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DR. NAJIBA AL SHEZAWY SPEECH & FOUNDER LETTER AFRISUMMIT 2024 hubplus

Adherence to healthcare regulations is fundamental to ensuring patient safety and maintaining the integrity of medical practices. Compliance ensures that healthcare providers follow established standards, protocols, and laws, protecting patients and upholding high care quality. It reduces risks, prevents fraud, and builds trust between patients and healthcare systems.

By strictly adhering to these regulations, healthcare organizations not only protect their patients but also enhance their operational efficiency and reputation. In essence, compliance is about committing to ethical practices, continuous improvement, and delivering high-quality healthcare services, and that is the aim and core-stone of our principals.

DR. MONA AL MOUSSLI SPEECH & FOUNDER LETTER AFRISUMMIT 2024

Imagine a world where life-saving medicines reach patients faster, where regulatory barriers dissolve, and global health standards rise together. This is the promise of harmonization and reliance in the healthcare regulatory industry.

Harmonization unites us under shared regulatory standards and a focused vision, reducing barriers and accelerating the delivery of crucial medications. This core value, combined with reliance, fosters trust and cooperation among regulatory bodies, enabling them to expedite approvals by leveraging each other's expertise.

The World Health Organization reports that regulatory reliance can reduce approval times for new medicines by up to 50% in some regions, showcasing its critical role in improving access to essential treatments. By collaborating in this way, we cultivate a spirit of mutual support and shared commitment, ensuring that vital medicines are swiftly and reliably available to enhance lives worldwide. Our collective unity and interdependence are pivotal for paving the way toward a future of empowered and independent regulatory practices.

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MR. AHMED ASHOUR **SPEECH & FOUNDER LETTER** AFRISUMMIT 2024



Business growth in Africa's healthcare sector is not just an opportunity; it's a critical necessity for the continent's future. With a rapidly growing population and expanding urban centres, the demand for quality healthcare is skyrocketing.

This creates an unprecedented chance for businesses to innovate and invest in areas like telemedicine, pharmaceuticals, and medical infrastructure. The potential for positive impact is enormous businesses that commit to addressing Africa's unique healthcare challenges will not only see substantial returns but will also contribute to the region's overall development.

Investing in healthcare isn't just good business; it's a vital step toward transforming lives and ensuring that everyone has access to the care they need.



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AGENDA

DAY 1: 3 November 2024

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08:30 - 09:15

COFFEE AND REGISTRATION

09:15 - 09:45

Opening Ceremony

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AfriSummit Welcome Address Dr. Mona Al Moussli Chairman of AfriSummit



Development and Capacity Building Affairs Egyptian Drug Authority (EDA)



AfriSummit Welcome Address

Dr. Ahmed Ashour Chair of the Organizing Committee for AfriSummit Egypt



Dr. Rasha Ziada Chairman Assistant for Professional



AfriSummit Opening Remarks Dr. Hisham Stait Vice Chairman, Unified Procurement Authority - Egypt



Welcome Remarks - Titanium Sponsor Mr. Ramez Sawiris R&D Lead - Haleon MEA

09:45 - 10:45

Session 1: Current Landscape of Pharmaceutical Regulations in Africa -**Challengesand Opportunities**



Moderated by Mrs. Bunmi Femi-Oyekan Regulatory Lead, Accord & Access (Snr. Director) Pfizer



AMRH support to the Operationalisation of AMA

Dr.Nancy Ngum Public Health Officer- AUDA NEPAD

Q & A Panel Discussion: Regulatory Pathways: Harmonization, Industry Shifts, and Strengthening Public-Private Collaboration



Pharm. Mrs. Sybil Nana Ama Ossei Agyeman Yeboah Regulatory Consultant & CEO of SNAAP Access

Mr. Karim Wanga (M Pharm)

Senior Principal Regulatory Officer

Pharmacy & Poisons Board (PPB

ECOWAS/WAHO

IGAD

Kenya



SADC MRH - ZAZIBONA Mrs. Sakhile Dube-Mwedzi Program Coordinator -SADC MRH ZAZIBONA

IFPMA MS. Zainab Aziz Associate Director RA Policy & Strategic Operations, SSA Novartis



Grand Nile Tower, Cairo - Egypt

10:45 - 11:30

Session 2: Egypt National Regulatory Updates



Moderated by Dr. Inas Chehimi Senior Director - Head of Regulatory Affairs Middle East and Africa Novartis



Egypt Regulatory Updates

Dr. Yasmine Mohamed Hisham Manager of The Evaluation Unit For Registration Files of Imported Human Pharmaceuticals in Central Administration of Pharmaceutical Products Egyptian Drug Authority (EDA)





Unified Procurement Authority (UPA)

Dr. Hisham Stait Vice Chairman, Unified Procurement Authority - Egypt

11:30 - 12:00

0 12.00

Coffee and Networking Break

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12:00 - 13:00

Session 3: Harnessing Potential: Africa's Journey to Pharmaceutical Reliance: Panel Discussion



Moderated by Dr. Eman Wahdan Egypt regulatory Head for Opella

Panelist

(EDA)

Presenter

Mr. Karim Wanga (M Pharm) Senior Principal Regulatory Officer Pharmacy & Poisons Board (PPB) Kenva

Dr. Hebatallah Ibrahim Abdel-Salam

Egyptian Drug Authority

General Manager of Biological Products

General Administration & Head of Biological

Products Marketing Authorization Administration



Presenter

Sonia Sebai Ben Amor. MD Head of National Control Laboratory National Regulatory Authority Tunisia

Panelist - Industry perspective

Dr. Najlaa Fathy Regulatory Affairs Head, GDD Novartis



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Session 4: Innovation and Accessibility: Shaping the OTC Landscape in Africa

13:00 - 14:00



Moderated by Pharm. Mrs. Sybil Nana Ama Ossei Agyeman Yeboah Regulatory Consultant & CEO of SNAAP Access



Empowering Access: Strategic Insights into Self-Care Products in Pharma Mr. Ramez Sawiris R&D Lead - Haleon MEA



Regulatory Pathways in Self-Care: Mastering the Switch Dr. Marwa Souei Head of Regulatory Affairs across Africa Middle East & Turkey Opella



Panelist Dr. Shereen Abdelgawad Head of the Central Administration of Pharmaceutical Care Egyptian Drug Authority (EDA)



Panelist Sonia Sebai Ben Amor. MD Head of National Control Laboratory National Regulatory Authority Tunisia



Panelist Dr. Haidy Ahmed Director Regulatory Affairs North Africa Haleon





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14:00 - 15:00

Group Photo, Lunch and Networking

222, 20 1923.

15:00 - 15:45

Session 5: Attaining WHO Maturity Level and Collaboration Opportunities



Moderated by



Dr. Yousra Farid Regulatory Affairs | Quality Assurance Director & Strategic Project Lead - Gulf Levant & Emerging Markets Abbott



Presenter

Prof. Saleh A. Bawazir Prof. of Clinical Pharmacy & CEO of Bawazir Pharma Consulting Center

Panelist

Dr. Emil Ivan Mwikarago Technical Analyst, Assessment of Medical Devices. In Vitro Diagnostics (IVDs), Vaccines, & Biologicals Rwanda Food & Drugs Authority (Rwanda FDA)



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Panelist Dr. Zivanai Makoni Head of Division Evaluation & Registration – Medicines Control Authority of Zimbabwe (MCAZ)

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Faculty of Pharmacy

About Our Program

Since its establishment in 1997, the Faculty of Pharmacy has been a pioneer in pharmacy education in Egypt. In January 2023, it has expanded its international exposure and became among the first cohort of Faculties of Pharmacy in Egypt to receive International-Accreditation (online evaluation) from the Accreditation Council of Pharmacy (ACPE), USA, for its various programs. The Faculty's goal is to provide a strong professional program with a balanced foundation in basic, biomedical, pharmaceutical, and social sciences that advance to pharmacotherapeutic knowledge and pharmacy practice experiences. The faculty graduates competent and skilled pharmacy professionals within an environment committed to scientific research, community engagement, and social accountability.

Academic Program

The Faculty offers two Internationally-Accredited programs:

A) PharmD Program

The faculty offers a six-year program (5 academic years and 1 year of internship) leading to a bachelor's degree of Pharmacy (PharmD). Students are required to complete 178 credit hours (67 courses) for graduation.

B) PharmD – Clinical Pharmacy Program

The faculty offers a six-year program (5 academic years and 1 year of internship) leading to a bachelor's degree of Pharmacy (PharmD – Clinical Pharmacy). Students are required to complete 178 credit hours (68 courses) for graduation.

Accreditation

National Authority for Quality Assurance and Accreditation of Education

Accreditation Council for Pharmacy Education (ACPE) - USA

The [PharmD/PharmD Clinical Pharmacy Programs) of the Faculty of Pharmacy, Misr International University has been granted International -Accreditation (online evaluation) by the Accreditation Council for Pharmacy Education, 190 South LaSalle Street, Suite 3000, Chicago, Illinois, 60603-3446, United States of America, TEL +1 (312) 664-3575; FAX +1 (866) 228- 2631, website <u>www.acpe-accredit.org</u>

International Affiliations

St. John's University College of Pharmacy and Health Science (SJU), USA, Creighton University, School of Pharmacy and Health Professions, USA, Gulf Medical University, UAE, and the Faculty of Pharmacy, MIU, will engage in cooperative educational and research activities for faculty and students, which may include visiting faculty, study abroad, collaborative research programs, experiential training programs, seminars, workshops, and service programs.

International Advanced Pharmacy Practice Experience (APPE)

Students have the opportunity to participate in Clinical Rotations as part of the student exchange program at St. John's University (SJU), College of Pharmacy and Health Sciences, Creighton University, School of Pharmacy and Health Professions, Omaha, Nebraska, USA and Gulf Medical University, UAE.

















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15:45 - 16:45

Session 6: Empowering Local Production: Advancing Pharmaceutical Manufacturing and Localization in Africa



Moderated by Dr. Alaa Attia **Business Development Director** FIPICO



Building a Sustainable Pharma Ecosystem: **Regulatory Perspectives on Localization in Africa** Dr. Zakieh Ibrahim Al-Kurdi Regulatory Affairs & Public Policy Director for EMEA Region - U.S. Pharmacopeia (USP)



Panelist Dr. Claudy Raymond Tarazy Chairman & Managing Director One Pharma Medics

Q & A Panel Discussion :Collaborating for Sustainable and Efficient Nearshoring of Generics and Biosimilars



Moderated by Dr. Mohamed Larbi Jelassi Head of Market Access International SPIMACO



Panelists

Dr. Zineb Housni Pharmacist Inspector, Evaluator of Marketing Authorization Files For Medicinal Products for Human - Directorate of Medicines and Pharmacy Morocco



Panelists Dr. Ahmed El-lekawy









Panelists Dr. Eric Konan Director of the Regulatory Affairs Department ETHICA



Panelists

Panelists

Dr. Hebatallah Ibrahim Abdel-Salam General Manager of Biological Products General Administration & Head of Biological Products Marketing Authorization Administration Egyptian Drug Authority (EDA)



Mr. Karim Wanga (M Pharm) Senior Principal Regulatory Officer Pharmacy & Poisons Board (PPB) Kenya



Coffee & Networking





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17:15 - 18:00



Moderated by Mrs. Simone Rudolph-Shortt Chairperson MDMSA



Botswana Regulatory Updates Ms. Ntsetselele Kago Manager, Human Medicines Unit Botswana Medicines Regulatory Authority (BoMRA)

Session 7: Southern Africa National Regulatory Updates



Zambia Regulatory Updates

Mr. Lvoko Nvambe Director Marketing Authorisation Zambia Medicines Regulatory Authority (ZAMRA)



Zimbabwe Regulatory Updates Dr. Zivanai Makoni Head of Division Evaluation and Registration Medicines Control Authority of Zimbabwe (MCAZ)

O & A Panel Discussion





Namibia Regulatory Updates

Ms. Fransina Nambahu Registrar of Medicines at Namibia Medicines Regulatory Council (NMRC) of the Ministry of Health and Social Services (MoHSS)



End of Day 1





Healthcare Technologies

Drug Safety and Track & Trace System for a Safer, Healthier Africa!



Pharmaceutical Track & Trace System



e-Prescription



Hospital Information System



Personal Health Record



Population Health Management



Healthcare Interoperability

AI & Analytics



Health Information Exchange

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AGENDA DAY 2: 4 November 2024

09:00 - 09:30

COFFEE AND NETWORKING

09:30 - 09:45

Opening Remarks Day 2



Dr. Ahmed El-Kamhawy Country Head Opella

09:45 - 10:45

Session 1: Unlocking the Future: Regulatory Pathways & Innovations in Biosimilars & Biologics



Moderated by Dr. Yara Hussein Director, Regional Regulatory Hub Team lead – MERAST Specialty Care Business Unit Lead Pfizer Biopharmaceutical GRS IRSP



Overview of Biosimilars in MENA: Comparative Assessment of Biosimilars PAC Guidelines in MENA

Safa' Abu Gharbiah, PhD. Senior Director Regulatory Affairs, MENA Hikma Pharmaceuticals



Innovating with AI in Biologics: Ethical & Regulatory Frontiers in Africa

Dr. Fatima Zaid Abu Zanat Regional Director of Regulatory Affairs & Scientific Office – Middle East Turkey & Africa Ipsen

Q & A Panel Discussion



EDA Dr. Ahmed El-lekawy Innovative Products' Registration Manager – Egyptian Drug Authority (EDA)



EDA Dr. Asmaa Ahmed Abdel-Ghaffar Mohammed Researcher and Head of Biotechnology Lab Egyptian Drug Authority (EDA)



DMP Tunisia Sonia Sebai Ben Amor. MD Head of National Control Laboratory National Regulatory Authority Tunisia

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November 2024



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10:45 - 11:30

Session 2: National Regulatory Updates EAC



Moderated by Dr. Daniella Munen Head of External Affairs Africa Health Business



Kenya Regulatory Updates





Rwanda Regulatory Updates

Uganda Regulatory Updates

Dr. Rachel Juliet Mujawimana

Dr. Emil Ivan Mwikarago Technical Analyst, Assessment of Medical Devices, In Vitro Diagnostics (IVDs), Vaccines, & Biologicals Rwanda Food & Drugs Authority (Rwanda FDA)



Ethiopia Regulatory Updates Mr. Abebe Alamneh Vice Chairman of East African Regulatory Affairs Professionals Association (EARAPA) & Medicine Registration Expert Ethiopia Food and Drug Authority (EFDA)

Q & A Panel Discussion





Inspector of Drugs National Drug Authority (NDA) Uganda



Ms. Pamela Ajwang Regulatory Officer National Drug Authority (NDA) Uganda

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November 2024



11:30 - 12:00

12:00 - 13:00

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COFFEE AND NETWORKING BREAK

Session 3: Vaccine Regulations in Africa: Harmonization & Access for Public Health Impact



Moderated by Dr. Mariham Gergis Submission Excellence Lead – Emerging Market EMEA Regulatory Center Johnson and Johnson Innovative Medicine



Harmonizing Vaccine Regulatory Pathways in Africa : **Enhancing Preparedness for Future Health Emergencies** Pharm. Jacqueline Acquah

Senior Regulatory Affairs Strategy Lead

MEA - Coalition for Epidemic Preparedness

Strengthening Vaccine Manufacturing Capabilities in Africa: A Strategic Approach to Ensuring Self-Sufficiency and Resilience



National Network for the African Reliance Laboratories Status and Its Impact

Dr. Doaa Rady Lot Release Administration Manager Egyptian Drug Authority (EDA) & Chairperson for AMQF Vaccine Subcommittee



Dr. Mariam Raouf Wefky Ghobrial Technical Specialist (Life Sciences) Access Health International (AHI)

Innovations

(CEPI)

Q & A Panel Discussion



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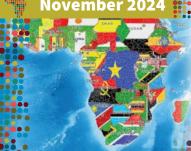
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November 2024



Session 4: Ensuring Safety and Compliance: Regulatory Perspectives in

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RISUMMIT

Grand Nile Tower, Cairo - Egypt

13:00 - 14:00

Moderated by

Track & Trace & Serialization



Mr. Christopher Oduor Senior Regulatory Affairs Manager Middle East, Africa and CIS Novo Nordisk

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Complete Control: How End-to-End Traceability





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Fireside chat Mr. Jihad Tayara Chief Executive Officer of **EVOTEO**



Ms. Tutku Kazan Marketing Director VISIOTT

Q & A Panel Discussion: Securing Africa's Supply Chain: Advances in Track & **Trace & Serialization Technologies**



Panelists Mr. Mete Karaca Executive Board Member Tiga Healthcare Technologies



Panelists Mr. Lyoko Nyambe Director Marketing Authorisation Zambia Medicines Regulatory Authority (ZAMRA)



Panelists Dr. Aliou Ndiaye Pharmacist in Drug Serialization Department Senegalese Pharmaceutical Regulatory Agency (ARP)



Panelists Ms. Nuran Idris Manager Healthcare Africa GS1 Global Office

14:00 - 15:00

LUNCH AND NETWORKING

15:00 - 15:30

Session 5: NRA Pharma Regulatory Updates - North Africa



Moderated by Dr. Amina Fazila Laras Regulatory Affairs Manager French Speaking Africa Cluster Abbott



Tunisia Regulatory Updates Dr. Mariam Aounallah Project Manager National Agency of Medicines & Health Products in Tunisia (ANMPS)

Q & A Panel Discussion





Morocco Regulatory Updates Mr. Michael Faust RCC Business Consultant EXTEDO



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GRANT GRIFFIN

Individual Member Fellow (FRAPS) **Education Committee** Membership Committee **RAC** Certified

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15:30 - 16:30



Moderated by Dr. Yasmine Maher El-Shebiny Director of Regulatory Affairs MSD Egypt Cluster (Egypt, Libya, Sudan, & Yemen)

eCTD in Africa's Regulatory Landscape

Session 6: Digital Transformation in Pharma: Navigating e-Labeling &



Harmonisation: Africa becomes One through one eCTD specification Dr. Madelein Terblanche Senior Operations Consultant VECTOR Life Sciences



Dr. Mariam Aounallah Project Manager National Agency of Medicines & Health Products in Tunisia (ANMPS)

Q & A Panel Discussion



E-Labeling Presentation

Dr. Rehab Mehrez Manager of the General Administration of Pharmaceutical References & Leaflets Central Administration of Pharmaceutical Care Egyptian Drug Authority (EDA)



Data Consistency through Production, Supply Chain & Regulatory Business Processes Mr. Michael Faust

RCC Business Consultant EXTEDO



16:30 - 17:00

COFFEE AND NETWORKING

17:00 - 17:30

Session 7: AI Revolution: Shaping the Future of Pharmaceutical Innovations



Moderated by Dr. John M. Mwangi Regulatory Policy & Science Lead Bayer Pharmaceuticals



AI & R&D in Pharmaceutical Industry

Dr. Neveen Kamel Director of Regulatory Affairs (Egypt, Maghreb Countries, Developing Africa Markets) Merck



Enhancing Regulatory Preparedness through Digital Collaboration: CEPI's Framework for Accelerated Access during Public Health Emergencies

Dr. Alessandro Lazdins Regulatory Policy and Intelligence Manager Coalition for Epidemic Preparedness and Innovations (CEPI)







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17:30 - 18:00

Moderated by Dr. Eric Konan Director of the Regulatory Affairs Department ETHICA

Session 8: West African NRA Pharma Regulatory Updates





Q & A Panel Discussion



17:30 - 18:00

NRA Break Out Round Table Discussions



Ivory Coast Regulatory Updates Dr. Chantalle Affoue Director of Approval of Drugs and Other Pharmaceutical Products Ivorian Pharmaceutical Regulation Authority (AIRP)



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REGULATORY AFFAIRS MANAGER **REGULATORY AFFAIRS ASSOCIATE** REGULATORY MANAGEMENT ANALYST DIRECTOR OF SUPPLY, REGULATORY, QUALITY & PV EXPORT MANAGER HEAD OF GLOBAL RA DEVELOPMENT AND STRATEGY **REGULATORY AFFAIRS SPECIALIST** REGULATORY SCIENCES SENIOR MANAGER REGIONAL STRATEGIST MANAGER REGULATORY SCIENCES MANAGER **REGULATORY SCIENCES SPECIALIST CLUSTER LEAD - SUB** HEAD OF REGULATORY SCIENCES SENIOR REGULATORY SCIENCES MANAGER TECHNICAL DIRECTOR MEA REGULATORY AFFAIRS DIRECTOR SENIOR REGULATORY AFFAIRS ASSOCIATE **REGULATORY AFFAIRS SECTION HEAD** REGULATORY AFFAIRS MANAGER REGULATORY AFFAIRS SENIOR SPECIALIST **REGULATORY & QUALITY DIRECTOR** SENIOR ASSOCIATE REGULATORY & AFFILIATE LABELLING COORDINATOR **REGULATORY PHARMACIST** LEAD REGULATORY PHARMACIST QUALITY ASSURANCE MANAGER GMP ARCHITECT SENIOR RA ASSOCIATE **RA AFFAIRS MANAGER** SENIOR RA ASSOCIATE HFAD OF RA **RA COMPLIANCE MANAGER** SENIOR REGULATORY ASSOCIATE ERMC LIFECYCLE MANAGEMENT RA PROFESSIONAL ERMC LIFECYCLE MANAGEMENT SUB-TEAM LEAD ASSOCIATE DIRECTOR, RA POLICY AND STRATEGIC OPERATIONS HEAD, RA POLICY AND STRATEGIC OPERATIONS REGULATORY AFFAIRS ASSOCIATE REGULATORY AFFAIRS MANAGER REGULATORY AFFAIRS SPECIALIST **REGULATORY AFFAIRS MANAGER** RA SENIOR SPECIALIST SNR REGULATORY AFFAIRS MANAGER, RESPONSIBLE PHARMACIST SNR REGULATORY AFFAIRS PHARMACIST, DEPUTY RESPONSIBLE PHARMACIST **REGULATORY AFFAIRS PARTNER** SENIOR MANAGER REGULATORY AFFAIRS EQUITY RESEARCH ANALYST, HEALTHCARE AND PHARMACEUTICALS **REGULATORY AFFAIRS HEAD** SALES HEAD SOLUTION CONSULTANT **RA MANAGER** ASSOC DIR, REGULATORY AFFAIRS PRINCIPAL, RA SPECIALIST REGULATORY AFFAIRS ASSISTANT MANAGER GENERAL MANAGER COUNTRY MANAGER REGULATORY AFFAIRS ASSISTANT MANAGER GENERAL MANAGER

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