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GUIDELINES FOR PREPARATION OF A SITE MASTER FILE FOR PHARMACEUTICAL MANUFACTURING FACILITIES

Introduction

1. A site master file is a document prepared by the manufacturer containing specific and factual Good Manufacturing Practice (GMP) information about the production and/or control of pharmaceutical manufacturing operations carried out at the named site and any closely integrated operations at adjacent and nearby buildings. If only part of a pharmaceutical operation is carried out on the site, the site master file need describe only those operations, e.g., analysis, packaging.
2. When submitted to a regulatory authority, the Site Master File will provide information on the manufacturer's operations and procedures that will used in the efficient planning and undertaking of a GMP inspection. It will also be used in the assessment of facilities that undergo document assessment.
3. The Site Master File should have an edition number and an effective date. Valid Site Master Files should be submitted for the above mentioned purpose.
4. A site master file should be succinct and, as far as possible, not exceed 25 A4 pages.
5. A Site Master File for each manufacturing site from where drugs intended to be registered for sale and use on the Ugandan market together with the completed GMP inspection application form must be submitted to:

The Executive Secretary/Registrar
National Drug Authority
Plot 46-48 Lumumba Avenue
P.O Box 23096, Kampala, UGANDA

Layout of the SMF

Front page

Table of contents

1. General information

1.1 Brief information on the firm (including name and address), relation to other sites and, in particular, and any information relevant to understanding the manufacturing operations.

1.2 Pharmaceutical manufacturing activities as licensed by the national authority.

1.3 Any other manufacturing activities carried out on the site.

1.4 Name and exact address of the site, including telephone, fax, and 24-hour telephone numbers.

1.5 Type of products manufactured on the site, and information about any specifically toxic or hazardous substances handled, mentioning the way they are manufactured (in dedicated facilities or on a campaign basis).

1.6 Short description of the site (size, location, and immediate environment and other manufacturing activities on the site).

1.7 Number of employees engaged in production, quality control, storage, and distribution.

1.8 Use of outside scientific, analytical, or other technical assistance in relation to manufacture and analysis.

1.9 Short description of the quality management system of the firm responsible for manufacture.

2. Personnel

2.1 Organization chart showing the arrangements for quality assurance, including production and quality control.

2.2 Qualifications, experience, and responsibilities of key personnel.

2.3 Outline of arrangements for basic and in-service training and how records are maintained.

2.4 Health requirements for personnel engaged in production.

2.5 Personnel hygiene requirements, including clothing.

3. Premises and equipment

3.1 Simple plan or description of manufacturing areas with indication of scale (architectural or engineering drawings not required).

3.2 Nature of construction and finishes.

3.3 Brief description of ventilation systems. More details should be given for critical areas with potential risks of airborne contamination (schematic drawings of the systems are desirable). Classification of the rooms used for the manufacture of sterile products should be mentioned.

3.4 Special areas for the handling of highly toxic, hazardous, and sensitizing materials.

3.5 Brief description of water systems (schematic drawings of the systems are desirable), including sanitation.

3.6 Description of planned preventive maintenance programmes for premises and of the recording system. Equipment

3.7 Brief description of major equipment used in production and control laboratories (a list of equipment is not required).

3.8 Description of planned preventive maintenance programmes for equipment and of the recording system.

3.9 Qualification and calibration, including the recording system. Arrangements for computerized systems validation. Sanitation

3.10 Availability of written specifications and procedures for cleaning manufacturing areas and equipment.

4. Documentation

4.1 Arrangements for the preparation, revision, and distribution of necessary documentation for manufacture.

4.2 Any other documentation related to product quality that is not mentioned elsewhere (e.g., microbiological controls on air and water).

5. Production

5.1 Brief description of production operations using, wherever possible, flow sheets and charts specifying important parameters.

5.2 Arrangements for the handling of starting materials, packaging materials, and bulk and finished products, including sampling, quarantine, release, and storage.

5.3 Arrangements for the handling of rejected materials and products.

5.4 Brief description of general policy for process validation.

6. Quality control

6.1 Description of the quality control system and of the activities of the quality control department. Procedures for the release of finished products.

7. Contract manufacture and analysis

7.1 Description of the way in which the GMP compliance of the contract acceptor is assessed.

8. Distribution, complaints, and product recall

8.1 Arrangements and recording system for distribution.

8.2 Arrangements for the handling of complaints and product recalls.

9. Self-inspection

9.1 Short description of the self-inspection system.

10. Shelf life / Stability determination program

10.1 General policy for the determination of the shelf-life and stability of products manufactured at the site.

References:

1. WHO Guidelines for drafting a Site Master File (SMF)
2. National Drug Policy and Authority Regulations, 1995 (Part V)
3. PIC/S Explanatory notes on the preparation of a Site Master File PE-008, 2007