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Edition



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For A Healthier Africa

Hilton Grand Nile Hotel, Cairo - Egypt

2nd - 5th November 2025



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Dr. Najiba Al Shezawy

Co-Chairman | AfriSummit

Regulatory dialogue is key to stronger health systems in Africa. AfriSummit unites stakeholders to share insights, align with global standards, and drive impactful change.



Dr. Mona Al Moussli

Chairman | AfriSummit

Africa's healthcare sector is projected to expand by over 10% each year, and AfriSummit 2025 ensures this growth is guided by collaboration, mutual support, and robust regulatory frameworks. It is the place where Africa's regulatory and pharmaceutical leaders come together sharing expertise, learning from one another, and building stronger, more resilient healthcare systems for the future.

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Dr. Ahmed Ashour

Chair of the Organizing Committee
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In healthcare, strong business connections and collaboration fuel innovation, access, and growth. We are here to united and foster partnerships that drive impact across Africa's evolving health landscape.



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AFRISUMMIT
2nd - 5th November 2025

AGENDA

DAY 1: 2 November 2025

08:30 - 09:00

COFFEE AND REGISTRATION

09:00 - 10:00

Opening Ceremony



Dr. Mona Al Moussli
Chairman of AfriSummit



Dr. Najiba Al Shezawy
Co-Chairman of the AfriSummit



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



H.E. Dr. Ali Ghamrawy
Chairman of the Egyptian
Drug Authority (EDA)



Dr. Hisham Badr
Vice Chairman UPA



Mr. Asif Alavi
General Manager for North Africa
Haleon

10:00 - 11:00

Session 1: Unity in Action: Convergence, Harmonization & Work-Sharing Across Africa



Moderated by
Dr. Fatima Zaid Abu Zanat
Regional Director of Regulatory Affairs & Scientific Office
Middle East, Turkey & Africa, Ipsen Pharma

Panel Discussion:



Dr. Nancy Ngum
Public Health Officer- AUDA
NEPAD



Mrs. Sakhile Dube-Mwedzi
Program Co-ordinator
(SADC MRH), ZAZIBONA



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



Dr. Sonia Sebai Ben Amor
Head of the National Control
Laboratory, National Regulatory
Authority, Tunisia



Dr. Bunmi Femi-Oyekan
Regulatory Lead (Snr Director)
Accord and Access, Pfizer



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11:00 - 11:45

Session 2: NRA Pharma Regulatory Updates - North Africa



**Moderated by
Neeven Kamel**
Head of Regulatory Affairs North Africa
Egypt, French Speaking Africa & Scientific

Egyptian Druh Authority Regulatory Updates & Reliance Progress



Dr. Mariam Maged Moris Mosaad
Human Variation Administration Manager
Egyptian Drug Authority (EDA)

Latest Regulatory Updates from Tunisia: Focus on the eCTD Implementation Project



Dr. Sameh Ben Tkhayat
Head of Pharmaceutical Industries
Department National Agency for Medicines
& Health Products (ANMPS)
Tunisia

Regulatory Reliance: Accelerating Access to Medicines Through Collaboration and Mutual Trust



Dr. Naoual Assam
Deputy Director of Technical & Regulatory Affairs
in the Directorate of Pharmaceutical Product Registration
National Agency for Pharmaceutical Products (ANPP)

11:45 - 12:05

Coffee and Networking Break

12:05 - 13:15

Session 3: Africa's Journey to WHO Maturity Level 3: Milestones & the Path Forward



**Moderated by
Dr. May Badran**
Regulatory Director for Egypt
Saudi and Africa, Abbott

Achieving WHO Maturity Level 3: Africa's Journey & the Regional Path Forward



Ms. Diana Diaz Guzman
Senior Regulatory Intelligence Manager at
the United States Pharmacopoeia (USP)
Regulatory System Strengthening (RSS)
consultant for the World Health
Organization (WHO).

Strength in Every Byte: Data Integrity as Africa's Path to Maturity Level 3



Dr. Madelein Terblanche
Senior Operations Consultant
Vector Life Sciences



Ms. Khanyisile Nkuku
Medical device & IVD Registration Officer
South African Health Products Regulatory
Authority (SAHPRA)

From Establishment to Recognition: EDA's Success Story Toward WHO ML3



Dr. Dalia Abou Hussein
QA General Manager
Egyptian Drug Authority
(EDA)

Panel Discussion: Regulatory System Advancement: Country Insights on Achieving WHO ML3



Ms. Diana Diaz Guzman
Senior Regulatory Intelligence Manager at
the United States Pharmacopoeia (USP)
Regulatory System Strengthening (RSS)
consultant for the World Health
Organization (WHO).



Ms. Khanyisile Nkuku
Medical device & IVD Registration Officer,
South African Health Products Regulatory
Authority (SAHPRA)



Dr. Folasade Oso
Chief Regulatory Officer
National Agency for Food &
Drug Administration & Control
(NAFDAC)



Dr. Madelein Terblanche
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Dr. Dalia Abou Hussein
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13:15 - 14:00

Session 4: Access First: Unlocking the Power of OTC for Self-Care Across African Communities



Moderated by
Ms. Marlene Moonsamy
Managing Director
PHARMICI (Pty) Ltd

Panel Discussion:



Dr. Haidy Morsy
Director of Regulatory Affairs
Egypt & North Africa
Haleon



Dr. Abeer Elbehairy
General Manager of Pharmacy Practice
General Administration
Egyptian Drug



Dr. Folasade Osho
Chief Regulatory Officer
National Agency for Food &
Drug Administration & Control
(NAFDAC)



Dr. Amal Fathy
Science Hub Head for AMET
Opella

14:00 - 15:00

Group Photo, Lunch and Networking

15:00 - 16:00

Session 5: NRA Pharma Regulatory Updates - West Africa



Moderated by
Mr. Merouane Mouri
Director, Regulatory Science Lead,
North and French West Africa
Pfizer

The West Africa Medicines Regulatory Harmonization Initiative: Impact on Access to Medical Products



Dr. Pierre K. Tchamdja
Professional Officer in charge of
Pharmaceuticals West African Health
Organization (WAHO)

The Pharmaceutical Regulatory Framework in Côte d'Ivoire: AIRP, a Model Independent Administrative Authority & Its Progress



Dr. Audrey Dindji Kodja
Head of Vigilance & Clinical Trials Department
Ivorian Pharmaceutical Regulatory Authority
(AIRP)

Pharmaceutical Regulation in Benin: Updates from the Supervisory Board of the Pharmaceutical Sub-Sector



Dr. Nathalie Migan Diogo
Pharmacist, Chair of Supervisory Board of the
Pharmaceutical Sub-Sector (CS-SSP) Chair of the
National Committee for the Coordination of the
Fight against Substandard and Falsified Health
Products (CNCLP)

Current Regulatory Landscape in Nigeria & West Africa or Future Directions for Pharma Regulatory Frameworks in Nigeria and the Region



Dr. Folasade Osho
Chief Regulatory Officer
National Agency for Food &
Drug Administration & Control (NAFDAC)

Serialization Project in Senegal



Mr. Ndaly Fall
Head of the Data Division
Senegalese Pharmaceutical
Regulator Agency (ARP)

Current Updates in Pharmaceutical Regulation FDA Ghana



Ms. Evelyn Aseawa Paintsil
Regulatory Officer with the Food &
Drugs Authority (FDA)
Ghana

16:00 - 17:00

NRA Roundtable Discussions

16:00 - 17:00

Coffee and Registration



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AGENDA

DAY 2: 4 November 2025

08:30 - 09:00 COFFEE AND REGISTRATION

09:00 - 09:15 Opening Remarks Day 2



Mr. Gökem Aydin
Chief Marketing Officer
VISIOTT

09:15 - 10:15 Session 1: Made in Africa: Empowering Local Pharmaceutical Manufacturing



Moderated by
Dr. Khaled Rozza
Regulatory Affairs Lead Gulf
Acino

**Navigating African Capabilities in
Pharmaceutical Localization**



Dr. Rawya Kredly
Director of Medical & Regulatory Affairs
Julphar

**Empowering Africa's Manufacturers: USP's Support for
Local Manufacturers, Medicines Quality and Access**



Dr. Sara Nageeb Elhelaly
Public Policy and Regulatory Affairs
Sr. Manager, USP-EMEA

Panel Discussion: Public-Private Partnerships: Enhancing Local Capacity and Ensuring Quality Standards in Pharma Manufacturing



Dr. Mariam Maged Meris Mosaad
Human Variation Administration Manager
Egyptian Drug Authority
(EDA)



Mr. Nathan Seyoum
Regional Coordinator, East Africa Regulatory
Affairs Professionals Association (EARAPA)
External Medicine Assessor, EFDA Lecturer,
Addis Ababa University



Dr. Rawya Kredly
Director of Medical & Regulatory Affairs
Julphar



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2nd - 5th November 2025

10:15 - 11:15

Session 2: Ensuring Safety and Compliance: Regulatory Perspectives in Track & Trace & Serialization



Moderated by
Dr. Mai Magd Sedqi
Regulatory Affairs Lead (Egypt, Libya, Sudan, & Yemen)
Merck Sharp & Dohme (MSD), Egypt

Fireside Chat: Securing the Supply Chain:
Egyptian Track & Trace Project Update



Dr. Nourhan El-Manzalawy
Head of Follow-up and Decision Support Unit
Central Administration of Pharmaceutical
Policies & Market Access, Egyptian Drug Authority
(EDA)

Strengthening Pharma Regulations:
Leveraging e-Prescriptions for Industry Advancement



Mr. Gökem Aydın
Chief Marketing Officer
VISIOTT



Mr. Mete Karaca
Executive Board Member
Tiga Healthcare Technologies

Fireside Chat: An Overview of the Uganda National Health Products Traceability Strategy 2024/25 – 2028/29



Dr. Rachel Juliet Mujawimana
Inspector of Drugs
Uganda National Drug Authority



Mr. Marwan Zeidan
Executive Board Member
Tiga Healthcare Technologies

Panel Discussion: Building a Unified Track & Trace System in Across Africa



Mr. Nyambe Lyeko
Director of Marketing Authorisation
Zambia Medicines Regulatory Authority
(ZAMRA)



Dr. Folasade Osho
Chief Regulatory Officer
National Agency for Food &
Drug Administration & Control (NAFDAC)

11:15 - 11:45

Coffee and Networking Break

11:15 - 11:45

Session 3: Advancing Regulatory Convergence: Strengthening Capacity and Harmonizing Pathways for Biologics, Biosimilars, and Conventional Medicines



Moderated by
Dr. Angeline Achoka
Senior Regulatory Affairs Manager SSA
QPPV Kenya

**Streamlining Biosimilar Development through
Regulatory Convergence**



Mr. Raja Sekhar Vanga
Vice President - Global Regulatory Affairs
Biocon Biologics Limited

**Harmonizing Post-Approval Change Processes for
Conventional Medicines**



Ms. Marlene Moonsamy
Managing Director
PHARMICI (Pty) Ltd

Panel Discussion: Strengthening African Regulatory Capacity of Biologics & Biosimilars



Mr. Varma Bhupathiraju
Associate Vice President
Global Regulatory Affairs
Biocon Biologics Limited



Dr. Samar Hamed
Biologics Registration Administration
Manager, Egyptian Drug Authority
(EDA)



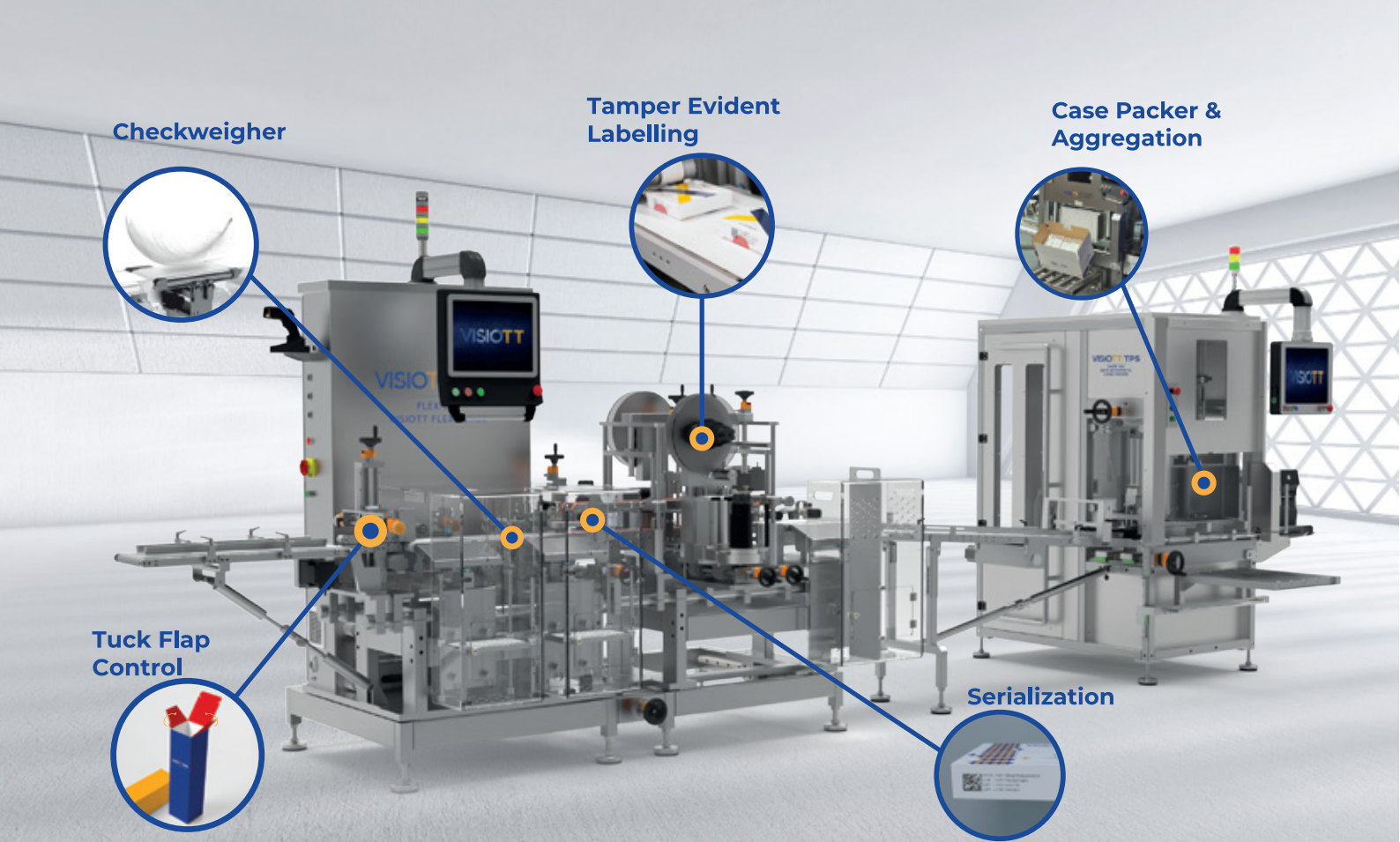
Dr. Sonia Sebai Ben Amor
Head of the National Control
Laboratory, National Regulatory
Authority, Tunisia



Mr. Makram Atef
Regulatory Affairs Senior Manager - Egypt
Merck Group



Dr. Khadijah O. Ade-Abiodun
Director (Vaccines, Biologics & Medical
Devices Registration and Regulatory Affairs)
National Agency for Food and Drug
Administration and Control (NAFDAC)



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2nd - 5th November 2025

12:45 - 13:15

Session 4: NRA Pharma Regulatory Updates - East Africa



**Moderated by
Dr. George Kamal**
Regional Regulatory Affairs Hub Head
MEAR (Middle East, Africa, Turkey, Russia &
CIS Markets), Merck Group

**Regulatory Insights from the National Drug
Authority-Uganda: GMP and Marketing Authorization**



Dr. Rachel Juliet Mujawimana
Inspector of Drugs
Uganda National Drug Authority

PPB, Kenya



Ms. Khanyisile Nkuku
Medical device & IVD Registration Officer
South African Health Products Regulatory
Authority (SAHPRA)

**Strides to Regulatory Excellence; The Ethiopian Food &
Drug Authority (EFDA) and Its Momentum of Change 2025**



Mr. Abebe Alamneh Kassahun
Vice Chairman East Africa Regulatory Affairs Professionals
Association (EARAPA), Senior Medicine Registration Expert
Ethiopia Food and Drug Authority
(EFDA)

13:15 - 14:15

Lunch and Networking

14:15 - 15:00

Session 5: Regulatory Resilience: Preparing for Health Emergencies & Supply Chain Disruptions



**Moderated by
Dr. Heba Nabil**
Regulatory Sciences Director
Pfizer

**Leveraging Digital Health Technologies for Regulatory Resilience Resilient Regulation in Action:
CEPI's role in Preparing for Emergencies and Supply Chain Disruptions**



Mr. Arthur Sichivula
ICT Manager
Zambia Medicines Regulatory Authority
(ZAMRA)



Dr. Jacqueline Acquah
Senior Regulatory Affairs Lead
Middle East & Africa, Coalition for Epidemic
Preparedness Innovations (CEPI)

**Advancing Local Manufacturing, Streamlining Emergency Approvals, & Strengthening Supply Chain Integrity:
Lessons from the COVID-19 Pandemic and Beyond**



Dr. Folasade Osho
Chief Regulatory Officer
National Agency for Food &
Drug Administration & Control (NAFDAC)

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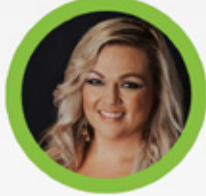
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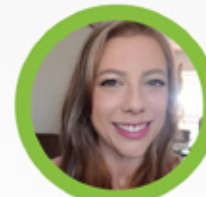
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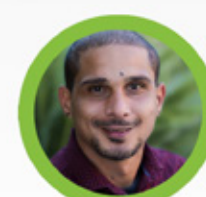
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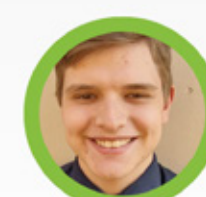
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15:00 - 15:45 Session 6: NRAs Pharma Regulatory Updates - Southern Africa



Moderated by
Dr. Heba El Balakousy
Regional Regulatory Lead, Africa
Viatris

ZAMRA, Zambia



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

**Ensuring Compliance and Enhancing Oversight:
BoMRA's Regulatory Progress**



Ms. Zukiswa Raditladi
Director of Licensing & Enforcement,
Botswana Medicines Regulatory Authority

Efficient Enabler of Access to Safe, Effective and Quality Health Products



Mr. Lucky Marageni
Medicine Registration Officer (MRO)
South African Health Products Regulatory Authority
(SAHPRA)

15:45 - 16:05 Coffee and Networking Break

16:05 - 17:15 Session 7: AI & Digitalization: Pioneering a New Era in Regulatory Affairs



Moderated by
Dr. Naglaa Fathy
Head of Regulatory Affairs, Novartis
Egypt

Fireside Chat: Smart Labeling in Action: Compliance & Technology



Mr. Marc Chaillou
Head of Sales Europe &
Global Strategic Projects
Schlatender Hase



Dr. Rehab Mehrez
Manager of the General Administration of
Pharmaceutical References and leaflets
Egyptian Drug Authority (EDA)

Scaling Artificial Intelligence for Smarter Regulation



Dr. Shima Salah Sayed
Health Informatics Specialist & BI Developer
Egyptian Drug Authority (EDA)



Dr. Asmaa Yousry
Quality Assurance Unit Manager &
Senior Pharmacist, Pharmaceutical
Information Systems (PIS) - PPMA
Egyptian Drug Authority (EDA)

AI in Data Analytics for Track and Trace Systems



Mr. Mete Karaca
Executive Board Member
Tiga Healthcare Technologies



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

**Fireside Chat: Driving Digital Transformation
in Africa: A Health Authorities**



Mr. Martin Schmid
Chief Operating Officer
corneo GmbH



Dr. Sameh Ben Tkhayat
Head of Pharmaceutical Industries Department
National Agency for Medicines and Health Products (
ANMPS), Tunisia

Path to a Digitalized Regulatory Environment



Pharmaceutical Track & Trace System



e-Prescription



Hospital Information System



Personal Health Record



Population Health Management



Interoperability



HIE Suite



AI & Analytics

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Smart Labeling in Action: Compliance, Technology & Regulation



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4:15 - 5:15pm**

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17:15 - 18:00

Session 8: Building a Stringer Future: Aligning Regulatory Frameworks with Local Vaccine Production in Africa



Moderated by
Dr. Mariham Gergis
Submission Excellence Lead
Emerging markets - EMEA RMC
Johnson & Johnson Innovative Medicine

Laying the Regulatory Groundwork for Local Vaccine Production: Lessons from Nigeria



Dr. Khadijah O. Ade-Abolade
Director (Vaccines, Biologics & Medical
Devices Registration and Regulatory Affairs)
National Agency for Food and Drug
Administration and Control (NAFDAC)

Bridging Preclinical and Clinical Evaluation to Vaccine Development and Local Manufacturing Readiness



Dr. Omnia Ayman
Manager of Biological Protocols Unit &
GCP Inspector, Egyptian Drug Authority
(EDA)

Panel Discussion: Regulation to Reliance in Building Africa's Vaccine Ecosystem



Dr. Khadijah O. Ade-Abolade
Director (Vaccines, Biologics & Medical
Devices Registration and Regulatory Affairs)
National Agency for Food and Drug
Administration and Control (NAFDAC)



Dr. Omnia Ayman
Manager of Biological Protocols Unit &
GCP Inspector, Egyptian Drug Authority
(EDA)



Dr. Samar Roshdy
Senior Regulatory Affairs Manager
GSK Egypt

18:00 - 18:30

Coffee and Networking Break



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