National Agency for Food & Drug Administration & Control (NAFDAC)
Drug Evaluation & Research (DER) Directorate

GUIDELINES FOR PRE-PRODUCTION INSPECTION OF PHARMACEUTICAL MANUFACTURING FACILITIES IN NIGERIA

1. GENERAL

1.1 These guidelines are for the interest of the general public and in particular the pharmaceutical manufacturing companies in Nigeria.

1.2 It is necessary to emphasize that, no regulated product should be manufactured, imported, exported, advertised, sold, or distributed in Nigeria unless it has been registered in accordance with the provisions of the Food, Drugs and Related Products Act Cap F33 LFN 2004 (and the accompanying guidelines.

1.3 A drug product should not be manufactured in Nigeria unless the facility has been inspected, found to comply with Good Manufacturing Practices and an Authority to Manufacture pharmaceutical products is issued by NAFDAC.

1.4 These guidelines prescribe the minimum requirements necessary for the issuance of Authority to Manufacture Pharmaceutical products.

2. APPLICATION FOR INSPECTION

2.1. An application for Pre-Production Inspection should be made on the company's letter-headed paper and addressed to:
The Director, Drug Evaluation & Research Directorate, NAFDAC Office Complex, Apapa Oshodi Expressway. Isolo, Lagos. The exact location address (NOT P.O. Box) of the proposed factory, functional e-mail address, telephone number(s) and intended product formulation lines should be stated.

2.2. An electronic copy of the detailed factory layout showing man and material flow, room classifications and pressure differentials between adjoining areas should be attached.

2.3. The above application should be sent to der.pharmaquarters@nafdac.gov.ng

2.4. Upon submission of the application letter, a payment advice for the review of the factory layout would be sent to the company's email.

2.5. On receipt of the payment advice, the below-listed steps should be followed to make payment for the inspection:

2.5.1. Visit www.remita.net to generate a Remita invoice and print out a copy of the invoice.

2.5.2. Visit the nearest commercial bank to make the payment.

2.5.3. Collect an official receipt of payment from the Finance & Accounts Section; 3rd Floor, NAFDAC Office Complex, Isolo, Lagos or the nearest NAFDAC office (for applicants outside Lagos).

2.6. The receipt of payment should be submitted via der.pharmaquarters@nafdac.gov.ng using the same email thread with which the payment advice was sent to the company.

2.7. Upon satisfactory outcome of the layout review, a payment advice for the Pre-Production Inspection of the facility would be sent to the company's email.

2.8. The receipt of payment for the inspection and electronic copies of the following documents should be submitted.

2.8.1. Site Master File of the proposed facility

2.8.2. Evidence of company incorporation

2.8.3. Evidence of License to Practice of the Superintendent and Production Pharmacists by the Pharmacists Council of Nigeria

2.8.4. Company Quality Manual

2.8.5. Validation Master Plan for the facility

3. SCHEDULING OF FACILITY FOR INSPECTION

3.1. Upon submission of evidence of payment to DER Directorate, the facility is scheduled for inspection at the earliest convenient date.

4. DOCUMENTATION

The following documents should be made available during the inspection

4.1. Site Master File
4.2. Current Annual Licence to Practice of the Superintendent and Production Pharmacists issued by the PCN.
4.3. Letters of Appointment and Acceptance of key officers.
4.4. Credentials of the key officers. (Minimum qualification should be first degree in the relevant disciplines)
4.5. Job Descriptions for the key personnel
4.6. Validation master Plan for the facility
4.7. Documentary evidence showing Qualification of Production and Laboratory Equipment
4.8. Documentary evidence showing Analytical Method Validation/Verification
4.9. Documentary evidence showing Water System Validation (where applicable)
4.10. List of Production and Quality Control equipment and their identification numbers
4.11. Any other relevant documents.

5. GOOD MANUFACTURING PRACTICE REQUIREMENTS

5.1. Please refer to the NAFDAC Good Manufacturing Practice for Pharmaceutical Products. Guidelines 2024 available at www.nafdac.gov.ng for full guidance.
5.2. Post-approval changes such as modification of facilities, introduction of new production lines, changes in /replacement of major utilities or manufacturing equipment should warrant a notification to and approval by NAFDAC. However, minor post approval changes such as equipment parts may only be listed and managed in line with manufacturers' change management procedures.

6. TARIFF

6.1. Please refer to the appropriate section in the NAFDAC Approved Tariffs available at www.nafdac.gov.ng
6.2. All fees attract 7.5% VAT.

7. CORRESPONDENCE

All correspondence should be addressed to:
The Director-General (NAFDAC)
Attn: The Director,
Drug Evaluation & Research Directorate
1st Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Expressway Isolo, Lagos State.
NAFDAC website: www.nafdac.gov.ng
E-mail address: der.pharmaquarters@nafdac.gov.ng

Note:

- All submissions should be made to der.pharmaquarters@nafdac.gov.ng or at the Office of the Director, DER; 1st Floor, NAFDAC Office Complex, Isolo Industrial Estate, Apapa-Oshodi Expressway Isolo, Lagos or the nearest NAFDAC Office (for applicants outside Lagos).
- Inspection reports for all inspections would be shared with the company. Unsatisfactory outcome of inspection leads to a stop in the process clock until the applicant responds satisfactorily to the directives.