HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

DECEMBER 2019

GUIDANCE NOTES ON PREPARATION OF A SITE MASTER FILE FOR GOOD DISTRIBUTION PRACTICE CERTIFICATION

HSA
Health Sciences Authority

A Site Master File (SMF) is a document prepared by the company containing specific and factual Good Distribution Practice (GDP) information about the storage, distribution and deliveries operations carried out at the named site. If only part of these operations is carried out on the site, the SMF needs only to describe those particular activities, e.g. storage only.

HOW AND WHEN SHOULD A SITE MASTER FILE BE SUBMITTED?

A SMF should be concisely written in English and, as far as possible, not exceed 25-30 A4 sheets.

The SMF should be a part of the documentation belonging to the quality management system. The SMF should have an edition number, the date it becomes effective and the date by which it has to be reviewed. The sheets should be paginated and bound to ensure the integrity of the document. Wherever possible, simple plans, outline drawings or schematic layouts are preferred instead of narratives. These plans, drawings etc., can be in larger format to ensure legibility.

The document may be submitted as soft/electronic copy, preferably in readable format (e.g. doc, txt, pdf extension). Image file (such as tiff, jpg extension) may be accepted. The file size of the submitted SMF should be less than 2 MB while maintaining legibility.

The SMF should be updated regularly whenever changes are made. Each Appendix in the SMF can have an individual effective date, allowing for independent updating. Submission of the latest version of the SMF is required upon voluntary application for the GDP Certification. Subsequent updates to the SMF need not be submitted unless upon request by the Health Sciences Authority.

CONTENT OF SITE MASTER FILE

1. GENERAL INFORMATION ON THE COMPANY

1.1 Contact information on the company

1.1.1 Name and official address of the company;

1.1.2 Names and street addresses of the site, buildings and warehouse units located on the site;

1.1.3 Identification number of the site as e.g. GPS details of the site or any other geographic location system;

1.1.4 Contact information of the company including 24 hrs telephone number of the contact personnel in the case of product defects or recalls.

1.2 Description of the site

1.2.1 Provide a map (Appendix 1) indicating the location of the site(s) and the surrounding area. Mark the site(s);

1.2.2 The size of the site, type of buildings and their ages;

1.2.3 Description of the surrounding area and use of properties nearby.

1.3 Authorised activities of the site

1.3.1 Information of the relevant licence issued by the Competent Authority, including the validity period and any conditions and/or restrictions to the licence;

1.3.2 Brief description of import, export, distribution and other activities as authorised by the relevant Competent Authority;

1.3.3 Type of products currently handled;

1.3.4 Other sites (if any)

1.4 Toxic, hazardous or highly sensitising substances handled (if any)

1.4.1 Type of toxic, hazardous or highly sensitising substances handled, specifying if the substance is handled under a contractual agreement with a contract giver;

1.4.2 Description of how such substances are handled and precautions taken.

1.5 Any other operations carried out on the site

Description of non-pharmaceutical activities on-site, if any.

1.6 Employees

1.6.1 Organisation chart showing the arrangements for key personnel (Appendix 2);

1.6.2 Number of employees engaged in administration, warehousing, distribution and transportation, Technical & Engineering Support Services and the total number of the above, indicating part-time or full-time.

1.7 Outsourced activities

Name, address, telephone number and the activity undertaken by each of the contract acceptors.

1.8 Quality management system

1.8.1 The company's Quality Policy;

1.8.1.1 Description of the elements of the quality management e.g. organisational structure, responsibilities, procedures, processes;

1.8.1.2 Description of the audit programmes (self-inspection or audits by external organisations undertaken);

1.8.1.3 Description of how audit criteria are selected and results are reviewed to demonstrate the adequacy of the quality system in relation to the objective i.e. quality and integrity of the product. (see also Chapter 7);

1.8.1.4 Record if other standards such as ISO 9000 etc. are used by the company.

2. PERSONNEL

2.1 Qualifications, experience and responsibilities of key personnel

2.1.1 Brief details of academic qualifications, work-related qualifications and years of relevant experience since qualifying. Include their names.

2.1.2 Job descriptions for the key personnel.

2.2 Personnel training

2.2.1 Description of training programme including induction and continuous training, as follows:

(a) Explain how training needs are identified and by whom.
(b) Give details of training relative to GDP requirements.
(c) State the form of training e.g. in-house, external, and how practical experience is gained and which staff are involved.
(d) Explain how the effectiveness of training is assessed e.g. by questionnaire.
(e) Explain how retraining needs are identified.
(f) Explain how training records are maintained.

3. PREMISES AND FACILITIES

3.1 Layout of premises

3.1.1 Provide a site layout plan highlighting all warehousing and other functional areas labelled with the name/purpose of each area (Appendix 3);

3.1.2 Description of the controls available to prevent unauthorized access.

3.2 Ventilation systems

Brief description of ventilation systems etc.

Note 1: More details should be given for critical areas, e.g. cold room, freezer room.

Note 2: To reduce the narrative, schematic drawings should be used. The

3.3 Special areas for the handling of highly toxic, hazardous and sensitising materials.

Follow the same layout as 3.2.1 above for description of special areas for the handling of highly toxic, hazardous and sensitizing materials.

3.4 Maintenance

Brief description of the planned preventive maintenance programme:

(a) Explain who is responsible for planned preventive maintenance (carried out by the company) and servicing (carried out by an outside contractor).
(b) Explain the written procedures and contractual details for outsourced work.
(c) Explain the written procedures and reporting forms for maintenance and servicing including the information such as type/frequency of service/checks, details of service, repairs and modifications.
(d) Explain how the maintenance that could affect product quality clearly is identified.
(e) Explain how the reports are made known to the users.

3.5 Cleaning

Brief description on cleaning activities for the warehousing areas:

(a) Explain if there are written procedures for cleaning and specifications for cleaning agents and their concentration for the method of cleaning and the frequency.
(b) Explain the cleaning methods (and their frequency) for the vehicles.

3.6 Policy on the storage of materials

3.6.1 Segregation and control on the materials/products of different status (e.g. quarantine, rejects, approved, etc.)
3.6.2 Storage of the materials/products e.g. pallet racking
3.6.3 Storage conditions for narcotic and psychotropic substances, if any
3.6.4 Pest control programme

4 STOCK HANDLING AND STOCK CONTROL

4.1 Arrangements and recording system for distribution

4.1.1 Description of receiving, handling and storage of materials:

(a) Type of checks conducted on the materials

(b) Despatch order using Earliest-Expiry-First-Out (EEFO) or First-In-First-Out (FIFO) and identify the lot number

(c) Methods of distribution to customers

4.1.2 Records of Distribution permitting full batch traceability from the supplier to the customer in terms of the date of sale, customer details and quantity despatched.

4.1.3 Stock take procedure including the information on how it is being conducted and its frequency.

4.1.4 Measures used to verify that each customer/recipient is legally entitled to supply or receive medicinal products to/from the distributor and the medicinal products are genuine and not counterfeit.

4.2 Deliveries and transportation

4.2.1 Description of how the security, storage condition and protection of the quality of materials are considered during transportation.

4.2.2 Description of the vehicle fleet available.

(a) Number of vehicles and their capacity

(b) Is the vehicle dedicated?

(c) Is the vehicle specially adapted to transport special materials (e.g. cold chain products, radioactives)

(d) How are the transport routes planned?

5. DOCUMENTATION

5.1 Document control

Brief description on the arrangements for the preparation, review, revision, distribution and retention of necessary documents, including storage of master documents and documents that are archived off-site containing the following information: List of types of documents/records; Name and address of storage site and an estimate of time required to retrieve documents from the off-site archive.

5.2 Any other documents related to product quality which is not mentioned elsewhere

5.2.1 Training procedures

5.2.2 Computer Programme Specifications

(a) Access to the system (internet, intranet) and the authorisation for granting access

(b) Handling of audit trail and the frequency of review

(c) Backup procedures

5.2.3 Calibration

5.2.4 List and briefly explain the use of any additional standard documentation used routinely.

6. PRODUCT COMPLAINTS AND PRODUCT RECALLS

6.1 Complaints

Brief description of the system for handling complains:

(a) Explain if there is a written procedure for product complaints.
(b) Explain who is responsible for logging, classifying and investigating complaints.
(c) Explain how written records are prepared.
(d) Explain who reviews these records.
(e) Explain how long these records are kept.

6.2 Recalls

Brief description of the system for handling recalls, including who is responsible for coordinating product recalls and who notifies the Competent Authority of recalls. Explain if there is a written procedure describing the sequence of actions to follow including:

(a) Retrieval of distribution data;
(b) Notification of customers;
(c) Receipt/segregation/inspection of returned products;
(d) Investigation/reporting of cause;
(e) Reporting corrective action.

7. SELF INSPECTION

Brief description of the self inspection system with focus on criteria used for selection of the areas to be covered during planned inspections, practical arrangements and follow-up activities.

8. OUTSCOURCED ACTIVITIES

Brief description of the technical contract between the contract giver and acceptor and the way in which the GDP compliance, or compliance with other appropriate standards, is assessed. The selected standards should be assessed for the suitability of its application. The type of activities undertaken by the contract acceptor should be specified.

Appendix 1 Map indicating the location of the site(s) and the surrounding area.
Appendix 2 Organisation chart
Appendix 3 Site layout plan

REFERENCE

1. PIC/S PE 008: Explanatory Notes for Pharmaceutical Manufacturers on the Preparation of a Site Master File

END OF DOCUMENT

HEALTH SCIENCES AUTHORITY

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For enquiry or feedback, please go to:
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