NATIONAL PHARMACEUTICAL CONTROL BUREAU

# Guidance Note For Biological Products Manufacturing Facility Establishment In Malaysia

GMP 1 Section, CENTRE FOR COMPLIANCE AND LICENSING
1st May 2015

## 1.0 INTRODUCTION

The guide is established to facilitate and provide guidance to organisations in setting up a manufacturing facility for medicine-based biological products in Malaysia, including cell and tissue products, blood/plasma derived products and biotechnology products.

## 2.0 GUIDELINES IN USE

Applicants must be fully aware and understand the legal requirements and guidelines used in initiating the set up of manufacturing facility in Malaysia. For this purpose, the guide enlisted the related regulations and guidelines for applicants' reference;

a) *Regulations*

- Control of Drugs and Cosmetics Regulations 1984
- Sales of Drugs Act 1952

b) *Guidelines*

- PIC/S Guide to Good Manufacturing Practice for Medicinal Product; http://www.picscheme.org/
- Drug Registration Guidance Document; www.bpfk.gov.my
- Guideline on Good Distribution Practice; www.bpfk.gov.my
- Guidance Document and Guidelines for Registration of Biosimilars in Malaysia www.bpfk.gov.my

The list is non exhaustive. Applicants are encouraged to acquire additional information and to share other guidelines used with NPCB.

## 3.0 SET UP PROCESS

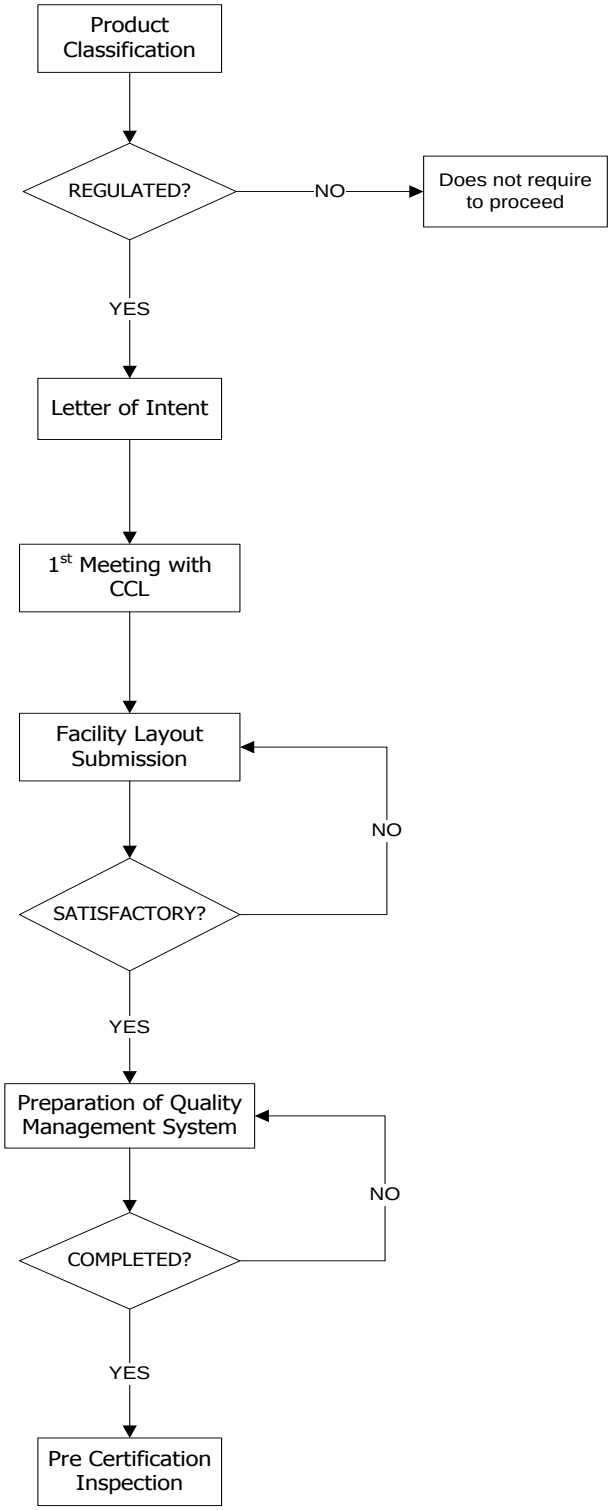


Figure 1: General Process Flow Chart for the Manufacturing Facility Set Up

### 3.1.1 Product Classification

The purpose of this step is to classify the product of intent, which by the regulations Sale of Drugs Act 1957 and Control of Drugs and Cosmetics 1984, requires to be registered. Please apply through form **BPFK-300 Product Classification Application**. However, this step is not compulsory for the applicant.

### 3.1.2 BPFK-505 Letter of Intent

Upon classification of products, applicant may then submit **BPFK-505 Set Up for Biological Based Product Manufacturing Facility *Letter of Intent*** to Centre for Compliance and Licensing (CCL), National Pharmaceutical Control Bureau for further arrangement.

This step is required to arrange a meeting with CCL before the commencement of the manufacturing facility. CCL will not entertain any arrangement that comes without the application form.

Currently, there is no payment charged for this arrangement.

### 3.1.3 Meeting with CCL

During this stage, the applicant will be required to present a concise presentation of **company's background, product/s information, a clear, defined facility layout plan** along with the **manufacturing process flow** and other related information. The presentation will be held at CCL for approximately one hour, otherwise stipulated.

### 3.1.4 Facility Layout Submission

If the applicant intends to proceed with the application after the presentation, please submit an application through **BPFK-503 *Borang Permohonan Penilaian Pelan Susun Atur Premis Pengilang*** along with the required supporting documents as stated in the application form. The application is free of change until further notice.

Applicants are **strongly advised** to consult other related authorities such as *CKAPS, local municipal council, fire department or others, for any issue pertaining to the facility set up.

### 3.1.5 Preparation of Quality Management System (QMS)

Upon facility layout plan and other authorities' approval, applicant may begin the set up of the Quality Management System for the facility according to guidelines mentioned in Chapter 2.0. This includes the construction of the facility, qualifications of equipments and Standard Operating Procedures (SOPs) preparation, etc.

**In case of delay** of any sort, applicant is responsible to inform CCL through official letters or e-mails prior to the agreed completion date. In failure to do so, may result in new application submission.

### 3.1.6 Pre-Certification Inspection

Once the preparation finalised, a Pre-Certification inspection will be conducted. Applicant is required to apply through **BPFK-504 Application for Good Manufacturing Practice (GMP) Inspection** for this purpose.

*Note:* All mentioned document in this chapter are obtainable from www.bpfk.gov.my .

## 4.0 DEPARTMENT/ PERSON IN-CHARGE

For any queries pertaining to this guidance note, applicants may contact;

GMP 1 Section
Centre for Compliance and Licensing
National Pharmaceutical Control Bureau
Ministry of Health Malaysia
Lot 36 Jalan Universiti
46200 Petaling Jaya, SELANGOR

**Telephone no.**: 03 7801 8557 (Desk Officer)
**Fax no.**: 03 7957 1200

**E-mail address:** gmp@bpfk.gov.my

**Website:** http://www.bpfk.gov.my

## 5.0 RELATED AUTHORITIES

For matters related to licensing of the private healthcare related facility, applicants are advised to contact;

*Cawangan Kawalan Amalan Perubatan Swasta (CKAPS)
Bahagian Amalan Perubatan
Kementerian Kesihatan Malaysia
Aras 3, Blok E1, Kompleks Kerajaan Parcel E,
Pusat Pentadbiran Kerajaan Persekutuan,
62590 PUTRAJAYA

**Telephone no.** : 03-88831307 / 03-88831277 / 03-88831278
**Fax no.** : 03-88810901 / 03-88810902

**E-mail address**: ckaps@moh.gov.my

**Website**: http://medpcs.moh.gov.my

## 6.0 FREQUENTLY ASKED QUESTIONS (FAQs)

1. Does NPCB issue a manufacturing license after the pre-certification inspection?

   No. However, upon acceptable GMP status, the company will receive a **Good Manufacturing Practice (GMP) Certificate** to signify the manufacturer's compliance to the guides. It is also valid for three (3) years.

2. What should I do if the GMP Certificate expires?

   Upon the expiration of the GMP Certificate, the applicant is encouraged to apply through BPFK-504 Application for GMP Manufacturing Practice (GMP) Inspection form which is available on www.bpfk.gov.my.

3. Does cell and tissue establishment require an annual certification?

   As of this guide is written, no certification will be issued out to cell and tissue establishments. However, beginning year 2016, the Good Manufacturing Practice (GMP) Certificate will be issued out to all said establishments and it is valid for three (3) years.

4. Is there any charge for the applications mentioned?

   Currently, no charge imposed for BPFK-503 *Borang Permohonan Penilaian Pelan Susun Atur Premis Pengilang*. However, a charge of RM1000/day/person (maximum total of RM10,000) will be imposed on the application sent for BPFK-504 Application for Good Manufacturing Practice (GMP) Inspection.

5. What is a repacker?

   The definition can be referred from the Explanatory Notes for Repackers in the Drug Registration Guidance Document (DRGD) which obtainable from www.bpfk.gov.my.

6. Who should I contact if I still have questions about the biological products?

   In relation to;
   a) Manufacturing facility set up/GMP related issue : GMP 1 Section, Centre for Compliance and Licensing, NPCB
   b) Product registration enquiry: Biotechnology Section, Centre for Product Registration, NPCB