Introduction

The purpose of the SMF is to provide the Inspector with an introduction to the company and its activities prior to the commencement of the inspection and to demonstrate to the Inspector that the site is ready for the inspection.

It also serves to be a foundation document for the company onto which other information can be placed in order to build a holistic picture of how the unit operates. Companies have found it useful in identifying gaps in their approach to the quality system. The SMF should be designed to be up-dated easily

This guide describes the core components of a SMF suitable for a company holding an importer's or wholesaler's licence.

As each company is different in its structure and activities, there will be some parts that will be more relevant than others.

It is important that the content is not limited to just items recommended in this guide but that the SMF is inclusive of all the company's relevant details.

WARNING: DO NOT COPY THE ATTACHED SITE MASTER FILE IN ITS TOTALITY. It is provided as an illustration of how a site master file may look like. Some of the practices documented are actually poor practices that need to be improved upon.

Format

This guide will indicate the usual length of each section by insertion of a box such as the one below. This is only a recommended length and some companies may require the inclusion of details, which results in much longer sections while others will be much shorter.

Process flow charts and drawings are preferred to long narrative descriptions. The complete SMF should ideally be no more than 25 A4 pages long.

MDB Pte Ltd

SITE MASTER FILE

Prepared by _____{Signature}_____ Date __DD/MM/YYYY__
Name
Appointment *[e.g. Admin Manager]*

Approved by _____{Signature}_____ Date __DD/MM/YYYY__
Name
Appointment

Document No.: SMF, Version No 01, Effective Date: 1st Jan 2008
[Document should be numbered and versioned based on company's documentation procedure]

C.1 General Information

C.1.1 MDB Pte Ltd located at 11 Biopolis way, Helios, Singapore 138667, was established in 2001. MDB Pte Ltd is an importer and wholesaler of western pharmaceuticals and medical devices. MDB Pte Ltd sources medical devices from USA and Europe.

C.1.2 Licences Held:
MDB Pte Ltd holds a Medicinal Product – Wholesale Licence issued by Health Sciences Authority (Licence No. XXXXXX). No conditions imposed.

[List all licences by both local and overseas authority]

C.1.3 Other operations carried out on the site includes administrative (HR, Finance), Sales and Marketing and warehousing.

C.1.4 Name and Address of Site
MDB Pte Ltd
11 Biopolis way, Helios, Singapore 138667
Telephone: 61234567
Fax: 61234567

Contact Person(s):
Mr XXXX YYYY
Email: GM@ mdb.com.sg
Telephone: 91234567 (after office hours)

[repeat if more than one contact person is desired]

C.1.5 Types of products handled.
C.1.5.1 See Annex A for a list of products
C.1.5.2 The company does not store any toxic or hazardous substances including antibiotics, hormones, cytostatics on site.

[If handling toxic or hazardous substances, storage and any special precautions must be highlighted for each. Example: Poisons are kept in locked safes, where only the GM and QA manager can access]

C.1.6 Short description of the site
C.1.6.1 See Annex B for a map of the company's location.
C.1.6.2 The site is located in the Biopolis research area. The building is a JTC managed research building.
C.1.6.3 The site has a floor area of 200 sq. meters. Drawing of the site and the description of the activities are in Annex C.

C.1.7 Number of employees
C.1.7.1 Administration = 5
C.1.7.2 Warehousing = 4
C.1.7.3 Distribution = 2
C.1.7.4 Transport = 0
C.1.7.5 Sales and Marketing = 5
C.1.7.6 Technical & Engineering Support Service = 0
C.1.7.7 Total of the above = 16

C.1.8 Use of outside administrative or other technical assistance in relation to the operation
C.1.8.1 ABC Freight Forwarding Pte Ltd
12 Biopolis Way
Singapore 1234
Tel: 62345678
Fax: 62345678
Transport of goods to customers
C.1.8.2 XYZ Service Center
Singapore 1235
Tel: 63456789
Fax: 63456789
Technical support office of XYZ products. Provides direct technical and engineering support services for customers of XYZ products.

C.1.9 Quality Management System
C.1.9.1 Quality Policy: On-time delivery of quality goods
C.1.9.2 The Admin Manager is responsible for the quality system
C.1.9.3 MDB Pte Ltd is certified to Good Distribution Practice for Medical Devices in Singapore (GDPMDS). The General Manager reviews the results after each audit to demonstrate the adequacy of the system. MDB Pte Ltd is not certified to any other quality management system standards.
C.1.9.4 Audit program

Program	**Organisation**	**Frequency of audit**
Internal audit/self audit	Company's own internal audit team	Annual
Good Distribution Practice for Medical Devices in Singapore	SURE Quality Certification Services Pte Ltd	Annual
Medicinal Product – Wholesaler licence	Manufacturing Quality Audit Division, Health Sciences Authority	Annual

C.2 Personnel

C.2.1 Organogram of MDB Pte Ltd is attached as Annex D.

C.2.2 The qualifications, experience and responsibilities of key personnel are as follows:

(1) General Manager
Mr XXXX YYYY
Education: MBA, ZZZ University
2001 – present General Manager
1995 – 2000 Quality Manager, ZZZ Ltd
Responsible for operations of company
(2) Admin Manager
Ms FFFF GGGG
Education: Diploma in Accounting, XYZ Polytechnic
2003 – present Admin Manager
2001 – 2002 Finance Executive
Responsible for general administration including HR and Finance of the company.

C.2.3 Training

C.2.3.1 Training needs are identified by General Manager on a need to basis.

C.2.3.2 GDP training is conducted by the Warehouse Manager. The scopes are documentation and proper warehousing methods

C.2.3.3 Training programs are conducted in-house via on-the-job training.

C.2.3.4 The supervisor assesses the efficacy of the training sessions for the trainee.

C.2.3.5 Administration department is responsible for keeping training records for each staff member in their personnel files.

C.2.3.6 All training records are kept in the HR Records Room.

C.3 Premises and facilities

C.3.1 Floor plan in Annex C shows the warehousing area.

C.3.2 Ventilation in the warehouse is provided by fans at locations indicated in Annex G. The fans are serviced when they break down . There is a thermograph measuring the temperature and humidity of the warehouse average temperature is 25 – 30 degree C, 70-80% RH.

C.3.3 No toxic, hazardous or sensitising materials are stored on site.

C.3.4 There is no planned preventive maintenance programme. Repair is made as and when required.

C.3.5 There is no procedure for cleaning of the warehouse. The floor is swept on a daily basis.

C.3.6 Storage of medical devices

C.3.6.1 A product label identifies the status of the product. Goods of same status are placed together in the warehouse.

Label	Status
Pending	New goods pending checks on quantity and conditions
OK	Goods accepted for distribution
Rejected	Goods to be disposed or returned to supplier
Hold	Goods not to be distributed

C.3.6.2 Medical devices are stored on wooden pallets; and stacked on shelves. Temperature sensitive products are stored in the fridge. The temperature in the fridge is checked on a daily basis and recorded.

C.3.6.3 There is no storage of narcotic and psychotropic substances on site.

C.3.6.4 Monthly spraying of pesticides by contractor.

C.4 Stock handling and stock control

C.4.1 Arrangements and recording system for distribution

C.4.1.1 Goods received are checked for quantity and condition. Damaged goods and expired products are labeled as “Rejected” for return to supplier. Accepted goods are stored to allow retrieval by a ‘first in first out’ system, based on lot numbers.

C.4.1.2 Details of date of delivery, device name, quantity, batch / lot number are captured in the delivery order.

C.4.1.3 Stocktaking is done on the annual basis in March.

C.4.2 Deliveries and Transportation

C.4.2.1 Medical devices are picked from the warehouse and packed into carton boxes. Temperature sensitive products are place in insulated box with ice packs to maintain the temperature.

C.4.2.2 Transport company ABC is contacted to perform transportation and delivery service.

C.5 Documentation

C.5.1 Preparation, revision and distribution of documents for GDPMDS

C.5.1.1 There is no formal documentation system in place, there is a list of all existing documents and their revision
C.5.1.2 When a new document is required or a new revision required, the General Manager will assign the relevant manager to prepare or revise the documents. After preparation/revision, the General Manager will approve the document for distribution. The Admin Manager is responsible for distribution of the documents to the staff who need to use it.
C.5.1.3 The master copy of the documents is filed by the Admin Manager.
C.5.1.4 Company procedure, SOP-GDP-DC-01-R1, explains the standard format and preparation of GDP documents.
C.5.1.5 Changes to all controlled documentation must be authorised by the General Manager before implementation.
C.5.1.6 All company procedures that become obsolete are maintained on the database for at least 5 years.
C.5.1.7 All documents can only be accessed through the company intranet, which has a built-in approval system for modifications. Documents stored on the company intranet are backed up on a regular basis by the IT support unit.

C.6 Complaints and FSCAs

C.6.1 Medical Device Complaints
C.6.1.1 The Sales Manager is responsible for logging and classifying the complaints. The Sales Manager is responsible for investigating the complaints according to procedure (SOP – MDC – R1).
C.6.1.2 A response letter is prepared for each complaint.
C.6.1.3 A written investigation report is stored on the company database.
C.6.1.4 The General Manager reviews the complaint investigation reports.
C.6.1.5 Complaint records are maintained for a period of five years on top of the projected useful life of the medical device.

C.6.2 Medical Device FSCAs
C.6.2.1 There is a written procedure for product FSCAs (SOP–FSCA–R1).
C.6.2.2 The Sales Manager is responsible for coordinating product FSCAs.
C.6.2.3 The Sales Manager is responsible for notifying HSA.
C.6.2.4 FSCAs can be effected below the wholesale level. Please refer to SOP-FSCA-R1.

C.7 Self Inspection

C.7.1 Self Inspection System
C.7.1.1 The Admin Manager sets an annual audit schedule with the approval of the General Manager.

C.7.1.2 The self-inspection audit will assess whether the business activities comply with the documented procedures.
C.7.1.3 Results of the self-inspection are submitted to the General Manager
C.7.1.4 Any area with deficiency will have follow-up inspection.

C.8 Contract activities

SURE Quality Certification Services Pte Ltd is contracted to perform the GDPMDS audit. SURE Quality Certification Services Pte Ltd will contact the Sales Manager to arrange for an audit on an annual basis.

Transport company, ABC Freight Forwarding Pte Ltd, is contracted to perform transportation.

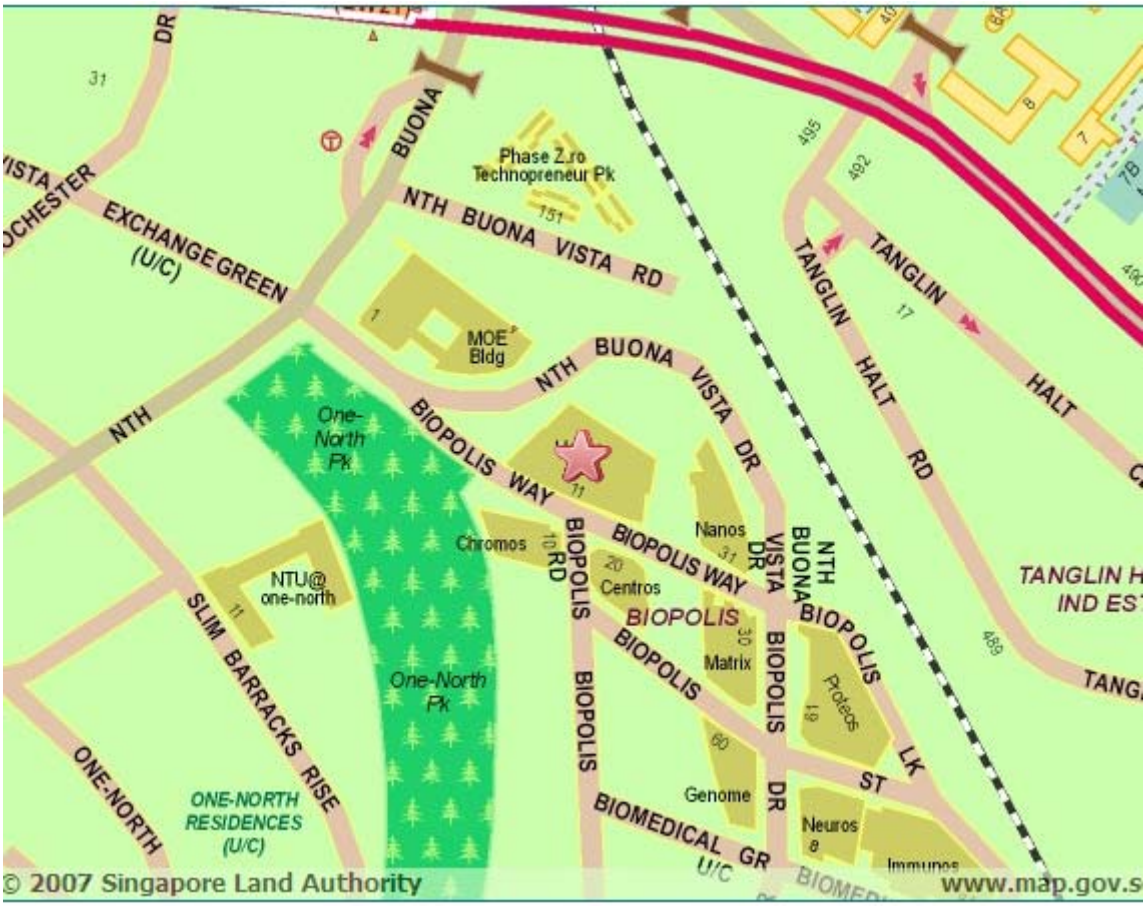
Annex A

List of medical devices imported and supplied:

Dental precision attachment, ball
Dental repair kit, ceramix
Drill Handpiece, dental, electrically-powered
Drill motor, dental, electrically-powered

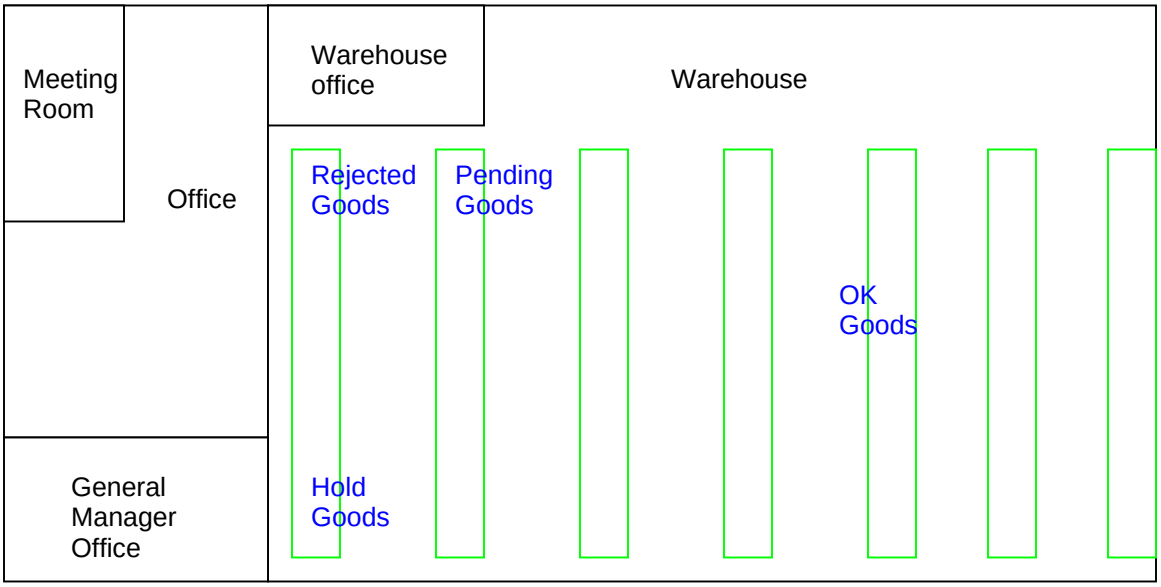
Annex B

Map of company's location



Annex C

Site Floor plan



Annex D

Organogram of MDB Pte Ltd