Site Master File (SMF-BE)

For Blood Establishments in Malaysia

1st June 2016, 1st Edition

Introduction

This guidance note is issued specifically for blood establishments in Malaysia and must be read alongside the Guidelines on Site Master File issued by Centre for Compliance and Licensing (CCL), National Pharmaceutical Control Bureau.

The reference made to Guidelines on Site Master File should be applicable to the blood establishment settings. A Site Master File should contain adequate information but, as far as possible, not exceed 25-30 pages plus appendices. Simple plans, outline drawings or schematic layouts are preferred instead of narratives. The Site Master File, including appendices, should be readable when printed on A4 paper sheets.

The purpose of this document is to provide guidance for the blood establishments on how to create basic information about their activities that can be useful to the regulatory authority in planning and conducting Good Manufacturing Practice (GMP) inspections.

Content of Site Master File for Blood Establishments (SMF-BE)

1. General Information

Full name of the blood establishment
- This may include the name of the Department/Division/Unit that performs the function

Establishment street address
- Please state all addresses if it involves several sites.

Telephone number
- Contact information of the establishment including 24 hours telephone number of the contact personnel in the case of product defects or recalls.

Fax number

Email address

1.1 Activity Summary

Please tick relevant boxes or indicate the activities carried out on site

A: Site Activity	Please tick √ (may tick more than one)	Remarks (if any)
Collection	☐	
Testing	☐	
Processing	☐	
Storage	☐	
Distribution	☐	
Importation	☐	
Exportation	☐	
Others (Please specify)		
B: Products (Blood Components)	**Please tick √ (may tick more than one)**	**Remarks (if any)**
Whole blood	☐	
Red Blood Cells (RBC)	☐	
Platelets	☐	

Plasma	☐	
Fresh Frozen Plasma	☐	
Plasma Cryoprecipitate Reduced	☐	
Cryoprecipitate	☐	
Leukocytes/Granulocytes	☐	
Buffy Coats	☐	
Others (Please specify)		
C: Site Processes	**Please tick √ (may tick more than one)**	**Remarks (if any)**
Whole blood donation	☐	
Apheresis	☐	
Washing	☐	
Splitting	☐	
Cryopreservation	☐	
Cell selection	☐	
Leukocyte depletion	☐	
Freezing	☐	
Irradiation	☐	
Others (Please specify)		

1.2 Any other activities carried out on the site

- Description of non-blood related activities on-site, if any.

1.3 Types of Blood* collected by the establishment:

- Description of collection methods. For example whole blood, manual apheresis, automated apheresis, autologous or allogeneic

1.4 Processing methods

- Brief description on processing methods to produce blood components using flow charts, if possible.

1.5 Number of donors in the previous years (e.g: at least previous 3 years)

1.6 Number of produced blood components in the previous years (e.g: at least previous 3 years)

1.7 Quality control testing methods

1.8 Details of hospitals and blood banks supplied

1.9 Operation hours of the establishment

2. Quality Management System of the Establishment

2.1 Short description of the Quality Management System (QMS) of the establishment

- State the establishment's Quality Policy;
- Information of activities for which the site is accredited and certified, including dates and contents of accreditations, names of accrediting bodies.

2.2 Release procedure of blood/blood component

- General description of batch releasing procedure.

2.3 Management of suppliers and contractors

- A brief summary of the establishment/knowledge of supply chain and the external audit program;
- Brief description of the qualification system of contractors and other critical materials suppliers;
- Use of outside scientific, analytical or other technical assistance in relation to manufacture and analysis;
- List of contract manufacturers and laboratories including the addresses and contact information and flow charts of supply-chains for outsourced manufacturing and Quality Control activities.

2.4 Quality Risk Management (QRM)

- Brief description of QRM methodologies used by the establishment as well as its scope.

2.5 Product Quality Reviews

- Brief description of methodologies used.

3. Personnel

3.1 Details of responsible personnel

- Name of the responsible person
- Name of Establishment Director
- Name of Medical Director
- Name of the Head of Quality Control and/or Quality Manager
- Name of the Production Manager

3.2 Total number of staff

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

3.4 Personnel hygiene requirements, including clothing

3.5 Organisation chart indicating how many people are working in collection, processing, quality control, quality assurance, administration, storage and transport.

4. Facilities

4.1 Short description of the site (size, location and adjacent environment)

4.2 Number of outside collection sites, number of mobile sites (busses)

4.3 Description of the processing and storage facilities indicating the number of rooms, their dimensions and environmental classification, where relevant. Simple floor plan of collection, production and laboratory areas.

4.4 Description of preventive maintenance programs and recording system.

4.5 Description of environmental monitoring system (e.g. temperature, relative humidity)

5. Equipment

5.1 Brief description of major production and control laboratory equipment

5.2 Qualification and calibration including recording system

5.3 Arrangements for computerized systems validation

- The name of the computer software must be specified.

6. Documentation

6.1 Arrangements for the preparation, revision and distribution of necessary documentation for collection of blood and manufacture of blood products

6.2 Give example of donor questionnaire

7. Contracts / Agreements with other Organisations

7.1 List or describe activities carried out by a third party (e.g., testing, cleaning, storage, transport)

- Indicate which steps and name of the organisation that acts as the third party.

8. Haemovigilance System

8.1 Serious Adverse Effect (SAE) / Serious Adverse Reaction (SAR) investigation and reporting system and management of look-back procedures

9. Complaints and Product Recall

9.1 Describe the arrangements for the handling of complaints and product recalls

10.Signature and Date (Preparation and Approval)