# INFORMATION NOTE

## Preparing for a continental GMP Inspection by AMRH inspectors in support of the Pilot for Human Medicinal Products Listing

To: **Manufacturers participating in the Continental Pilot**
From: **African Medicines Regulatory Harmonization (AMRH)**
Subject: **Pre-inspection document submission for GMP compliance assessment**

### Introduction

This information note outlines the key documents manufacturers should submit electronically to gmp@amrh.org ahead of a scheduled continental Good Manufacturing Practice (GMP) inspection by AMRH inspectors. Providing this information in advance allows inspectors to prepare effectively and gain an understanding of your manufacturing site's operations. A well-organized submission streamlines the inspection process and facilitates a more focused continental GMP assessment.

### Required Documents

Please submit the following documents electronically at least 15 days after the submission of your dossier or prior to your scheduled inspection (where applicable):

1. **Quality Policy:** This document outlines your commitment to quality pharmaceutical manufacturing that adheres to continental GMP regulations.
2. **Quality Manual:** This comprehensive document details your quality management system (QMS) and its implementation across the organization.
3. **Site Master File (SMF):** This file compiles essential information about your facility.
4. Site layout and facility of interest's material and process flow schematic drawing.
5. **Validation Master Plan (VMP):** This plan outlines your approach to validating processes, equipment, and cleaning procedures, ensuring they meet GMP and quality expectations.
6. **Standard Operating Procedures (SOPs) Index:** A list of all SOPs available for all manufacturing processes and activities:
7. Where applicable, **list of products, batch numbers and quantities** exported to any African Union member states participating in the AMRH program in the preceding two years to the inspection date.
8. **Approved and current organizational chart/ organogram** showing the key personnel and departments at the manufacturing facility.
9. **Where applicable; GMP certifications held (such as from country of origin, SRAs, or WHO PQ inspections)**

### Benefits of Pre-Submission

- Allows AMRH inspectors to tailor their inspection plan to your specific operations and ensure alignment with continental GMP guidelines.
- Reduces on-site inspection time, minimizing disruption to your manufacturing activities. This may also allow for the GMP Technical Committee to opt for the desk assessment or remote inspections.
- Facilitates a more focused and efficient inspection process focused on areas requiring deeper evaluation.

By working together, we can ensure a smooth and efficient continental GMP inspection that upholds the highest quality standards for medicines across Africa.

### Contact Information

For any questions regarding this information note or the pre-inspection document submission process, please contact the AMRH Secretariat at gmp@amrh.org and copy to: amrh@nepad.org

AMRH
African Medicines Regulatory Harmonisation Programme