MANUFACTURING & QUALITY AUDIT DIVISION
CENTRE FOR DRUG ADMINISTRATION

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

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GUIDANCE NOTES

Subject: PREPARATION OF A SITE MASTER FILE FOR GOOD DISTRIBUTION PRACTICE CERTIFICATION

WHAT IS A SITE MASTER FILE?

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, eg storage only.

HOW AND WHEN SHOULD A SITE MASTER FILE BE SUBMITTED?

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

The Site Master File should have an edition number and an effective date, and preferably be submitted on loose individually numbered A4 sheets. The sheets should be ring-bound to ensure the integrity of the document. Wherever possible, simple plans, outline drawings or schematic layouts should be used instead of narrative. These plans, drawings etc., should fit on A4 sheets of paper.

The document may be submitted as soft/electronic copy, preferably in readable format (eg doc, txt, pdf extension). Image file (such as tif, 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. Submission is required only upon voluntary application for the GDP Certification. Subsequent updates to the submitted SMF need to be re-submitted only upon request.

The format and heading of the site master file should be set out as follows:-

Chapter 1

C.1 GENERAL INFORMATION

C.1.1	Brief information on the site (including name and address), relation to other sites and, particularly, any information relevant to the understanding of the GDP operations.

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(Not more than 250 words or one A4 sheet)

C.1.1 *Outline the company's activities, other sites (if any), in addition to the site which is the subject of this report.*

C.1.2	GDP operations as licensed by the Competent Authorities.

GUIDANCE

C.1.2.1 *Indicate whether the site has been approved by your own national authority, or any foreign Competent Authority (if the latter, name the authority and state the scope of approval, indicating if it is the same or different description from that in the application).*

C.1.2.2 *Quote the relevant document (licence) as issued by the Competent Authority. State the period of validity of licence document (if the validity of the document is given in the country concerned). Any conditions and/or restrictions should be stated.*

C.1.3	Any other operations carried out on the site.

GUIDANCE

C.1.3 *This covers both pharmaceutical and non-pharmaceutical activities.*

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

GUIDANCE

C.1.4.1 *Name of Company, Site Address and Mailing Address (if different from site address).*

C.1.4.2 *Telephone and Fax Nos. of contact person.*

C.1.4.3 *24-hour contact Telephone No.*

C.1.5	Type of actual products handled on the site and information about specifically toxic or hazardous substances handled, mentioning the way they are handled and precautions taken.

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C.1.5.1 *Quote the type of products handled, specifying if the product is handled under a contractual agreement with a contract giver.*

C.1.5.2 *Note any toxic, hazardous, highly sensitising substances handled e.g. antibiotics, hormones, cytostatics. Note whether special precautions were taken for such products.*

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

GUIDANCE
(Not more than 250 words or one A4 sheet).

C.1.6.1 *Provide a map indicating the location of the site(s) and the surrounding area. Mark the site(s). Describe the surrounding area and use of properties near by.*

C.1.6.2 *The size of the site, types of buildings and their ages.*

C.1.6.3 *Other activities on the site.*

C.1.7	Number of employees engaged in administration, warehousing, distribution and transportation.

GUIDANCE
(Note: Include employees working only part-time on full-time equivalent basis.)

C.1.7.1 Administration
C.1.7.2 Warehousing
C.1.7.3 Distribution
C.1.7.4 Transport
C.1.7.5 Technical & Engineering Support Services
C.1.7.6 Total of the above

C.1.8	Use of outside administrative or other technical assistance in relation to the operation (if so, see Chapter 8 for details).

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For each outside contractor (including contract delivery companies), give:

C.1.8.1 Name, address, telephone no. and fax. no. of contractor.

C.1.8.2 Brief outline of the activity being undertaken in not more than 100 words or half an A4 sheet.

C.1.9	Short description of the quality management system of the company.

GUIDANCE
(Not more than 750 words or three A4 sheets).

C.1.9.1 State the company's Quality Policy.

C.1.9.2 Describe the elements of the quality management e.g. organisational structure, responsibilities, procedures, processes.

C.1.9.3 Describe the audit programmes (self-inspection or audits by external organisations undertaken).

C.1.9.4 *Describe how 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)*

C.1.9.5 *Record if standards such as ISO 9000 etc are used by the company.*

Chapter 2

C.2 PERSONNEL

C.2.1	Organisation chart showing the arrangements for key personnel.

GUIDANCE

C.2.1 *Organogram for key function as described in the procedures. Record senior managers and supervisors only.*

C.2.2	Qualifications, experience and responsibilities of key personnel.

GUIDANCE

C.2.2.1 *Brief details of academic qualifications, work-related qualifications and years of relevant experience since qualifying. Include their names.*

C.2.2.2 *Job descriptions for the key personnel.*

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

GUIDANCE

C.2.3 *Give brief details of the training programme and include induction and continuous training, as follows:*

C.2.3.1 Describe how training needs are identified and by whom.

C.2.3.2 Give details of training relative to GDP requirements.

C.2.3.3 State the form of training e.g. in-house, external, and how practical experience is gained and which staff are involved.

C.2.3.4 Explain how the effectiveness of training is assessed e.g. by questionaire.

C.2.3.5 Explain how retraining needs are identified.

C.2.3.6 Give brief details of training records kept.

Chapter 3

C.3 PREMISES AND FACILITIES

C.3.1	Simple layout plan and description of warehousing areas with indication of scale (architectural or engineering drawings not required).

GUIDANCE

C.3.1 Layout of premises

C.3.1.1 Provide a site layout plan highlighting all warehousing and other functional areas.

C.3.1.2 Describe the controls available to prevent unauthorized access.

C.3.1.3 Provide a simple plan of each area with indication of scale. Label areas and annotate plan with names.

C.3.1.4 Plans should be legible and on A4 sheets. Plans could be on A3 sheets if considered necessary

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C.3.2	Brief description of ventilation systems. More details should be given for critical areas providing special storage conditions.

GUIDANCE

C.3.2 *Brief description of ventilation systems etc. (500 words or two A4 sheets).*

Note 1: *More details should be given for critical areas*

Note 2: *To reduce the narrative, schematic drawings should be used. The following data should be given:*

C.3.2.1 *Design criteria e.g.*
- Specification of the air supply
- Temperature
- Humidity

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

GUIDANCE

C.3.3 *Follow the same layout as C.3.1 above for description of special areas for the handling of highly toxic, hazardous and sensitizing materials.*

C.3.4	Maintenance (description of planned preventive maintenance programmes and recording system).

GUIDANCE

C.3.4 *Maintenance (250 words or one A4 sheet).*

Note : *For the purpose of this guide "maintenance" is carried out by the manufacturer and "servicing" is by an outside contractor.*

C.3.4.1 *Describe the planned preventive maintenance programme.*

C.3.4.2 *Who is responsible for maintenance and servicing?*

C.3.4.2 *Are there written procedures and contractual details for outside work?*

C.3.4.3 *Are there written procedures and suitable reporting forms for maintenance and servicing? Do the documents record type/frequency of service/checks, details of service, repairs and modifications?*

C.3.4.4 *Are the maintenance routines that could affect product quality clearly identified?*

C.3.4.5 *Are the reports made known to the users?*

C.3.5	Availability of written specifications and procedures for cleaning the areas.

GUIDANCE

C.3.5 *Cleaning procedures for the areas.*

C.3.5.1 *Are there written procedures for cleaning and specifications for cleaning agents and their concentration for the method of cleaning and the frequency?*

C.3.5.2 *What are the cleaning methods (and their frequency) for the vehicles?*

C.3.6	Policy on the storage of materials.

GUIDANCE

C.3.6.1 *How are materials of different status (eg quarantine, rejects, approved, etc) segregated and controlled, e.g. by computer, labels?.*

C.3.6.2 *How are the materials stored e.g. pallet racking?*

C.3.6.3 *Describe the storage conditions for narcotic and psychotropic substances, if any*

C.3.6.4 *Describe the pest control programme*

Chapter 4

C.4 STOCK HANDLING AND STOCK CONTROL

REQUIREMENT

C.4.1	Arrangements and recording system for distribution.

GUIDANCE

C.4.1.1 *Description of receiving, handling and storage of materials*
a) Type of checks conducted on the materials?
b) Does the despatch order ensure first in first out (FIFO) and identify the lot number?
c) What are the methods of distribution to customers?

C.4.1.2 *Records of Distribution*

Do the retained records permit full batch traceability from the factory to the customer in terms of the date of sale, customer details and quantity despatched?

C.4.1.3 *Stock take procedure. Include information on how it is being conducted and its frequency.*

REQUIREMENT

C.4.2	Deliveries and transportation.

GUIDANCE

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

C.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 (eg cold items, radioactives)
d) How are the transport route planned?

Chapter 5

C.5 DOCUMENTATION

C.5.1	Arrangements for the preparation, revision and distribution of necessary documentation, including storage of master documents.

GUIDANCE

Note : *This section refers to all documentation used in GDP activities.*

C.5.1 *Arrangement for the preparation, revision and distribution of documentation*

C.5.1.1 *Is there a description of the documentation system?*
C.5.1.2 *Who is responsible for the preparation, revision and distribution of documents?*
C.5.1.3 *Where are the master documents stored?*
C.5.1.4 *Is there a standard format and instruction of how documents are to be prepared?*
C.5.1.5 *How is the documentation controlled?*
C.5.1.6 *For how long are the documents kept?*
C.5.1.7 *Detail any arrangement for electronic or microfilmed records.*

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

GUIDANCE

C.5.2 Other documentation related to product quality

Are the following documents available and in use?

C.5.2.1 Training Procedures
C.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
C.5.2.3 Documentation Control
C.5.2.4 Calibration
C.5.2.5 List and briefly explain the use of any additional standard documentation used routinely.

Chapter 6

C.6 PRODUCT COMPLAINTS AND PRODUCT RECALLS

REQUIREMENT

C.6.1	Arrangements for the handling of complaints and product recalls.

GUIDANCE

C.6.1.1 Complaints

C.6.1.1.1 Is there a written procedure for product complaints?
C.6.1.1.2 Who is responsible for:
a) Logging;

b) Classifying;
c) Investigating complaints

C.6.1.1.3 Are written reports prepared?

C.6.1.1.4 Who reviews these reports?

C.6.1.1.5 For how long are complaint records kept?

C.6.1.2 Product Recalls.

C.6.1.2.1 Is there a written procedure which describes 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.

C.6.1.2.2 Who is responsible for coordinating product recalls?

C.6.1.2.3 Who notifies the Competent Authority of complaints and recalls?

C.6.1.2.4 Is the Competent Authority involved in complaints and the decision to recall?

C.6.1.2.5 Can recalls be effected below wholesale level?

Chapter 7

C.7 SELF INSPECTION

REQUIREMENT

C.7.1	Short description of the self-inspection system (see Para. C.1.9.4).

GUIDANCE

C.7.1.1 *Describe how the self-inspection system verifies that those activities that have a bearing on product quality comply with the planned arrangement.*

C.7.1.2 *Are there documented procedures for the self-inspection system and for the follow-up actions?*

C.7.1.3 *Are the results of the self-inspection documented, brought to the attention of the personnel having responsibility for the area and activities inspected?*

C.7.1.4 *Does the system ensure that those responsible for the area or activity take timely corrective action on the deficiencies found?*

Chapter 8

C.8 CONTRACT ACTIVITIES

REQUIREMENT

C.8.1	Description of the way in which the compliance of the contract acceptor is assessed.

GUIDANCE

C.8.1 *Describe briefly the details 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.*

REFERENCE

1. PIC/S PE 008-1 (effective 01 November 2002): Explanatory Notes for Industry on the Preparation of a Site Master File

END OF DOCUMENT

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REVISION HISTORY

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