



Call for Expression of interest

Biological and/or Vaccine Manufacturing Facilities to Host Mock Inspections by AMRH GMP Inspectors

The African Medicines Regulatory Harmonization (AMRH) program is pleased to invite expressions of interest (EoI) from biological and/or vaccine manufacturing facilities to participate in our GMP Technical Committee mock inspection program.

Program Objective:

This program aims to build the capacity of African regulatory Good Manufacturing Practice (GMP) inspectors by conducting simulated inspections at operational facilities. The mock inspections will provide valuable practical experience for inspectors while familiarizing participating facilities with the continental GMP standards and inspection procedures to be implemented by the African Medicines Agency (AMA).

Benefits for Participating Facilities:

- 1. Gain firsthand experience with the AMRH continental GMP inspection process.
- 2. Identify areas for potential improvement in your facility's adherence to GMP standards.
- 3. Enhance understanding of the upcoming continental GMP regulations and guidelines.
- 4. Demonstrate your commitment to quality and regulatory compliance.

Important Information:

- 1. The mock inspections will be conducted by qualified AMRH inspectors.
- 2. All costs associated with the inspections will be covered by the AMRH program.
- 3. The outcomes of the mock inspections will be for learning purposes only and will

have no regulatory implications for the participating facilities.

Eligibility:

- 1. Operational biological and/or vaccine manufacturing facilities located in Africa and outside Africa.
- 2. Strong commitment to maintaining high GMP standards.

Submission Process:

Interested facilities should submit an Eol by Friday, August 30, 2024 to amrh@nepad.org with the heading, EOI Mock inspections_ GMP TC. The EoI should include the following information:

- 1. Facility name and location
- 2. Type of biological or vaccine products manufactured
- 3. Contact information (name, title, email, phone number)

Selection Process:

AMRH will select a limited number of facilities to participate in the program based on the eligibility criteria and the diversity of products and geographic locations represented.

For further inquiries, please contact: AMRH Secretariat | amrh@nepad.org

We encourage all eligible facilities to submit an EoI and participate in this important capacity-building initiative.

