HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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MEDICAL DEVICE GUIDANCE

GN-03: Guidance on Preparation of a Site Master File for Licensing

Revision 3

HSA
Health Sciences Authority

PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. If you need specific legal or professional advice, you should consult your own legal or other relevant professional advisers.

In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

CONTACT INFORMATION

For further information, please contact:

Medical Device Branch
Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-01 Helios
Singapore 138667

Fax: (65) 6478 9028
Email: hsa_md_info@hsa.gov.sg
Website: www.hsa.gov.sg

1. INTRODUCTION

1.1. Purpose

This document provides guidance on preparation of a Site Master File (SMF).

1.2. Background

The SMF is a document prepared by the company containing specific and factual Good Distribution Practice for Medical Devices (GDPMDS) information about the storage, distribution, deliveries and secondary assembly operations carried out at the named site. If only a number of these operations are carried out at this site, the SMF only needs to describe those particular activities, e.g. storage.

1.3. Scope

This document is applicable to persons who manufacture, import and supply by wholesale medical devices in Singapore.

1.4. Definition

SECONDARY ASSEMBLY: means the process of repackaging a medical device from its original packaging into another packaging, without breach of the primary packaging, before the medical device is sold or supplied.

2. HOW AND WHEN SHOULD A SITE MASTER FILE BE SUBMITTED?

A Site Master File should be written in concise English and, as far as possible, not exceed 20 A4 sheets. The Site Master File should have an edition number and an effective date. Where possible, simple plans, outline drawings or schematic layouts should be used instead of narrative. All of the above should be written to fit on A4 paper.

The SMF should be updated whenever changes are made. Submission is only required upon request by the Authority. The SMF is to be submitted as a soft/electronic copy. The submission can be in the form of a Microsoft Word document (.doc) or Adobe portable document format (.pdf). The file size of the submitted SMF should be less than 2 MB although legibility has to be maintained.

3. CONTENT OF SITE MASTER FILE

This document has been set out in such a manner that each requirement for the SMF will be accompanied by guidance detailing how the requirements should be interpreted. Refer to Annex I for the format of a SMF.

4. REFERENCE

I. PIC/S PE 008-2 (1 July 2004): Explanatory Notes for Industry on the Preparation of a Site Master File
II. MQA/CDA GUIDE-MQA-022-01 (Effective 1 Jan 2005): Guidance Notes on Preparation of a Site Master File for Good Distribution Practice Certification

ANNEX 1

SITE MASTER FILE

	REQUIREMENTS	GUIDANCE
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**	In not more than 250 words (one A4 page), outline the company's activities, other sites (if any), in addition to the site that is the subject of this report.
C.1.2	**GDP operations as licensed by the Competent Authorities**	1. Indicate whether the site has obtained approval from any authority in Singapore, or any Competent Authority overseas (in the case of the latter, provide the name of the authority in question and state the scope of approval, indicating if any similarities or differences exist in this application). 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**	This covers both medical device related and non-medical device related activities. Secondary assembly activities, if performed, are to be specified.

C.1.4	**Name and exact address of the site, including telephone and fax numbers**	1. Name of company, site address and mailing address (if different from site address) 2. Telephone, fax nos. and email address of contact person
C.1.5	**Type of medical devices handled on the site and information about specifically toxic or hazardous substances handled, mentioning the way they are handled and precautions taken**	1. Quote the type of medical devices handled, specifying if the medical device is handled under a contractual agreement with a contract giver. 2. Note any toxic, hazardous, highly sensitising substances handled e.g. antibiotics, hormones, cytostatics. Note whether special precautions were taken for such medical devices. (List the appropriate licence numbers where applicable)
C.1.6	**Short description of the site (size, location and immediate environment and other activities on the site)**	1. Provide a map indicating the location of the site(s) and the surrounding area. Mark the site(s). 2. Other activities on the site, including secondary assembly line, if applicable.
C.1.7	**Number of employees engaged in administration, warehousing, distribution ,transportation and secondary assembly***	(Note: Include employees working only part-time on full-time equivalent basis. Indicate if activity is outsourced.) 1. Administration 2. Warehousing 3. Distribution 4. Transport 5. Secondary assembly (if applicable)

C.1.8	**Use of outside administrative or other technical assistance in relation to the operation (if so, see C.8 for details)**	For each work process outsourced or sub-contracted (including contract delivery companies), give:- 1. Name, address, telephone no. and fax. no. of contractor 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**	(Not more than 750 words or three A4 sheets). 1. Describe the elements of the company structure, responsibilities and procedures. 2. Describe the audit programmes and organisations undertaken. 3. Describe the management review system. 4. Record if the company has been certified to industry standards (e.g. ISO 9000, ISO 13485:2003)

C.2	**PERSONNEL**	
C.2.1	**Organisation chart showing the arrangements for key personnel**	Organogram listing key personnel has to be constructed. Record senior managers and supervisors only.
C.2.2	**Qualifications, experience and responsibilities of key personnel**	1. Brief details of academic qualifications, work-related qualifications and years of relevant experience since qualifying. Include their names 2. Job descriptions for the key personnel
C.2.3	**Outline of arrangements for basic and in-service training and how records are maintained**	Give brief details of the training programme and include induction and continuous training, as follows:- 1. Describe how training needs are identified and by whom. 2. Give details of training relative to GDP requirements, including secondary assembly (if applicable) 3. State the form of training e.g. in-house, external, and how practical experience is gained and which staff are involved. 4. Explain how the effectiveness of training is assessed e.g. by questionnaire. 5. Explain how retraining needs are identified. 6. Give brief details of training records kept.

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)**	Layout of premises 1. Provide a site layout plan highlighting all warehousing and other functional areas. 2. Describe the controls available to prevent unauthorised access. 3. Provide a simple plan of each area with indication of scale. Label areas and annotate plan with names. 4. Plans should be legible and on A4 sheets. Plans could be on A3 sheets if considered necessary.
C.3.2	**Brief description of ventilation systems. More details should be given for critical areas providing special storage conditions**	Brief description of ventilation systems etc. 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:- 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**	Follow the same layout as above for description of areas specially designated for the handling of highly toxic, hazardous and sensitising materials.

C.3.4	**Maintenance (description of planned preventive maintenance programmes and recording system)**	Maintenance Note: For the purpose of this guide, "maintenance" is carried out by the company and "servicing" is by an outside contractor. 1. Describe the planned preventive maintenance programme. 2. Who is responsible for maintenance and servicing? 3. Are there written procedures and contractual details for outside work? 4. 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? 5. Have the maintenance routines that could affect medical device quality been clearly identified? 6. Are the reports made known to the users?
C.3.5	**Availability of written specifications and procedures for cleaning the areas**	1. Cleaning procedures for the areas. 2. Are there written procedures for cleaning and specifications for cleaning agents and their concentration for the method of cleaning and the frequency? 3. What are the cleaning methods (and their frequency) for the vehicles?
C.3.6	**Policy on the storage of medical device**	1. How are medical devices of different status (eg quarantine, rejects, approved, etc) segregated and controlled, e.g. by computer, labels? 2. How are the medical devices stored e.g. pallet racking? 3. Describe any special storage or handling conditions such as cold chain management. 4. Describe the pest control programme.

C.4	**STOCK HANDLING AND STOCK CONTROL**	
C.4.1	**Arrangements and recording system for distribution**	1. Description of receiving, handling and storage of medical device:- a. Checking of medical devices at point of receipt. 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? 2. Records of Distribution:- a. 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? 3. Stocktaking procedure. Include information on how it is being conducted and its frequency.
C.4.2	**Deliveries and transportation**	1. Description of how the security, storage condition and protection of the quality of medical device are considered during transportation. 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 medical device (e.g. cold items, radioactive substances) d. How is the transport route planned (e.g. for cold items, radioactive substances)?

C.5	DOCUMENTATION	
C.5.1	**Arrangements for the preparation, revision and distribution of necessary documentation, including storage of master documents**	This section refers to all documentation used in GDPMDS activities. Arrangement for the preparation, revision and distribution of documentation:- 1. Is there a description of the documentation system? 2. Who is responsible for the preparation, revision and distribution of documents? 3. Where are the master documents stored? 4. Is there a standard format and instruction of how documents are to be prepared? 5. How is the documentation controlled? 6. For how long are the documents kept? 7. Detail any arrangement for electronic or microfilmed records.

C.6	MEDICAL DEVICE COMPLAINTS AND FIELD SAFETY CORRECTIVE ACTION	
C.6.1	**Arrangements for the handling of complaints**	Complaints 1. Is there a written procedure for medical device complaints? 2. Who is responsible for:- a. Logging; b. Classifying; c. Investigating complaints. 3. Are written reports prepared? 4. Who reviews these reports? 5. For how long are complaint records kept?
C.6.2	**Arrangements for the handling of field safety corrective action**	Field safety corrective actions 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 medical devices; d. Investigation/reporting of cause. e. Reporting corrective action. 2. Who is responsible for coordinating medical device field safety corrective actions? 3. Who notifies the Competent Authority of field safety corrective actions? 4. Can field safety corrective actions be effected below wholesale level?

C.7	INTERNAL AUDITS	
C.7.1	**Short Description of the internal audit system**	1. Describe how the internal audit system verifies that those activities that have a bearing on medical device quality comply with the planned arrangement. 2. Are there documented procedures for the internal audit system and for the follow-up actions? 3. Are the results of the internal audit documented, brought to the attention of the personnel having responsibility for the area and activities inspected? 4. Does the system ensure that those responsible for the area or activity take timely corrective action on the deficiencies found?

C.8	CONTRACT ACTIVITIES	
C.8.1	**Description of the way in which the compliance of the contract acceptor is assessed**	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.

C.9	**SECONDARY ASSEMBLY (if applicable)**	
C.9.1	**Description of the secondary assembly process**	1. Information describing the medical devices that are to be repackaged, the equipment used in the assembly activities. 2. List of applicable work instructions and operational procedures for secondary assembly, including details of operational conditions and processes for the labeling and packaging.
C.9.2	**Description of the documentation process for traceability**	1. Description of the documentation system for batch assembly records? 2. Who is responsible for verifying and approving the batch assembly records? 3. Is there a standard format and instruction of how documents are to be prepared? 4. How is the documentation controlled? 5. For how long are the batch assembly records retained? 6. Does the batch assembly record identify the amount assembled and approved for distribution?
C.9.3	**Description of the materials control established**	1. Prior to repackaging, a. Are the incoming medical devices checked for integrity of package and seal? b. Are the incoming medical devices appropriately labeled? c. (If applicable) are the special storage conditions for the incoming medical devices adhered to? 2. Are the packaging materials appropriately purchased, handled and controlled? 3. Do the repackaged medical devices bear all the original labeling information (including instructions for use, label and any other informational sheet or leaflet, etc.)?

C.9.4	**Description of the good assembly practice**	Written procedures for the following, if performed:- 1. Assembly operation 2. Printing operations 3. Cleaning and maintenance of assembly equipment 4. Calibration of assembly equipment
C.9.5	**Description of quality control implemented**	Written procedures for finished medical device assessment, including:- 1. Review of packaging documentation, 2. Compliance with finished medical device specification and examination of finished product.

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Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

Medical Device Branch
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way, #11-03 Helios
Singapore 138667
www.hsa.gov.sg
T: 6866 3560
F: 6478 9028

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