PROFESSIONAL PROFILES OF FDA GCP INSPECTORS

1. Dr. Delese Mimi Darko

Dr. Delese Mimi Darko graduated from Kwame Nkrumah University of Science and Technology (KNUST) with a Doctorate Degree in Pharmacology and a Bachelor of Pharmacy, as well as a Master of Business Administration from the University of Northampton.

She has over 32 years of expertise in the field of food and medical product regulation, beginning with product testing in the laboratory and progressing to lead the marketing authorization, post approval safety monitoring of medicines, and clinical trials duties. Mimi was key in the FDA being designated as a Regional Centre of Regulatory Excellence in three critical areas by the NEPAD/African Medicines Regulation Harmonization (AMRH) in 2014: Medicines Safety (pharmacovigilance); Clinical Trials Oversight; and Drug Registration.

Dr. Darko established expert committees and initiatives, such as Patient Safety Centers and the Med Safety App, to enhance medicine safety locally. Her strategic partnerships with global entities like UK MHRA and WHO underscore her dedication to global standards.

Mimi rose through the ranks of the Food and Drug Administration (FDA) to the post of Deputy Chief Executive Officer before being appointed Chief Executive Officer in 2017, making her the FDA's first staff member to hold this position.

The FDA's regulatory system for both food and medical items has improved tremendously during her tenure.

The FDA attained WHO Maturity Level 3 for medicines and vaccines (non-producing) in 2020, and is therefore deemed to operate as a stable, well-functioning, and well-integrated regulatory system.

In 2022, the Drugs Laboratory attained WHO Maturity Level 4 and was designated as a WHO-Prequalified Quality Control Laboratory, making it the first laboratory in West/Central Africa to do so.

She is leading the FDA to play a key role in making Ghana a vaccine-manufacturing country.

Mimi currently chairs the Steering Committee of the WHO African Vaccines Regulatory Forum (AVAREF) and a member of the CEPI Advisory Board, and the COVAX Maternal Immunization Working Group.

2. Mr. Eric Karikari Boateng

Mr. Eric Karikari Boateng, a pharmacist with a master's degree in pharmacy (Pharmacology and Toxicology) from Zaporozhye State Medical University, Ukraine, has over 24 years of experience in Quality Control and Assurance of pharmaceuticals and Biopharmaceutical products. He currently serves as the Director of the Centre for Laboratory Services and Research at the Food and Drugs Authority (FDA) Ghana, overseeing the Quality Control of drugs and Biopharmaceuticals.

He is a Senior Reviewer of CMC (Chemistry, Manufacturing, and Controls) dossiers for New Biological Applications, focusing on well-characterized Biologics, vaccines, recombinant proteins (such as Insulin and epoetins), and Biosimilars. As a lead inspector, he has conducted over 20 GCP and GLP inspections.

As a key assessor of Quality, Clinical, Non-clinical and Statistics aspects of critical Clinical trial applications, he has a wealth of experience and knowledge in the conduct of Clinical trials. He serves as a key resource person in the training of regulators from other African countries on dossier assessment of CTD modules 3,4 and 5 during RCORE fellowship trainings.

He holds the position of secretary for the Technical Advisory Committee on Clinical Trials and is also actively involved in the Technical Coordinating Committee (TCC) of the African Vaccines Regulatory Forum (AVAREF) and holds certifications including GMP Pharmaceutical Professional from the American Society of Quality (ASQ).

Mr. Karikari Boateng also contributes as a facilitator at the United States Pharmacopoeia (USP) in Ghana, where he trains personnel from National Regulatory Authorities (NRAs) across Africa in the review of Marketing Authorization Applications (MAA) for Biologics and small molecules. His expertise lies in protein characterization, particularly Glycan Analysis, protein purification, and Bioassays.

3. Dr. (Mrs.) Yvonne Adu Boahen

Dr. (Mrs.) Yvonne Adu-Boahen is a dynamic and seasoned pharmacist with extensive expertise in regulatory affairs, particularly clinical trials oversight. She holds a Doctor of Pharmacy degree from Kwame Nkrumah University of Science and Technology, and an MSc in Pharmacy from Voronezh State University. As a Fellow (Public Health) of the Ghana College of Pharmacists, she combines her academic prowess with practical experience to advance pharmaceutical standards and regulatory practices in Ghana and beyond.

Currently, Dr. Adu-Boahen serves as the Chief Regulatory Officer and Head of the Clinical Trials Department at the Food and Drugs Authority (FDA) in Accra, Ghana. She has held this position since December 2012, showcasing over 18 years of experience in regulatory affairs. Her role involves being the chief assessor of Clinical Trials Applications and a lead inspector during Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP) inspections.

Under Dr. Adu-Boahen's leadership, the Clinical Trials Department reached several important milestones. In 2014, it was recognized as a Regional Centre of Regulatory Excellence in Clinical Trials Oversight in Africa by AUDA-NEPAD as well as its attainment of WHO Global Benchmarking Maturity Level 3.

As a lead GCP inspector, Dr. Adu-Boahen has inspected over 50 clinical trial sites and has been pivotal in organizing GCP training programs for researchers and regulators in Ghana and sub-Saharan Africa. She developed the RCORE training manual and has trained over 70 African regulators, showcasing her dedication to capacity building and regulatory excellence.

Dr. Adu-Boahen chairs the Expert Working Group of Clinical Trials for WAHO and is a member of the WHO Regional Expert Advisory Committee for Traditional Medicine and COVID-19 Response. She participates in EU GCP Working Group workshops, leads joint AVAREF reviews meetings on clinical trial application, and serves on the Governing Board of the Pharmacy Council of Ghana, contributing to pharmaceutical policy development. Her expertise is highly sought after at international forums, where she frequently speaks on clinical trials oversight in Africa.

Dr. Adu-Boahen's exceptional leadership and dedication to regulatory excellence has significantly improved healthcare outcomes. Her extensive knowledge and practical experience make her a key figure in Ghana's pharmaceutical sector and across the African continent.

4. Mr. Nana Ansah Adjei

Nana Ansah-Adjei is a Principal Regulatory Officer, Head of Data Management Unit in the Clinical Trials Department at Food and Drugs Authority, Ghana. He is a multi-disciplinary healthcare professional with over two decades of experience as a pharmacist, combining expertise in pharmaceutical industry, medicines regulation, pharmacovigilance, and risk management.

Nana is committed to clinical trial oversight, protocol evaluation and Good Clinical Practice (GCP) inspections. Has extensive experience in reviewing and evaluating clinical trial protocols for scientific merit, quality assurance, adherence to GCP guidelines and regulatory compliance. He deploys his insurance expertise in reviewing clinical trial insurance policies for trials. He has trained researchers to

optimize study conduct, manage investigational products, monitor trial participant safety, and ensured data integrity from clinical trial commencement to completion.

Nana is proficient in conducting Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) and GCP inspections across various pharmaceutical facilities and clinical trials sites. He has inspected over 100 facilities and sites, evaluated documentation systems and quality control measures to ensure compliance with international standards. On health technology assessment, he conducts comprehensive evaluations of pharmaceuticals, medical devices, vaccines, herbal products and other medical technologies, assessing their clinical effectiveness, informing health decision-making processes, and potential impact on healthcare systems.

On the African continent, he has trained over 40 African medicines regulators and represented the FDA at WHO-AVAREF (African Vaccine Regulatory Forum) regulatory joint review meetings. He was a co- author of the Clinical Trials Training Manual for Capacity Building in RCOREs and other training institutions.
Nana Ansah Adjei is an RCORE-Clinical Trials Fellow, holds a BPharm degree in pharmacy from KNUST, a Master Supply Chain Management from Coventry University, UK and qualified Chartered Insurance Risk Manager from Chartered Insurance Institute-UK, He is currently pursuing a Master Health Economics at the School of Public Health, University of Ghana. He is Member of the Pharmaceutical Society of Ghana.

5. Mr. Richard Osei Buabeng

Mr. Richard Osei Buabeng serves as the Principal Regulatory Officer and Head of the Clinical Trial Compliance Unit at the Ghana Food and Drugs Authority (FDA). He holds an MPhil in Applied Epidemiology and Disease Control from the University of Ghana and a BSc in Biochemistry from the University of Cape Coast.

With over a decade of expertise in clinical trials authorization and monitoring, Richard is dedicated to advancing the regulation of clinical trials. He possesses outstanding interpersonal, presentation, and communication skills, developed through extensive professional interactions. Richard has played a significant role in elevating the FDA's global standing, contributing to the achievement of WHO global benchmarking maturity level 3 and ISO accreditation. He was instrumental in developing comprehensive guidelines and Standard Operating Procedures (SOPs) for the clinical trials department, thereby enhancing regulatory standards.

Internationally, Richard has represented the FDA in joint review meetings with WHO-AVAREF, aiding in global regulatory harmonization. He contributed to the transformation of the FDA into a Regional Centre of Regulatory Excellence in

Clinical Trials Oversight in Africa and collaborated with AUDA-NEPAD to strengthen clinical trial regulators across the continent. As a consultant facilitator for Good Clinical Practice (GCP) training, he has trained investigators, Contract Research Organizations (CROs), and sponsor sites. Additionally, he has conducted inspections of over 40 clinical trials, both locally and internationally, ensuring compliance with international standards.

Richard's qualifications as an epidemiologist, acquired through the CDC's advanced field epidemiology training program, enhance his expertise in public health surveillance, emergency response, epidemiology, and disease control. He actively participates in public health initiatives through memberships in FELANG and SOCRA, significantly contributing to disease outbreak investigations and the analysis of surveillance data in Ghana.

6. Mrs. Amma Asare

Mrs. Amma Frempomaa Asare is a Principal Regulatory Officer and the Head of the Clinical Trials Authorization Unit at the Ghana Food and Drugs Authority (FDA) with over 13 years of regulatory expertise in clinical trial oversight. She is dedicated to advancing clinical trial regulation and public health initiatives aimed at delivering innovative therapies to patients. Amma holds a Master of Public Health from the University of Ghana and a Bachelor of Science in Biochemistry from Kwame Nkrumah University of Science and Technology.

Throughout her career, she has assessed over forty clinical trial applications for pharmaceutical products, including small molecules, vaccines, biologics, and medical devices. She excels in non-clinical and clinical assessments, contributing significantly to the Marketing Authorization of these products. As a lead Good Clinical Practice (GCP) inspector, she has been involved with inspections at numerous study sites (research centers, teaching and regional hospitals) ensuring regulatory compliance across trials involving infectious diseases and non-communicable diseases.

Amma was instrumental in the FDA achieving the status of a Regional Centre of Regulatory Excellence in Clinical Trials Oversight in Africa in 2014 and attaining WHO Global Benchmarking Maturity Level 3. She actively contributes to capacity-building activities, serving as a consultant resource person for FDA GCP trainings and stakeholder engagement meetings in Ghana and the sub-region. Her involvement as a resource person in the AUDA-NEPAD Regional Centre of Regulatory Excellence (RCORE) Fellowship Training has trained over 70 African regulators since its inception in 2017.

She has participated in key international meetings and conferences, including joint AVAREF review meetings and the African Society of Pharmacovigilance (ASoP)

Conference. Amma has also authored publications such as the Clinical Trials Training Manual for Capacity Building in RCOREs and other training institutions. She is a member of the Society of Clinical Research Associates (SOCRA).

7. Ms. Samira Yakubu

Ms. Samira Yakubu is a pharmacist with over six years of experience specializing in regulatory pharmacy, particularly in clinical trial document review where she provides in-depth scientific knowledge in the drug development pathway and process. She holds a Master of Science in Clinical Drug Development from University College London and a Bachelor of Pharmacy from the University of Ghana.

Samira possesses strong skills in critical thinking, scientific evaluation of drug dossiers, and adherence to Good Clinical Practice (GCP) principles. Her professional background includes roles as a Regulatory Officer at the Food and Drugs Authority, where she evaluates clinical trial applications by reviewing clinical, non-clinical and quality data, conducts product quality assessments, and ensures compliance with regulatory standards. Samira has also served in leadership roles, including as a lead Inspector for clinical trial site inspections. She is certified in Research Methodology, Pharmacovigilance, statistics and Good Clinical Practice.

She has successfully conducted numerous GCP inspections identifying critical issues and ensuring that corrective actions are implemented effectively. Her contributions have been instrumental in maintaining the credibility and reliability of clinical research within her jurisdiction.

Samira's professional highlights include being a member of the emergency use authorization committee which was responsible for assessing and authorizing effective vaccines in a timely manner during the COVID-19 pandemic, co-authoring the Regional Centre of Regulatory Excellence (RCORE) manual which has been used to train over 60 regulators across Africa and partaking in the sentinel site monitoring during the pilot of the GSK malaria vaccine to ensure its effective in the real world setting.

She is a facilitator for trainings and workshops like the annual GCP training and RCORE fellowship training and has participated as a focal person for Ghana in the AVAREF Joint review meeting

Her educational background in clinical drug development and pharmacy, coupled with her comprehensive experience in leadership during inspections and training, demonstrates her commitment to advancing pharmaceutical regulations and clinical trial standards in Ghana and beyond.