

NATIONAL DRUG AUTHORITY



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PROCEDURE FOR ESTABLISHING A PHARMACEUTICAL AND MEDICAL DEVICES MANUFACTURING COMPANY

1. The applicant should register the manufacturing company with the registrar of companies and provide NDA with certified copies of the memorandum and articles of association.
2. The applicant should provide an environment impact assessment report from National Environment Management Authority (NEMA).
3. Authorization from the Uganda Investment Authority and City or Municipal council should also be obtained.
4. The applicant then submits intention to manufacture together with the following documents
 - a. Letter of intention to manufacture human medicines or medical devices
 - b. Company Profile
 - c. Architectural plan of the site.
 - d. NEMA impact assessment report
 - e. Authorization letter by the Uganda Investment Authority and or City or Municipal authorities.
5. The documents are reviewed and any additional information requested if necessary.
6. After satisfactory review of the preliminary documentation, the company is given approval to start construction.
7. Preliminary inspection is carried out at various stages of construction and setting up the site. These include
 - a. Site inspection before construction
 - b. Completion of construction of the building

- c. Completion of installation of support systems and equipment.
8. After commissioning the facility, the company submits a formal application for GMP inspection and a license to manufacture drugs or devices as the case may apply.
9. GMP inspection is conducted by NDA once the application form is submitted with all the required documentation and prescribed fees. These include:
 - a. Letter requesting for inspection
 - b. Completed application form for manufacture of pharmaceutical products or medical devices.
 - c. Site Master File
 - d. List of products to be manufactured at the facility
10. GMP compliance assessment and licensing of premises to manufacture medicines/medical devices for human and veterinary use is carried out by the Inspectorate department and approval granted by the Technical Committee of NDA following the normal procedure for inspection of local manufacturers.