

Karim Kacimi

Regulatory Affairs Manager, Algeria, Merck Group

Karim Kacimi is a PharmD from Algiers University with a PhD in Pharmacology on clinical trial applied to the establishment of biosimilarity. He has 10 years of experience in the field of regulatory affairs covering Algeria and French-speaking Africa. He is ongoing chair of the Algeria industry association regulatory workstream group.

Kelly Chibale

Neville Isdell Chair in African-centric Drug Discovery & Development

Kelly Chibale is a Professor of Organic Chemistry at the University of Cape Town (UCT) where he holds the Neville Isdell Chair in African-centric Drug Discovery & Development. He is also the founding Director of the South African Medical Research Council Drug Discovery & Development Research unit at UCT, the Founder and Director of the UCT Holistic Drug Discovery and Development Centre H3D, a Johnson and Johnson (J&J) Centre for Global Health Discovery. Kelly obtained his PhD in Synthetic Organic Chemistry from the University of Cambridge in the UK. This was followed by postdoctoral stints at the University of Liverpool in the UK and at The Scripps Research Institute in the USA. He was a Sandler Sabbatical Fellow at the University of California San Francisco, a US Fulbright Senior Research Scholar at the University of Pennsylvania School of Medicine, and a Visiting Professor at Pfizer in the UK.

Khadidja Bouguerra

Quality Management Officer, National Agency for pharmaceutical products, Algeria

Khadidja Bouguerra has a PhD in pharmacology. She has more than eight years as auditor ,evaluator of pharmaceutical files at National Laboratory for Pharmaceutical Products in Algeria. She also has more than three years as quality management officer at National Agency for Pharmaceutical Products in Algeria, and as teacher and researcher at university of sciences and technology Houari Boumediene.

Khadijah Ade-Abolade

Deputy Director, Drug Evaluation & Research, National Agency for Food and Drug Administration and Control, Nigeria

Khadijah Ade-Abolade is a Pharmacist and Fellow of the West African Postgraduate College of Pharmacists with over twenty years' experience working with the National Agency for Food and Drug Administration and Control (NAFDAC) across the Enforcement, Registration and Establishment Inspection Directorates.

She is currently a Lead Pharmaceutical Good Manufacturing Practice (GMP) Inspector and Quality Management Systems (QMS) Implementation Manager in the Drug Evaluation and Research Directorate, which is the Pharmaceutical GMP Inspectorate of NAFDAC. She is a key participant in the technical group responsible for the development of the NAFDAC GMP Regulations and Guidelines as well as ongoing review of these regulatory tools for continued adequacy. She is the lead for operational performance monitoring of the Pharmaceutical GMP Inspectorate and also a member of the NAFDAC Quality Management System Steering Committee. She is also a member of the NAFDAC Strategic Planning Committee.

She is the focal person for NAFDAC in the ongoing efforts in preparation for effective regulation of locally manufactured vaccines in Nigeria. She is a member of the National Technical Working Group for Local Vaccine Manufacturing and lead of the Regulatory Team in the Group. She has represented the Agency at several local and international meetings and trainings geared towards preparedness for sustainable local vaccine manufacturing in Nigeria.

Kirti Narsai

Owner, HealthValue Consulting, Senior Researcher – Nelson Mandela School of Public Governance, Strategic Health Advisor – Corporate Council on Africa

Kirti Narsai has 26 years of experience in technical & leadership roles in pharmaceutical, medical devices, FMCG and medical insurance industry with responsibilities across Africa. She has held board positions of companies, trade associations, Pan African and international organisations. She successfully designed & implemented new virtual organisational structure for government affairs across sub-Saharan Africa to support 3 commercial businesses and 2 non-commercial entities, including recruitment & training, strategy development & implementation.

Among others, she the led the initiative to harmonize pharmaceutical supply chain in the SADC region by addressing policy & operational barriers through the formation of a multi-stakeholder forum as a board member of the Nepad Business Foundation.

She is currently leading research on the creation of regional and continental value chains for the local manufacturing of vaccines in Africa under the AfCFTA as Principal Researcher at Nelson Mandela School of Public Governance.

She is a member of market design & demand intelligence workstream of PAVM.

Kristiina Puusaari

Digital Business Transformation Programme eSubmission Senior Coordinator, Digital Change Workstream Digital Business Transformation Task Force, EMA

Kristiina Puusaari joined the European Medicines Agency in January 2002 and has been focusing on implementation of electronic submissions at the agency since 2006. Kristiina is responsible for the implementation, coordination and maintenance of the eSubmission systems and processes at the agency and is a product owner for the PLM Portal eAF which will deliver replacements for the pdf format eAFs for the EU network.

Kristiina is also a Product Owner and a subject matter expert for eCTD v3.2.2, eCDT v4.0, the electronic Application Forms (eAFs), the eSubmission Gateway and Web Client, the Common Repository, the PSUR Repository and the business processes related to the eSubmissions. Kristiina works closely with the business and technical colleagues and the development teams.

Kristiina works closely with colleagues from the European Medicines Network (EMRN) and the pharmaceutical industry. Kristiina represents the EMA in eSubmissions related stakeholder groups and represents the EU region as the Regulatory Chair at the ICH M8.

Mafora Florah Matlala

Pharmacovigilance Manager, South African Health Products Regulatory Authority (SAHPRA)

Mafora Florah Matlala is Pharmacovigilance Manager at South African Health Products Regulatory Authority (SAHPRA). She has 11 years' experience in medicine regulation, 3 years as a Medicine Regulatory Officer within the Pharmaceutical and Analytical division and 8 years within pharmacovigilance. Mafora is a pharmacist with masters in pharmacovigilance and pharmacoepidemiology. She has attended different pharmacovigilance courses offered internationally including training by Uppsala Monitoring Centre.

She supports the National Immunisation Safety Expert Committee and is an active member of African Union Smart Safety Surveillance (AU-3S) Joint Signal Management Group (JSM) and Continental Safety Working Group (CWG), aimed at facilitating cross-country signal management for COVID-19 vaccines in Africa, to support action in the interest of public health and safety.

She previously worked in retail and hospital before joining medicine regulations.

Mariana Roldao Santos

Technical Officer, Facilitated Product Introduction, World Health Organization

Mariana Roldao Santos is a Pharmacist by background, holding a Doctor of Pharmacy Degree (PharmD) from University of Coimbra, Portugal, and spent the last 10 years building professional expertise in the areas of global access to quality-assured medicines and regulatory systems for medical products, both at the European and International levels.

Mariana is working for 5 years at WHO, firstly at the Regulatory Systems Strengthening team as Scientist and moving later on to the Facilitated Product Introduction Team as Technical Officer. Currently in the Facilitated Product Introduction team at WHO, she is responsible for the facilitated regulatory pathways activities as well as collaborative and reliance mechanisms for medicines and vaccines. She joined WHO after her professional experiences at the European Medicines Agency (EMA) in London, United Nations Development Programme (UNDP) in Ukraine and the Access to Medicine Foundation (ATMF) in Amsterdam.

Margareth Ndomondo-Sigonda

AMRH/AMA Advisor to AUDA-NEPAD & AUC

Until 30th June 2023, Margareth Ndomondo-Sigonda, has been working for AUDA-NEPAD as the Head of Health Programme. She was responsible for providing technical leadership and strategic oversight on health and pharmaceutical programs such as the African Medicines Regulatory Harmonization (AMRH) Initiative, the establishment of African Medicines Agency (AMA) as a specialized agency of the African Union (AU), and promotion of local production of pharmaceuticals in Africa. She also led the regulatory workstream of the AU Partnerships for African Vaccines Manufacturing (PAVM) Framework.

She previously served as Chief Pharmacist Ministry of Health Tanzania (1998), responsible for providing oversight on implementation of the national medicines policy. She also served as a regulator in her capacity as the Registrar of Pharmacy Board of Tanzania (1998-2003) and as the first Director General of the Tanzania Food and Drugs Authority (2003-2010). She holds a PhD in Pharmacology from the University of the Witwatersrand, Johannesburg, South Africa.

Marie Valentin

Facilitated Product Introduction Team Lead,
World Health Organization

Marie Valentin is a pharmacist specialized in drug product regulation with over 22 years of experience in regulatory affairs and product development, acquired both in the private and public sectors.

Since September 2023, Marie is the Team Lead for the Facilitated Product Introduction Team supporting the Member States by implementing various approaches and mechanisms, including collaborative procedures, reliance approaches, and joint activities at the national, regional, and international levels to facilitate and accelerate the introduction of priority medical products in countries.

She previously worked in the WHO Regulatory Convergence and Networks Team towards convergence, harmonization, reliance and system strengthening activities, supporting different regional regulatory networks and regulatory systems strengthening. She was actively involved in the finalization of the WHO documents on Good Regulatory Practices and Good Reliance Practices.

Before joining WHO in May 2019, Marie worked for 9 years at the European Medicines Agency in London as a Regulatory Affairs Officer where she was in charge of providing regulatory and procedural advice in relation to the development, evaluation and surveillance of medicinal products in the European Union as well as new EU legislation implementation. Before that, she worked in the pharmaceutical industry, contract research organization and consultancies in the United Kingdom, Spain and France.

Nankanja Ruth Mukiibi

Executive Director Sickle Cell Association, Uganda

Nankanja Ruth Mukiibi is a 49 year old female Ugandan citizen living with sickle cell disease. A teacher by profession and hold a B.A (Education) degree from Makerere University.

She is the Founder/ Executive Director Sickle Cell Association of Uganda. Among others, she has been board member at The Academy for Health Innovation, Infectious Disease Institute representing community perspective; board member of the School of Biomedical Sciences Research and Ethics Committee, Makerere University Kampala; member technical working committee for Non-communicable diseases Ministry of Health Uganda (MOH), and Member National Steering committee for Sickle Cell Disease, MoH.

Over the years she has participated on the core national planning teams of Ministry of Health namely, technical working committee for non- communicable diseases. She has also been on the national sickle cell steering committee where we worked on the National Health policy, Health sector strategic implementation plan, National Anemia policy and strategy plus reviewing the training manuals and clinical guidelines to consider Sickle cell issues.

Nevena Miletic

Regulatory Policy Head Eastern Europe, Middle East & Africa (EEMEA), Global Regulatory Policy, F. Hoffmann-La Roche

Nevena Miletic is a Regulatory and Policy professional, passionate about bringing innovative therapeutic solutions to patients in need around the world.

She is a pharmacist, with postgraduate studies in pharmacoeconomics, regulatory affairs and quality assurance, and a certified QP, with almost two decades of experience in pharmaceutical industry.

Currently she works in the Global Regulatory Policy group in F. Hoffmann-La Roche, Switzerland, and for the last seven years, she is chairing IFPMA Africa Regulatory Network, as well as IFPMA CPP Network. She is also a member of research-based pharmaceutical companies associations and boards (IFPMA Regulatory Science Committee, IFPMA Africa Engagement Committee, DIA Middle East & Africa Advisory Board, EFPIA ERAO, IATF etc.), involved in numerous meetings, workshops and projects with regulators, cross-industry and public-private collaborative platforms (e.g. Pre-ICDRA, ICDRA, SCoMRA, IMI/IHI etc.).

Nevena is a strong advocate for regulatory convergence and harmonization, as well as for modernization of regulatory frameworks to enable innovative approaches in drug development and review. She was and continues to be strongly committed in bringing the voice of industry to key discussions related to the African Medicines Regulatory Harmonization (AMRH) initiative advancement and towards African Medicines Agency - AMA establishment.

Nicholas Cappuccino

Chair, IGBA Science Committee,
International Generic and
Biosimilar Medicines Association

Dr. Nicholas Cappuccino currently serves as the Chair of the Science Committee for the International Generic and Biosimilar Medicines Association (IGBA) and represents IGBA on the ICH Management Committee and the ICH Assembly. Dr. Cappuccino is the Chief Executive Officer and Principal Regulatory Consultant of Pharmaceutical Intellectual Resource Services LLC, in Lambertville, NJ USA. Dr. Cappuccino has held the positions of Vice-President, Quality and Scientific Affairs, in Princeton NJ and Head of Global Quality for Dr. Reddy's Laboratories Ltd., located in Hyderabad, India.

Prior to these positions, Dr. Cappuccino was the Chief Scientific Officer of Eagle Pharmaceuticals Inc. in Woodcliff Lake, New Jersey, USA. Dr. Cappuccino was formerly the Executive Vice-President, Chief Scientific and Technical Officer of Andrx Pharmaceuticals and Watson Laboratories in Weston, Florida, USA. Prior to Andrx, Dr. Cappuccino was the Vice-President of Research and Development and a member of the Executive Management Committee for Sandoz Inc. in Princeton, NJ.

Paloma Tejada

Associate Director, Alliance Building

Paloma Tejada joined IFPMA in July 2020. She is the focal point for patient, health professional, and civil society engagement. Before joining IFPMA, Paloma launched Rare Diseases International, a global advocacy platform for rare disease patient organizations. Prior to this, Paloma was responsible for communications at the non-profit EURORDIS-Rare Diseases Europe.

She started the first Rare Disease Day and grew it from a European patient awareness day to a global communications campaign. Paloma began her career in global health as a Programme Coordinator for Médecins du Monde's international HIV/AIDS network. She has extensive experience working for non-governmental organizations in Europe, America, and Asia. She has a Masters in Development Management from the London School of Economics and Political Science (LSE) and holds a Bachelor in Communications and Print Journalism from The American University.

Pat Harding

Senior Advisor, Medicines Quality Organisation International, Eli Lilly and Company and EFPIA International Pharmacovigilance Group

Pat Harding has worked in quality/pharmacovigilance at Lilly for the past 20 years. Her current role is a Senior Advisor in the international region of the Medicines Quality Organisation (MQO), responsible for the creation and maintenance of the PSMFs and PSSFs within Lilly. Previously she created and implemented the Lilly pharmacovigilance compliance metrics processes including the late ICSR metrics

process. She has participated and led many GVP inspections in both front and back rooms. Pat is the Co-Chair of the EFPIA International Pharmacovigilance Group (IPVG) and also participates in the Middle East/Africa and CIS work streams within IPVG.

Patrick Tippoo

Chief Science and Innovation Officer (BIOVAC)
and Executive Director (AVMI)

Patrick Tippoo is the Chief Science and Innovation Officer at Biovac, responsible for vaccine product development. He is a founding member and the Executive Director of the African Vaccine Manufacturing Initiative (AVMI), advocating for the establishment of vaccine development and manufacturing capacity in Africa.

He served as Vice President of the Developing Country Vaccine Manufacturers Network (DCVMN) from 2019-2022 and now is an Advisor to the DCVMN board. He is also Chair of the Emerging Biopharmaceuticals Manufacturing Network (EBPMN) board.

Raj Long

Deputy Director – Integrated Development, Global Health,
Bill & Melinda Gates Foundation

An established multilingual senior executive with over 35 years of demonstrated success in regulatory, clinical development and accelerating access. Raj Long has considerable experience as a senior international regulatory executive in the pharmaceutical industry, combined with strategic experience as an advisor to the Department of Health & Social Care, European Union, Gates Foundation and World Health Organisation (WHO).

Raj is currently a Deputy Director for pharmacovigilance and Gene Drive regulatory at the Gates Foundation and supports the WHO COVID-19 vaccine manufacturing taskforce as the regulatory co-lead.

During the COVID-19 Pandemic, Raj was Consultant Advisor to the Chief Scientist of the WHO, as well as being a WHO co-lead on the COVAX Task Force on COVID-19 mRNA vaccine manufacturing initiative. Vice Chair of the World Dementia Council and has provided advice to numerous expert groups and government initiatives such as the G7 Global Action Against Dementia initiative and the Accelerated Access Review with NHS England. In her executive career, Raj held very senior international regulatory roles with responsibility for licensing innovative medicines in global pharmaceutical companies such as Bristol Myers Squibb, Novartis and GE Healthcare. As a recognition of Raj's significant contributions TOPRA (Organisation for Regulatory Professionals) awarded Raj with the Lifetime Achievement Award in 2020.

Additionally, in 2021 the UK Government appointed Raj to the Medicines and Healthcare products Regulatory Agency Board (MHRA) as a Non-Executive Director further consolidating her unique blend of private/public health expertise. In 2022, Raj was also appointed as an associate Executive Member of the to the newly

formed UK Health Security Agency Board (UKHSA). In 2023, Raj was also appointed as an Expert Reviewer to the Innovative Health Initiative (IHI) by the EC.

Sakhile Dube-Mwedzi

Co-ordinator, SADC Medicines Regulatory Harmonization (SADC MRH) Project

Sakhile Dube-Mwedzi is the Co-ordinator for the SADC Medicines Regulatory Harmonization (SADC MRH) Project. A pharmacist by profession and a regulatory scientist at heart, Sakhile has been involved with the project since 2015. Her role and responsibility are to support the Host Agency – the Medicines Control Authority of Zimbabwe, joint SADC/NEPAD Agency Secretariat and SADC Regulators Forum and coordinate overall project implementation, including ZaZiBoNa activities, across all SADC Member States.

She is an extensively experienced pharmaceutical expert and regulator with more than 25 years working in the pharmaceutical sector including but not limited to roles encompassing pharmaceutical regulatory consultancy; project management; and leading inspection teams to verify compliance with current Good Manufacturing Practices (cGMP). A former head of the inspectorate at the Medicines Control Authority of Zimbabwe, Sakhile has inspected over 200 pharma manufacturing facilities.

Samuel Asante-Boateng

Director of Drugs and Herbal medicine Registration Directorate, FDA Ghana

Samuel Asante-Boateng is a professional pharmacist trained at the KNUST Ghana 30 years ago and has also done further studies in MSc Pharm. Technology at the University of Bradford in UK. He has taken certificate courses in leadership, management, and administration at the Ghana Institute of management and Public Administration (GIMPA).

He currently works with the FDA Ghana as the Director of Drugs and Herbal medicine Registration Directorate. He has been working in regulation for the past 18 years. Before joining the FDA, Samuel Asante-Boateng worked in the pharmaceutical industry for 12 years.

He is part of the team of assessors at the FDA Ghana for the past 15 years and has also participated in a lot of GMP inspections in India, Indonesia, South Africa, China, Morocco, Tanzania, Kenya.

In support of the WA-MRH project, Samuel worked as the chair of the EWG-MPDER involved in the Regional joint assessment procedure in the ECOWAS region since its commencement in the year 2017. He led the team to develop a lot of guidelines, SOPs and guidance documents covering the activities of the EWG-MPDER. After the three-year term of office, Samuel is currently an ex-officio member of the EWG-MPDER.

Sean Burke

Regional Lead - International Pharmacovigilance, MSD

Sean Burke has 20 years working in pharmacovigilance, of which 11 have been as a director of pharmacovigilance for the affiliates at MSD. In his current role, Sean provides pharmacovigilance support to primarily the Eastern Europe, Middle East and Africa regions.

Sean supports in the development of local PSMF's at MSD, which are legislatively required or requested pre-inspection. He is responsible for Pharmacovigilance activities such as PV Intelligence and Operational activities within the International PV organization. Sean is a chairperson of two EFPIA PV working groups (Africa and the Middle East).

Shingai Machingaidze

Ag. Chief Science Officer, Africa CDC

Shingai Machingaidze is an epidemiologist and public health specialist. She has developed and led public health and clinical research programs that build the capacity of Africa-based scientists and institutions in Africa. Her expertise includes strategic engagement, planning and support of large public health programmes; conducting and managing clinical trials and clinical research; managing research grants and finances; as well as managing strategic partnerships and engagements with national, regional and international agencies. She has published in leading scientific journals and is a member of several institutional, regional and global advisory boards. She is currently the Ag. Chief Science Officer for Africa CDC as well as the Conference on Public Health in Africa (CPHIA) Secretariat Lead.

Stuart Walker

Independent Consultant in Pharmaceutical Medicine and Founder of both the Centre for Medicines Research (CMR) International and the Centre for Innovation in Regulatory Science (CIRS), United Kingdom

Professor Stuart Walker, BSC, PhD (London), MFPM, FRSC, FiBiol, FRCPath, is an independent Consultant in Pharmaceutical Medicine and Founder of both the Centre for Medicines Research (CMR) International and the Centre for Innovation in Regulatory Science (CIRS). UK

During his period in academia, he has taught pharmacy, medical and MBA students, supervised 30 PhD programmes, co-authored over 350 research papers and reports and co-edited 30 books in the fields of toxicology, drug development, clinical development, regulatory policies, the benefit/risk assessment of medicines & quality decision-making practices.

Professor Walker's initial business experience resulted from a period of eight years with Glaxo Group Research where he had international responsibility for several clinical research & Clinical Trial programmes. He pioneered some of the early international clinical development programmes and brought a number of major new

products to the market in the therapeutic areas of dermatology, ophthalmology, anaesthetics and asthma.

In 1981, he was invited to establish a new organization, namely the Centre for Medicines Research International, which over a period of 25 years became the leading consultancy in benchmarking drug development for the major international pharmaceutical companies.

In 2002, Professor Walker established the Centre for Medicines Research International Institute for Regulatory Science as a division of CMR International (now known as the Centre for Innovation in Regulatory Science).

For the past six years Professor Walker has been actively involved with more than 20 regulatory authorities in the African Continent evaluating their Regulatory Performance which has included the agencies within SADC, those within the EAC region as well as those involved in the ECOWAS region. In addition he has evaluated the effectiveness and efficiency of these three Regional Initiatives. He is involved in the three technical committees as they work towards the establishment of the African Medicines Agency. In this capacity he is supported through the Centre for Innovation in Regulatory Science by the Bill and Melinda Gates Foundation.

Susan Winks

Head of Research Operations and Business Development, H3D Holistic Drug Discovery and Development Centre

Dr Susan Winks (PhD, MBA) is the Head of Research Operations and Business Development at H3D. She manages the team of professional staff that support the interdisciplinary drug discovery work at the centre. Her role includes ensuring operational continuity and sustainable growth by long-term strategic planning, management of partnerships and stakeholders, fundraising and renewal of funding agreements, management of internal governance structures, and portfolio oversight. Since joining H3D in 2013, Dr Winks has worked closely with the Director to raise over $55 million in research funding, grown the centre from 12 to 76 staff members, and systematically introduced systems (governance, project management, HR, data management, mentorship etc.) and new capabilities to support sustainable growth.

Sylvia Vito

Africa Head, Sub-Sahara Africa & Frontier Markets, Eva Pharma International

Dr Sylvia Vito is a seasoned C-suite business executive with a medical professional background and over 18 years of experience in Healthcare Leadership across the African Cluster

She has worked extensively in the Healthcare & Pharma industry leading Africa in several capacities to drive commercial & Infrastructural developments, investments in healthcare systems strengthening & portfolio performance and community investments around Communicable, Non- Communicable diseases and Vaccines

The healthcare environment in Africa is changing at a rapid pace. Impacted by a fast, young growing population, lifestyle choices and environmental contributions, this means that Africa will continue to experience increasing pressures on an already fragile healthcare system.

By partnering with Governments, Professional Associations, Development Partners, disruptive startups & innovators, Sylvia believes that the Private Sector and Industry players should be able to not only support in building more resilient healthcare systems, but through concerted efforts make a meaningful, tangible, efficient and sustainable investment in Africa.

Teresa Eastwood-Kiefer

Chapter Leader, Regulatory Data and Content, Roche

Teresa Eastwood-Kiefer is an established regulatory leader, with over 18 years of experience in Pharmaceutical Development Regulatory, currently leading global data and content submission and automation teams within Roche. Teresa is an active member of the EFPIA eCTD Subgroup (Subgroup of European Regulatory Affairs Operations), actively contributing to EFPIA positions with regards to global adoption of digital solutions, electronic common technical document (eCTD) and common data standards, and cloud-based submissions. Teresa is a member of the newly established Industry Focus Group on EMA's Raw Data Pilot. A passionate advocate for innovation and digitalization, Teresa leads various automation and AI programs and she regularly assesses trends in industry and technology to proactively translate them into opportunities to increase efficiency and advance Roche's and industry's global submission strategies.

Thomas Nyirenda

Strategic Partnerships and Capacity Development Manager & Head of Africa Office, European and Developing Countries Clinical Trials Partnership (EDCTP)

Dr Thomas Nyirenda is Strategic Partnerships & Capacity Development Manager and Head of Africa Office of the European and Developing Countries Clinical Trials Partnerships (EDCTP). He has 28 years' experience of working in sub-Saharan Africa in Clinical Medicine, Public Health and Clinical Research. He trained in Medicine at University of St Andrews (Scotland), St Mary's Hospital (London) and Kamuzu University of Health Sciences (KUHeS) in Malawi. He studied Public Health training at London School of Hygiene and Tropical Medicine (LSHTM). He has held positions at Ministry of Health in Malawi, World Health Organisation (WHO) Stop TB Department in Geneva, and WHO Country Office in Malawi before joining EDCTP. He has had academic roles at University of Witwatersrand (South Africa), and the Department of Global Health of University of Stellenbosch (South Africa). He chairs the Advisory Board of Clinical Trials Community (CTC), and sits on committees at AUDA-NEPAD AMRH, TB Vaccine Initiative (TBVI), WHO Advisory

Group on Clinical Trials Coordination and Strengthening, AVAREF, GloPID-R Africa Hub, MRCT- Subject Matter Expert (SME) Group for ICH E8 training, and the Global Health Trials Network of University of Oxford.

Tim Powell

Director, Submission Sciences, Biogen

Tim Powell is responsible for managing a team of Global Delivery Managers who support regulatory submissions around the world. He is experienced in regulatory systems strategy and implementation and helping to define a roadmap for systems and data management, and is also the chair of the EFPIA eCTD Sub-Group where new & upcoming regulatory guidelines relating to eCTD and other telematics initiatives are discussed.

Uchenna Adesugba

Head, RA Policy & Strategic Operations, Novartis, Nigeria

Uchenna Adesugba is a trained pharmacist with 17 years of experience in the pharmaceutical and consumer goods sectors. She is currently the Head, RA Policy & Strategic Operations, SSA, Novartis based in Lagos, Nigeria. Before joining Novartis in December 2016, she has held Regulatory Affairs, Quality Assurance as well as Corporate Affairs & Communication roles in different organizations. In her current role, she is responsible for identifying policy issues and actions to shape the regulatory environment in SSA, developing regulatory strategy and acceleration plans for key products across the Region, clinical trials and compliance oversight. She is very passionate about improving access to safe, quality, and efficacious medicines for patients in Africa.

Vasee Moorthy

Senior Advisor, Research for Health Department,
WHO Science Division

Dr. Vasee Moorthy is Senior Advisor, Research for Health Department, WHO Science Division, Geneva, Switzerland. Since 2008, he has held progressively senior roles at WHO in malaria vaccine policy development, Ebola vaccine phase 1-2 trials, global norms in sharing research data and results during public health emergencies, WHO R&D Blueprint for action to prevent epidemics, global consensus on clinical trials policy norms, WHO COVID-19 Research & Innovation Roadmap and the WHO Solidarity Trial of therapeutics supporting clinical trials networks in over 40 Member States in all WHO regions, and most recently, the adoption of resolution (WHA75.8) on clinical trials. Prior to joining WHO, Dr. Moorthy worked as a medical researcher at the University of Oxford, UK (2005-2008); with an NGO, PATH, in USA (2003-2005); running a clinical trials programme at MRC Laboratories in The Gambia (1999-2003), and as a government medical officer in Kwazulu/Natal, South Africa (1996-1997). He received a B.A. and M.A. from the

University of Cambridge in Natural Sciences, a B.M.B.Ch medical degree and a Ph.D in malaria immunology and clinical trials both from the University of Oxford.

Victoria Palmi-Reig

International Affairs Officer, EMA

Victoria Palmi has worked at the EMA for over 20 years. She currently leads EMA international collaboration programs with WHO and Africa region at the international affairs office.

She has previously worked in the Evaluation of Medicines department as Product Lead in several Therapeutic areas leading initiatives of accelerated assessment, initial marketing authorisations and advanced therapies.

She has a degree in pharmacy from the University of Valencia (Spain) and René Descartes-Paris (France). Additional qualifications include Methodology of Clinical Trials, European Regulatory affairs, and Advanced Therapies.

Virginia Beakes-Read

Vice President, Global Regulatory Policy and Intelligence, Janssen Inc.

Ginny is VP, Global Regulatory Policy and Intelligence at Janssen Pharmaceuticals. She leads Janssen's Global Regulatory Policy efforts, working to shape the regulatory environment to support innovative drug development and patient access to new therapies. Previously Ginny led the Global Regulatory and R&D Policy group at Amgen, working on issues related to trial design, real world data, companion diagnostics, combination products, and other topics. Ginny joined Amgen from Eisai, where she led the Global Regulatory Policy team for 8 years. She was the Executive Director/Special Counsel, Regulatory Strategy and Law, and a member of the GRA and Legal Departments. Ginny previously worked at Genentech as Director, Regulatory Policy and Strategy.

Before Genentech, Ginny was at the Center for Drug Evaluation and Research (CDER), FDA where she was the Director, Division of Regulatory Policy II, Office of Regulatory Policy, for 8 years. She was responsible for the development of all regulations affecting CDER, crafting policy positions in areas such as biosimilars. Before that, Ginny was a US Army JAG, was prosecutor and appellate attorney. Ginny is an RN and started her career as an ICU in the US Air Force. Ginny holds B.S.N. and J.D. degrees from the University of Virginia.

Virginia Acha

Associate Vice President – Global Lead, Regulatory Policy, MSD

Virginia (Ginny) has worked in industry and academia throughout her career, combining interests in science policy research and innovation performance within and across organizations. She joined MSD in 2017 to lead regulatory policy efforts outside of the US for innovation that will lead to better treatment for patients globally. Since January 2020 this scope has expanded, as Ginny now leads the talented and experienced Global Regulatory Policy team for MSD. Ginny has been leading regulatory policy initiatives within industry and in MSD to address the COVID-19 imperatives, and to explore how this experience may prove a watershed for development and regulation of medicines for the future. Recently, this work has resulted in a publication on the European experience in Therapeutic Innovation and Regulatory Science with other publications in development. She has presented these findings and recommendations in key policy settings around the world.

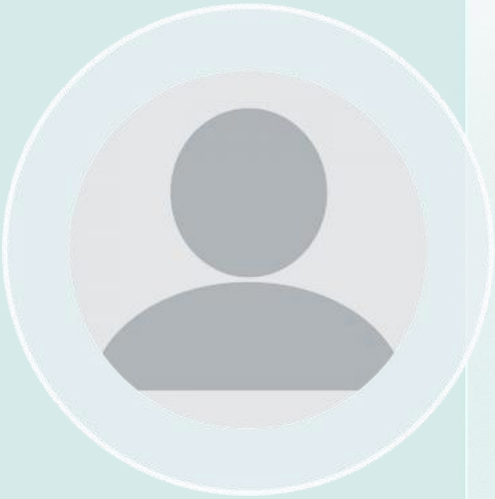
Before joining MSD, Ginny was the senior spokesman for the industry in the UK for research, medical and innovation policy (notably for BREXIT) at the UK trade association, ABPI. Previously, Ginny worked for Amgen in global regulatory policy and for Pfizer working on policy development in science and innovation in healthcare. She joined the pharmaceutical industry from Imperial College Business School, concluding over ten years as an innovation policy academic. Ginny was made a Fellow of The Organization of Professionals in Regulatory Affairs (TOPRA) in 2020.

Wilberforce O. Wanyanga

Pharmacist, Kenya

W.O. Wanyanga is a pharmacist in Kenya with long experience in formulation of public pharmacy policy and administration, supply management, pharmaceutical manufacturing and quality assurance and regional policy reviews and harmonization. He is past chairman of the Pharmaceutical Society of Kenya and participated in many local and international fora of discussing access of quality medicines and supporting pharmaceutical local manufacturing and change systems in the profession including membership to various Boards of management, professional body and regional activities. He is a pioneer member of the Board Federation of African Pharmaceutical Association (FAPMA) a continental organization of African-based manufacturers committed to developing the industry to meet Africa's need for affordable quality medicines.

W.O. Wanyanga has a key interest in the development of Local Pharmaceutical Manufacturing and the Strengthening of the Local Pharmaceutical Manufacturing sector. His most outstanding contribution working with UNIDO as National coordinator part of team developing policy and strategy documents alongside the GMP Roadmap in Kenya. Recent interventions include working with other experts Audits in afCTA and SADC region in capacity building in GMP in ARV value chain and the Status of Local Manufacturing of ARVs for PLHIV in Kenya.



Willemijn van der Spuij

Executive Director Europe, Worldwide Patient Safety, Bristol Myers Squibb & Chair of EFPIA International PV Group

Willemijn van der Spuij is the Executive Director Europe in the Worldwide Patient Safety Organisation in Bristol Myers Squibb. She is responsible for Patient Safety in the EU markets, Balkans, Baltics and CIS region and is based in Switzerland. Prior to her current role she held responsibilities for PV Intelligence & International Operations including the PSMF, the EU QPPV role and Training and Outsourcing activities. Willemijn holds a Nursing Degree from the Netherlands, a BA (Hons) in Sociology from Goldsmiths college, University of London, UK and an MSc in Pharmacovigilance from the University of Hertfordshire, UK. She is a member of the EFPIA Pharmacovigilance Expert Working Group and Chair of the EFPIA International Pharmacovigilance Group. Willemijn started her career in pharma in Quintiles with a focus on GCP activities and joined BMS in 2003 focusing on GVP activities.