

**2<sup>nd</sup> - 3<sup>rd</sup>  
November  
2025**



## DAY 1

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| 08:30 - 09:00 | <b>Coffee and Registration</b>                                                                 |                                                                                                                 |                                                                                                                         |
| 09:00 - 10:00 | <b>Opening Ceremony</b>                                                                        |                                                                                                                 |                                                                                                                         |
|               | Dr. Mona Al Moussli                                                                            | Chairman of the 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, Egyptian Drug Authority (EDA), Egypt                                                                  |                                                                                                                         |
|               | Dr. Hesham Badr                                                                                | Vice Chairman, Unified Procurement Authority, The Egyptian Authority for Unified Procurement (UPA), Egypt       |                                                                                                                         |
|               | Mr. Asif Alavi                                                                                 | General Manager North Africa, Haleon                                                                            |                                                                                                                         |
| 10:00 - 11:00 | <b>Session 1: Unity In Action: Convergence, Harmonization &amp; Work-Sharing Across Africa</b> | <b>Moderator: Dr. Fatima Zaid Abu Zanat</b>                                                                     | <b>Regional Director of Regulatory Affairs &amp; Scientific Office – Middle East, Turkey &amp; Africa, Ipsen Pharma</b> |
|               | Advancing Regulatory Harmonisation in Africa                                                   | Dr. Nancy Ngum                                                                                                  | Public Health Officer, African Union Development Agency – New Partnership for Africa's Development (AUDA-NEPAD)         |
|               | <b>Panel Discussion</b>                                                                        |                                                                                                                 |                                                                                                                         |
|               | Dr. Nancy Ngum                                                                                 | Public Health Officer, African Union Development Agency – New Partnership for Africa's Development (AUDA-NEPAD) |                                                                                                                         |
|               | Ms. Sakhile Dube-Mwedzi                                                                        | Program Co-ordinator, SADC MRH, ZAZIBONA                                                                        |                                                                                                                         |
|               | Dr. Mariam Aounallah                                                                           | Project Manager - Agency of Medicines and Health Products, ANMPS, Tunisia                                       |                                                                                                                         |
|               | Dr. Sonia Sebai Ben Amor                                                                       | Head of National Control Laboratory, National Regulatory Authority, Tunisia                                     |                                                                                                                         |
|               | Dr. Bunmi Femi-Oyekan                                                                          | Regulatory Lead (Snr Director) Accord and Access, Emerging Market, Pfizer                                       |                                                                                                                         |

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| <b>11:00 - 11:45</b> | <b>Session 2: NRA Pharma Regulatory Updates - North Africa</b>                                      | <b>Moderator:<br/>Dr. Neveen Kamel</b>          | <b>Head of Regulatory Affairs North Africa, Egypt, French Speaking Africa &amp; Scientific Office Manager, Merck</b>                                                       |
|                      | Egyptian Drug Authority Regulatory Updates and Reliance Progress                                    | Dr. Mariam Maged Moris Mosaad                   | Human Variation Administration Manager, Egyptian Drug Authority (EDA), Egypt                                                                                               |
|                      | Latest Regulatory Updates from Tunisia: Focus on the eCTD Implementation Project                    | Dr. Sameh Ben Tkhayet                           | Head of Pharmaceutical Industries Department, National Agency for Medicines and Health Products (ANMPS), Tunisia                                                           |
|                      | Regulatory Reliance: Accelerating Access to Medicines Through Collaboration and Mutual Trust        | Dr. Naouel Assam                                | Deputy Director of Technical and Regulatory Affairs in the Directorate of Pharmaceutical Product Registration, National Agency for Pharmaceutical Products (ANPP), Algeria |
| <b>11:45 - 12:05</b> | <b>Coffee and Networking Break</b>                                                                  |                                                 |                                                                                                                                                                            |
| <b>12:05 - 13:15</b> | <b>Session 3: Africa's Journey to WHO Maturity Level 3: Milestones and the Path Forward</b>         | <b>Moderator:<br/>Dr. May Badran</b>            | <b>Regulatory Director - Egypt, Saudi and Africa, Abbott</b>                                                                                                               |
|                      | Achieving WHO Maturity Level 3: Africa's Journey and the Regional Path Forward                      | Ms. Diana Diaz Guzman                           | Senior Regulatory Intelligence Manager, United States Pharmacopeia (USP)                                                                                                   |
|                      | Strength in Every Byte: Data Integrity as Africa's Path to Maturity Level 3                         | Dr. Madelein Terblanche<br>Ms. Khanyisile Nkuku | Senior Operations Consultant, VECTOR Life Sciences<br>Medical Device & IVD Registration Officer, South African Health Products Regulatory Authority (SAHPRA), South Africa |
|                      | From Establishment to Recognition: EDA's Success Story Toward WHO ML3                               | Dr. Dalia Abou Hussein                          | QA General Manager, Egyptian Drug Authority (EDA), Egypt                                                                                                                   |
|                      | <b>Panel Discussion: Regulatory System Advancement: Country Insights on Achieving WHO ML3</b>       |                                                 |                                                                                                                                                                            |
|                      | Ms. Diana Diaz Guzman                                                                               |                                                 | Senior Regulatory Intelligence Manager, United States Pharmacopeia (USP)                                                                                                   |
|                      | Dr. Madelein Terblanche                                                                             |                                                 | Senior Operations Consultant, Vector Life Sciences                                                                                                                         |
|                      | Ms. Khanyisile Nkuku                                                                                |                                                 | Medical Device & IVD Registration Officer, South African Health Products Regulatory Authority (SAHPRA), South Africa                                                       |
|                      | Dr. Dalia Abouhussein                                                                               |                                                 | QA General Manager, Egyptian Drug Authority (EDA), Egypt                                                                                                                   |
|                      | Ms. Folasade Osho                                                                                   |                                                 | Assistant Director, Deputy Quality Manager, National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria                                                 |
| <b>13:15 - 14:00</b> | <b>Session 4: Access First: Unlocking the Power of OTC for Self-Care Across African Communities</b> | <b>Moderator:<br/>Ms. Marlene Moonsamy</b>      | <b>Managing Director - PHARMICI (Pty) Ltd</b>                                                                                                                              |
|                      | <b>Panel Discussion</b>                                                                             |                                                 |                                                                                                                                                                            |
|                      | Dr. Haidy Morsy                                                                                     |                                                 | Director of Regulatory Affairs, Egypt & North Africa, Haleon                                                                                                               |
|                      | Dr. Abeer Elbehairy                                                                                 |                                                 | General Manager of General Administration of Pharmacy Practice, Egyptian Drug Authority (EDA), Egypt                                                                       |
|                      | Ms. Folasade Osho                                                                                   |                                                 | Assistant Director, Deputy Quality Manager, National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria                                                 |
|                      | Dr. Amal Fathy                                                                                      |                                                 | AMET Science Hub Head, Opella                                                                                                                                              |
| <b>14:00 - 15:00</b> | <b>Group Photo, Lunch and Networking</b>                                                            |                                                 |                                                                                                                                                                            |

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| 15:00 - 16:00 | Session 5: NRA Pharma Regulatory Updates - West Africa                                                                       | Moderator:<br>Mr. Merouane Mouri | Director, Regulatory Affairs lead North French West Africa, Pfizer                                                                                                                                          |
|               | The West Africa Medicines Regulatory Harmonization Initiative: Impact on Access to Medical Products                          | Dr. Pierre K. Tchamdja           | Pharmaceuticals Professional Officer, West African Health Organization (WAHO)                                                                                                                               |
|               | Current Regulatory Landscape in Nigeria                                                                                      | Ms. Folasade Osho                | Assistant Director, Deputy Quality Manager, National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria                                                                                  |
|               | The Pharmaceutical Regulatory Framework in Côte d'Ivoire AIRP, A Model Independent Administrative Authority and Its Progress | Dr. Audrey Dindji                | Head of Vigilance and Clinical Trials Department , Ivorian Pharmaceutical Regulatory Authority (AIRP), Côte d'Ivoire                                                                                        |
|               | Serialization Project in Senegal                                                                                             | Mr. Ndataly Fall                 | Head of Data Storage and Transfer, Serialization Department, Senegalese Pharmaceutical Regulatory Agency (ARP), Senegal                                                                                     |
|               | Pharmaceutical Regulation in Benin                                                                                           | Dr. Nathalie Migan Diogo         | Pharmacist, Chair of Supervisory Board of the Pharmaceutical Sub-Sector (CS-SSP), and Chair, National Committee for the Coordination of the Fight Against Substandard and Falsified Health Products (CNCLP) |
|               | Current Updates in Pharmaceutical Regulation - FDA Ghana                                                                     | Ms. Evelyn Aseawa Paintsil       | Regulatory Officer, Drugs and Nutraceuticals Department, Food and Drugs Authority (FDA), Ghana                                                                                                              |
| 16:00 - 17:00 | NRA Roundtable Discussions                                                                                                   |                                  |                                                                                                                                                                                                             |
| 17:00 - 17:45 | Coffee and Registration                                                                                                      |                                  |                                                                                                                                                                                                             |



## DAY 2

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| 08:30 - 09:00 | Coffee and Registration                                                                                                               |                                        |                                                                                                                                                                              |
| 09:00 - 09:15 | Opening Remarks Day 2                                                                                                                 |                                        |                                                                                                                                                                              |
|               | Mr. Gorkem Aydin                                                                                                                      |                                        | CMO, VISIOTT TPS                                                                                                                                                             |
| 09:15 - 10:15 | <b>Session 1: Made In Africa:<br/>Empowering Local Pharmaceutical Manufacturing</b>                                                   | <b>Moderator:<br/>Dr. Khaled Rozza</b> | <b>Regulatory Affairs Lead Gulf, Acino</b>                                                                                                                                   |
|               | Navigating African Capabilities in Pharmaceutical Localization                                                                        | Dr. Rawya Kredly                       | Director Medical & Regulatory Affairs, Julphar                                                                                                                               |
|               | Empowering Africa's Manufacturers: USP's Support for Local Manufacturers, Medicines Quality and Access                                | Dr. Sara Nageeb El-Helaly              | Public Policy and Regulatory Affairs Sr. Manager, The United States Pharmacopeia EMEA                                                                                        |
|               | <b>Panel Discussion: Public-Private Partnerships: Enhancing Local Capacity and Ensuring Quality Standards in Pharma Manufacturing</b> |                                        |                                                                                                                                                                              |
|               | Dr. Mariam Maged Moris                                                                                                                |                                        | Human Variation Administration Manager, Egyptian Drug Authority (EDA), Egypt                                                                                                 |
|               | Mr. Nathan Seyoum                                                                                                                     |                                        | External Medicine Assessor, Ethiopian Food and Drug Authority (EFDA), Ethiopia, and Regional Coordinator, East African Regulatory Affairs Professionals Association (EARAPA) |
|               | Dr. Rawya Kredly                                                                                                                      |                                        | Director Medical & Regulatory Affairs, Julphar                                                                                                                               |
| 10:15 - 11:15 | <b>Session 2: Ensuring Safety and Compliance:<br/>Regulatory Perspectives In Track &amp; Trace &amp; Seriallization</b>               | <b>Moderator: Dr. Mai Magd</b>         | <b>Regulatory Affairs Manager, Merck Sharp &amp; Dohme</b>                                                                                                                   |
|               | 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 and Market Access, Egyptian Drug Authority (EDA), Egypt                       |
|               |                                                                                                                                       | Mr. Gorkem Aydin                       | Chief Marketing Officer, VISIOTT TPS                                                                                                                                         |
|               | Strengthening Pharma Regulations: Leveraging e-Prescriptions for Industry Advancement                                                 | 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, National Drug Authority (NDA), Uganda                                                                                                                    |
|               |                                                                                                                                       | Mr. Marwan Zeidan                      | VP of Business Development and Customer Servicing, EVOTEQ                                                                                                                    |
|               | <b>Panel Discussion: Building a Unified Track &amp; Trace System In Across Africa</b>                                                 |                                        |                                                                                                                                                                              |
|               | Mr. Lyoko Nyambe                                                                                                                      |                                        | Director Marketing Authorisation, Zambia Medicines Regulatory Authority (ZAMRA), Zambia                                                                                      |
|               | Ms. Folasade Osho                                                                                                                     |                                        | Assistant Director, Deputy Quality Manager, National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria                                                   |
| 11:15 - 11:45 | Coffee and Networking Break                                                                                                           |                                        |                                                                                                                                                                              |

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| 11:45 - 12:45 | <b>Session 3: Advancing Regulatory Convergence: Strengthening Capacity and Harmonizing Pathways for Biologics, Biosimilars, and Conventional Medicines</b>                                                                                          | <b>Moderator:</b><br>Dr. Angeline Achoka   | <b>Senior Regulatory Affairs Manager SSA - QPPV Kenya, AstraZeneca</b>                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|               | 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|               | <b>Panel Discussion: Strengthening African Regulatory Capacity of Biologics &amp; Biosimilars</b><br>Mr. Varma Bhupathiraju<br>Dr. Samar Hamedo El Sayed Mohamed Rizk<br>Dr. Sonia Sebai Ben Amor<br>Mr. Makram Atef<br>Dr. Khadijah O. Ade-Abolade |                                            | Associate Vice President - Global Regulatory Affairs, Biocon Biologics Limited<br>Biologicals Registration Administration Manager, Egyptian Drug Authority (EDA), Egypt<br>Head of National Control Laboratory,<br>National Regulatory Authority (ANMPS), Tunisia<br>Regulatory Affairs Senior Manager, Egypt Merck<br>Director - Vaccines, Biologics & Medical Devices Registration & Regulatory Affairs<br>Directorate, National Agency for Food and Drug Administration and Control (NAFDAC),<br>Nigeria |
| 12:45 - 13:15 | <b>Session 4: NRA Pharma Regulatory Updates - East Africa</b>                                                                                                                                                                                       | <b>Moderator:</b><br>Dr. George Kamal      | <b>Regional Regulatory Affairs Hub Head – MEAR, Merck Group</b>                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|               | Regulatory Insights from the National Drug Authority-Uganda: GMP and Marketing Authorization                                                                                                                                                        | Dr. Rachel Juliet Mujawimana               | Inspector of Drugs, National Drug Authority (NDA), Uganda                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|               | Developments in Marketing Authorization Processes in Kenya                                                                                                                                                                                          | Dr. Kariuki Gachoki                        | Deputy Director, Product Evaluation & Registration,<br>Chairperson, Continental Forum of Heads of Registration and Marketing Authorization,<br>AMRH, Pharmacy and Poisons Board,<br>Ministry of Health, Kenya                                                                                                                                                                                                                                                                                               |
|               | Strides to Regulatory Excellence; The Ethiopian Food and Drug Authority (EFDA) and Its Momentum of Change 2025                                                                                                                                      | Dr. Abebe Alamneh                          | Medicine Registration Expert, Ethiopian Food and Drug Authority (EFDA), Ethiopia                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 13:15 - 14:15 | <b>Lunch and Networking</b>                                                                                                                                                                                                                         |                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 14:15 - 15:00 | <b>Session 5: Regulatory Resilience: Preparing for Health Emergencies &amp; Supply Chain Disruptions</b>                                                                                                                                            | <b>Moderator:</b><br>Dr. Heba Nabli        | <b>Regulatory Sciences Director, Pfizer and Chair, Regulatory Working Group (RWG) of the Egyptian Foundation for Pharmaceutical Research (EFPR)</b>                                                                                                                                                                                                                                                                                                                                                         |
|               | Leveraging Digital Health Technologies for Regulatory Resilience                                                                                                                                                                                    | Mr. Arthur Sichivula                       | ICT Manager, Zambia Medicines Regulatory Authority (ZAMRA), Zambia                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|               | Resilient Regulation in Action: CEPI's role in Preparing for Emergencies and Supply Chain Disruptions                                                                                                                                               | Dr. Jacqueline Acquah                      | Senior Regulatory Strategy Lead Africa & Middle East, Coalition for Epidemic Preparedness Innovations                                                                                                                                                                                                                                                                                                                                                                                                       |
|               | Advancing Local Manufacturing, Streamlining Emergency Approvals, and Strengthening Supply Chain Integrity: Lessons from the COVID-19 Pandemic and Beyond                                                                                            | Ms. Folasade Osho                          | Assistant Director, Deputy Quality Manager,<br>National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria                                                                                                                                                                                                                                                                                                                                                                               |
| 15:00 - 15:45 | <b>Session 6: NRAs Pharma Regulatory Updates - Southern Africa</b>                                                                                                                                                                                  | <b>Moderator:</b><br>Dr. Heba El Balakousy | <b>Regional Regulatory Lead - Africa, Viatris</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|               | Ensuring Compliance and Enhancing Oversight: BoMRA's Regulatory Progress                                                                                                                                                                            | Ms. Zukiswa Raditladi                      | Director Licensing and Enforcement, Botswana Medicines Regulatory Authority (BoMRA), Botswana                                                                                                                                                                                                                                                                                                                                                                                                               |
|               | ZAMRA: Regulatory Updates                                                                                                                                                                                                                           | Mr. Lyoko Nyambe                           | Director Marketing Authorisation, Zambia Medicines Regulatory Authority (ZAMRA), Zambia                                                                                                                                                                                                                                                                                                                                                                                                                     |
|               | SAHPRA: An Enabler of Access to Safe, Effective and Quality Health Products in South Africa                                                                                                                                                         | Mr. Lucky Marageni                         | Medicine Registration Officer, South African Health Products Regulatory Authority (SAHPRA), South Africa                                                                                                                                                                                                                                                                                                                                                                                                    |
| 15:45 - 16:05 | <b>Coffee and Networking Break</b>                                                                                                                                                                                                                  |                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

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| 16:05 - 17:15 | <b>Session 7: AI &amp; Digitalization: Pioneering a New Era in Regulatory Affairs</b>                                                                                                                                                                                                                                                                                                                                                                    | <b>Moderator:</b><br><b>Dr. Naglaa Fathy</b>                                                                                                                                                                      | <b>Regulatory Affairs Head GDD, Novartis</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|               | <p>Fireside Chat: Smart Labeling in Action: Compliance &amp; Technology</p> <p>Scaling Artificial Intelligence for Smarter Regulation</p> <p>AI in Data Analytics for Track and Trace Systems</p> <p>Towards a Unified Submission Paradigm: Enhancing Regulatory Preparedness through Collaboration and Technology</p> <p>Fireside Chat: Driving Digital Transformation in Africa: A Health Authorities Path to a Digitalized Regulatory Environment</p> | <p>Mr. Marc Chaillou</p> <p>Dr. Rehab Mehrez</p> <p>Dr. Shimaa Salah Sayed</p> <p>Dr. Asmaa Yousry</p> <p>Mr. Mete Karaca</p> <p>Dr. Alessandro Lazdins</p> <p>Mr. Martin Schmid</p> <p>Dr. Sameh Ben Tkhayet</p> | <p>Head of Sales Europe &amp; Global Strategic Projects, Schlafender Hase GmbH</p> <p>Manager of the General Administration of Pharmaceutical References and Leaflets, Egyptian Drug Authority (EDA), EDA</p> <p>Health Informatics Specialist &amp; BI Developer, Egyptian Drug Authority (EDA), Egypt</p> <p>Executive Board Member, Tiga Healthcare Technologies</p> <p>Senior Regulatory Policy and Intelligence Manager, Coalition for Epidemic Preparedness Innovations</p> <p>Chief Operating Officer, corneo GmbH</p>                                                                                                    |
| 17:15 - 18:00 | <b>Session 8: Building a Stronger Future: Aligning Regulatory Frameworks with Local Vaccine Production in Africa</b>                                                                                                                                                                                                                                                                                                                                     | <b>Moderator by:</b><br><b>Dr. Mariham Gergis</b>                                                                                                                                                                 | <b>Submission Excellence Lead - Emerging Markets - EMEA RMC, Johnson &amp; Johnson Innovative Medicine</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|               | <p>Laying the Regulatory Groundwork for Local Vaccine Production: Lessons from Nigeria</p> <p>Bridging Preclinical and Clinical Evaluation to Vaccine Development and Local Manufacturing Readiness</p> <p><b>Panel Discussion: Regulation to Reliance in Building Africa's Vaccine Ecosystem</b></p> <p>Dr. Khadijah O. Ade-Abolade</p> <p>Dr. Omnia Ayman</p> <p>Dr. Samar Roshdy</p>                                                                  |                                                                                                                                                                                                                   | <p>Director (Vaccines, Biologics &amp; Medical Devices Registration &amp; Regulatory Affairs), Directorate National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria</p> <p>Manager of Biological Protocols Unit and GCP Inspector, Egyptian Drug Authority (EDA), Egypt</p> <p>Director (Vaccines, Biologics &amp; Medical Devices Registration &amp; Regulatory Affairs), Directorate National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria</p> <p>Manager of Biological Protocols, Egyptian Drug Authority (EDA), Egypt</p> <p>Senior Regulatory Affairs Manager, GSK Egypt</p> |
| 18:00 - 18:30 | <b>Coffee and Networking Break</b>                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |