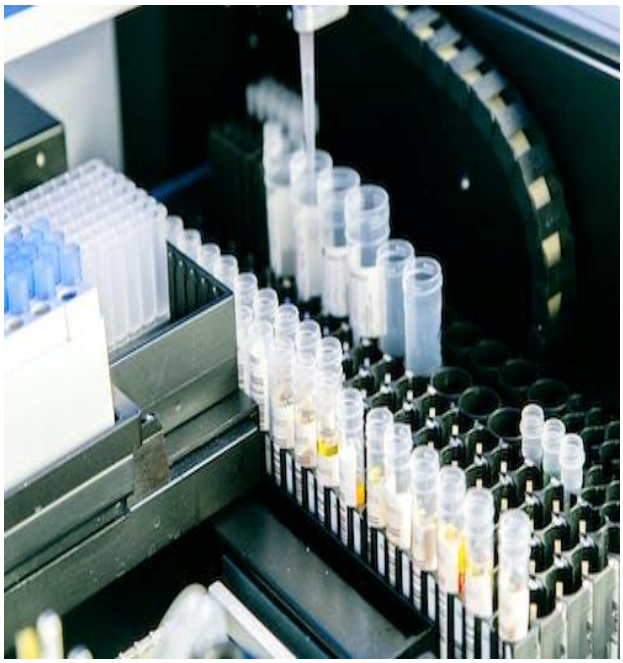
PHARMACY BOARD MALAYSIA
MINISTRY OF HEALTH MALAYSIA
2023

RECORD OF TRAINING AND EXPERIENCES OF PROVISIONALLY REGISTERED PHARMACIST (PRP)

Manufacturing Pharmaceutical Industry



<table>
<tr><td colspan="3">PERSONAL PARTICULARS
To be completed by the Provisionally Registered Pharmacist (PRP)</td></tr>
<tr><td>1</td><td>Full Name (as per I/C)</td><td></td></tr>
<tr><td>2</td><td>I/C Number</td><td></td></tr>
<tr><td>3</td><td>Provisional Registration Number</td><td></td></tr>
<tr><td>4</td><td>Contact Number (Mobile)</td><td></td></tr>
<tr><td>5</td><td>Home Address</td><td></td></tr>
<tr><td>6</td><td>E-mail Address</td><td></td></tr>
<tr><td>7</td><td colspan="2">Education Qualification<table><tr><td>Name of University</td><td></td></tr><tr><td>Qualification</td><td></td></tr><tr><td>Year of Graduation</td><td></td></tr></table></td></tr>
<tr><td>8</td><td>Scholarship / Sponsor</td><td></td></tr>
<tr><td>9</td><td colspan="2">Contact Person Details in Case of Emergency<table><tr><td>Name</td><td></td></tr><tr><td>Contact Number</td><td></td></tr></table></td></tr>
<tr><td colspan="3">TRAINING PREMISE PARTICULARS
Details of which approved by Pharmacy Board Division Malaysia (PBMD)</td></tr>
<tr><td>10</td><td>Name of Training Premise</td><td></td></tr>
<tr><td>11</td><td>Address of Training Premise</td><td></td></tr>
<tr><td>12</td><td>Duration of Training (Date)</td><td>to</td></tr>
<tr><td colspan="3">By signing, I confirm that all the information provided above is true.

Signature: Date:</td></tr>
</table>

1 INTRODUCTION

1.1 The Registration of Pharmacists Act 1951 stipulates that a person who is provisionally registered shall be required to obtain experience immediately upon being provisionally registered, engage in employment as a Provisionally Registered Pharmacist (PRP) to the satisfaction of the PharmacyBoard for a period of not less than one year.

1.2 The engagement as a PRP must be in any premises listed in the *Second Schedule* to be entitled to apply for full registration.

1.3 Every facility listed above in the Second Schedule is entitled to train the PRPs only as according to the number of qualified pharmacists who have been recognized as preceptors by the Pharmacy Board. This preceptor would serve as a guide and mentor throughout the PRP's time at the premise.

1.4 The Board may extend for not more than one year the period of employment of a provisionally registered person if the Board is not satisfied with the performance of the person as a pharmacist.

1.5 The provisional registration of a person shall be revoked if that person fails to engage in employment as a PRP to the satisfaction of the Pharmacy Board for a period of not less than one year in any premises listed in the *Second Schedule*.

2 PRP TRAINING MODULES AND RECORD

2.1 Preamble:

2.1.1 The manufacturing pharmaceutical industry is an emerging industry that requires specific sets of people competencies to align with the natureand challenges faced, internally and externally, by the industry.

2.1.2 By the end of the training, the PRP will be able to achieve key and functional competencies in the aspect of manufacturing sector. This shall then present diversity in the role, experience and contribution of the pharmacists in Malaysia.

2.2 Objective:

The training of pharmacists in the manufacturing sector aims to provide the pharmacists with sufficiently in-depth clarity in understanding themanufacturing of pharmaceutical products and to equip the pharmacists with relevant knowledge and skills required in the industry.

2.3 This record book is designed primarily to guide the provisionally registered pharmacists and their preceptors of various pharmacy disciplines in the training institution in coordinating activities and programs during the one-year provisional training.

2.4 This record book will be used for the purpose of **appraisals** by the Principal Preceptors and Master Preceptor, and will be submitted to the Pharmacy Board for the registration of the PRP as a fully registered pharmacist.

2.5 There are 6 main modules of training for the provisionally registered pharmacist [PRP] in the manufacturing pharmaceutical industry;

2.5.1 Production Process: Manufacturing and Packaging of Pharmaceutical Products

2.5.2 Logistics, Warehousing and Distribution of Pharmaceutical Products

2.5.3 Regulatory Affairs

2.5.4 Research & Development/ Technical Services Of PharmaceuticalProducts

2.5.5 Quality Assurance / Quality Control

2.5.6 Sales & Marketing of Pharmaceutical Products

2.6 The PRP is required to provide the following information;

2.6.1 Name, I/C Number, Name of Institution and period of training andall other requested information in this book.

2.6.2 Date of task completed and evidence of proof for each section/unit of attachment.

(If the columns indicated are insufficient, please use an additionalattachment.)

2.6.3 Each evidence given is to be endorsed by the immediate preceptor of the section/ unit.

2.7 The preceptor is required to complete the record by filling thefollowing;

2.7.1 Endorse the completion of each task with signature, name anddate in the column provided.

2.7.2 Level of performance is based on the following scale;

SCALE	RATING	DESCRIPTION
10	Outstanding	Exceed target within the stipulated duration with an extraordinary level of commitment in terms of quality and time, technical skills and knowledge, ingenuity, creativity, initiative and good attitude.
9	Excellent	Exceed target within the stipulated duration with good quality of work, efficiency, timeliness and good level of commitment.
8	Very Satisfactory	Target met within the stipulated duration with good quality of work, efficiency and timeliness.
7	Satisfactory	Target met within the stipulated duration
6	Average	Target met with extension.
5	Unsatisfactory	Target not met within the stipulated duration with good level of commitment.
4	Unsatisfactory	Target not met within the stipulated duration with average level of commitment.
1- 3	Very Unsatisfactory	Target not met within the stipulated duration with poor level of commitment.

The passing mark is 60 % for each respective section. The overall average should not be less than 60%.

2.7.3 The final **appraisal and Appendix A or Appendix A1** should be completed **by the Master Preceptor** at the end of the **12th month** of the training period. Certified copies of Appraisals andAppendix A or Appendix A1 shall be uploaded by PRP into Pharmacist Registration Management System (PRiSMA) for the Fully Registered Pharmacist (FRP) application. The **original log book** should be kept at the premise for a minimum period of three (3) years.

2.8 Criteria of Manufacturing Facility for Training of PRP

2.8.1 All Pharmaceutical Manufacturing Facilities, excluding those pharmaceutical manufacturers of Traditional Medicines and Health Supplements.

2.8.2 Pharmaceutical manufacturing facilities must meet current Good Manufacturing Practice (GMP) requirements and have a valid Manufacturing License issued by the Drug Control Authority (DCA) for the current year.

2.8.3 Manufacturing Facilities shall have Principal Preceptors and a Master Preceptor qualified and appointed by the manufacturing facility; and approved by the Pharmacy Board.

3 DUTIES AND RESPONSIBILITIES OF A PRECEPTOR

3.1 Type of preceptors

Master Preceptor:

a. Must be a Registered Pharmacist with at least 3 years working experience in manufacturing pharmaceutical industry (regardless of company attachment)
b. There shall be only ONE Master Preceptor in any company. (Decided by the company)
c. Eligible to hire PRP

Principal Preceptor:

a. Must have at least 3 years working experience in the respective function
b. Must be a Registered Pharmacist
c. Eligible to hire PRP

OR

a. Non-pharmacist (must be Head of Department)
b. Not eligible to hire PRP

3.2 Responsibilities of a Master Preceptor

3.2.1 To coordinate the whole PRP training program for all the modules, to monitor the PRP development throughout the training period and be responsible for the overall assessment.

3.2.2 To liaise with the respective Principal Preceptors and discuss the PRP's progress, development and finally to evaluate their performance.

3.2.3 The Master Preceptor may also play a role to train and evaluate the PRP for any particular component of the logbook that he or she is in charge of.

3.3 Responsibilities of a Principal Preceptor

3.3.1 To serve as a learning resource for the PRP. Ensuring the PRP receives necessary training to develop skills and behaviors expected as a competent pharmacist in the Manufacturing Pharmaceutical Industry.

3.3.2 To answer PRP queries or direct the PRP to the appropriate references and/or to show them areas of learning still to be covered.

3.3.3 To serve as a role model instilling professional values and attitudes and to explain to the PRP reasons for your actions when called upon to make professional judgements.

3.3.4 To attempt in providing a full range of professional advice and guidance; and to provide positive and corrective feedbacks during the training/learning process.

3.3.5 To assess PRP performances or delegate some of the assessment to another suitable person and to discuss the PRP strengths and weaknesses.

4 DUTIES AND RESPONSIBILITIES OF A PROVISIONALLY REGISTERED PHARMACIST [PRP]

4.1 Being a Provisionally Registered Pharmacist [PRP], you should;

4.1.1 At all-times comply with the directives and orders given to you by the Preceptors.

4.1.2 Aim to become a competent registered pharmacist by the end of the training period.

4.1.3 Undertake the training modules/ program with a positive attitude and a commitment to learn from the preceptor and other staff in the training environment.

4.1.4 Responsible in obtaining adequate working experience.

4.1.5 Be proactive in acquiring knowledge and skills by observation, reading and questioning others.

4.1.6 Extend your working hours beyond your normal working hours if required.

4.1.7 Always actively participate in professional development as it is essential to build on your undergraduate studies and keep abreast of current knowledge.

4.1.8 Be aware that; the Certificate of Satisfactory Experience, required under Section 6A(2) Registration of Pharmacists Act 1951 will only be issued to you if the average passing mark of your training performance must be **at least 60% for each section and the sum total of all the units.**

4.2 Overview of Competencies Training Schedule:

During the entire training duration, the PRP will be placed in the core Divisions/Departments in the Company under the guidance and supervision of the Principal Preceptor and supervised overallby a Master Preceptor. The duration of training in each module is as indicated in Table 1.1.

Mini project where indicated under the different modules are optional but it will be in the interest of the PRP to be given at least ONE(1) mini project throughout the period of training.

Table 1.1: Training Time-table

COMPETENCY TRAINING MODULES	DURATION (WEEKS)
PRODUCTION PROCESSES: THE MANUFACTURING AND PACKAGING OF PHARMACEUTICAL PRODUCTS	22-30
LOGISTICS, WAREHOUSING AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS	4-6
REGULATORY AFFAIR: REGISTRATION PROCEDURES, POST REGISTRATION ACTIVITIES AND RELATED LICENCES OF PHARMACEUTICAL PRODUCTS (Including one week attachment at NPRA)	4-6
RESEARCH & DEVELOPMENT OF PHARMACEUTICAL PRODUCTS	4-8
QUALITY ASSURANCE / QUALITY CONTROL	4-12
SALES & MARKETING OF PHARMACEUTICAL PRODUCTS	2-6
TOTAL	**52**

ASSESSMENT

PRODUCTION PROCESSES: THE MANUFACTURING AND PACKAGING OF PHARMACEUTICAL PRODUCTS

(Duration of Attachment: 22-30 weeks)

1. Understanding structure of the organization.

2. Familiarity with terminology, guidelines and specification related to manufacturing according to PIC/S GMP, ISO Certification and ICH documents.

3. Knowledge of Standard Operating Procedures (SOP's) and ability to adhere to theSOP during operation including safety and security in work area.

4. Knowledge and understanding in cleaning and sanitization including risk management in controlling cross contamination and its implications.

5. Knowledge of basic documentation used in production such as master formula, production record and their contents.

6. Knowledge of the manufacturing of various dosage forms of products eithersterile or non-sterile (e.g., tablets, capsules, soft-gels, creams, liquids, injectables, whichever is/ are manufactured in the plant) including:

    - the properties of ingredients used in the manufacturing process;
    - manufacturing processes and machinery employed in various dosage forms;
    - knowledge of essential & critical utilities used in manufacturing plant;
    - the properties of various dosage forms;
    - the packaging of finished products, including stability characteristics andstorage requirements;
    - understanding of the principles of Good Manufacturing Practice (GMP)

7. Knowledge on preventive maintenance master plan.

8. Knowledge on validation in production process.

9. Wherever permissible PRP is encouraged to participate in the steps mentioned.

SECTION 1: DOCUMENTATIONS IN MANUFACTURING

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature ofPreceptor
		1	2	3	4	5	6	7	8	9	10		
1	Knowledge on preparation of standard operating procedures (SOP's) and adhering to standard operating procedures during operations												
2	Knowledge on monitoring, storage, distribution and controlling SOP's												
3	Understanding of guidelines and specifications related to manufacturing according to PIC/S GMP, ISO & ICH guidelines - Target: 1 presentation / written assignment (topic: guideline / protocol)												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature ofPreceptor
		1	2	3	4	5	6	7	8	9	10		
4	Knowledge on preparing documentation - BMR / BPR, SOP, Status Labels • Drafting new document • Reviewing SOP and BMR - Target: Review 6 manufacturing SOPs throughout the duration of this module												
5	Knowledge of the content and importance of BMR/BPR: traceability etc. and status labels (examples: on hold, reject etc.) and its usage. - Target: Review 15 BMRs												
6	Knowledge on the role of pharmacist in handling of Controlled Drugs including documentation and management of Import / Export Permit. (Referring to Poison Act etc.) - Target: 1 presentation / written assignment												

SECTION 2: CORE MANUFACTURING PROCESS

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Able to explain the objectives of manufacturing function and processes, knowledge on the differences of sterile and non-sterile products, describe the meaning of the main terms used in production - Target: *Minimum 1 discussion session with preceptor/team												
2	Knowledge on the role of Production Planning and terminologies - Target: *Minimum 1 discussion session with preceptor/team												
3	Able to understand the basic component of ERP systems, how it works and the benefits, including demand and supply as well as procurement management for manufacturing needs. - Target: *Minimum 1 discussion session with preceptor/team												

*Remark: all the knowledge/task can be conducted in the same discussion session.

SECTION 3: MANUFACTURING RELATED ACTIVITIES

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Knowledge on different types of cleaning agents used: detergent, solvent cleaners, acid cleaners and abrasive cleaners. • Able to prepare cleaning agents. - Target: Prepare cleaning agents at least 3 times (preferably different type)												
2	Knowledge on different sanitizing terms: antiseptic, disinfectant, bactericide etc and different sanitization method: chemical, heat and radiation. • Perform sanitization and microbial sampling												
3	Knowledge on facility and equipment management • Perform replacement for consumable parts - Target: Perform replacements for at least 3 consumable parts												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
	related to utilities and equipment (example: filter)												
4	Knowledge on equipment master list, its foot print and preventive maintenance master plan.												
5	Knowledge on risk management in controlling cross contamination including patient safety, cost, reputation												
6	Knowledge of role of production in validation • Assist in validation / qualification process and report preparation - Target: Prepare at least 2 sets of documentation												
7	Knowledge and skill on preparing User Requirement Specification (URS) - Target: Prepare at least 1 URS on simple equipment or tools												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
8	Knowledge on main production operations, critical pathways for each process and control functions**.**												
9	Knowledge on process flow for • Formula calculation inBMR • pH adjustment • Perform IPQC checking - <u>Target:</u> Perform the following task for at least 3 times: o pH adjustment (if applicable) o IPQC testing												
10	Knowledge on the technology and functionality of each machine/ equipment used in each process, such as: Mixer, Granulator/ Oscillator, FBD, Oven, IBC, One-Pot Process, Compression machine, etc**.** - <u>Target:</u> Provide at least 1 training session to the production workers on any of this machine/equipment												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
11	To comprehend the technical knowledge on core production processes: Granulation, Sieving, Milling,Tablet Compression, Coating,Capsulation etc.												
12	Knowledge on essential & critical utilities used in manufacturing plant: plant steam, pure steam, HVAC system, compressed air, vacuum system, waste water treatment plant, dust extractor and water system. - <u>Target:</u> • Manually take daily recording of any two utilities for at least 1 week (*even if the company already has an automated system*) • 1 report on the review of the trending data of the chosen utility												
13	Knowledge on critical measurement /specifications of												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
	the different utilities in different types of manufacturing facility.												
14	Understanding the different packaging process and its requirements												

Sterile Production

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Knowledge on defining sterile product including the differences between terminally sterilized product and aseptic product and the process involved												
2	Knowledge on Sterility Assurance program												
3	Knowledge on application of aseptic technique												
4	Knowledge on different grade of clean room, its specification and qualification ofclean room - Target: Make1 formal presentation to the team on this subject												
5	Knowledge on personnel qualification												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
6	Knowledge on the critical parameters to monitor in clean room: Temperature, humidity, differential pressure, air flow velocity, air flow rate, air borne particulate count, air change rate, air flow direction, HEPA filter leakage test, containment test, recovery test.												
7	Knowledge on gowning procedure and able to demonstrate adherence to procedure - Target: Perform the gowning qualification successfully												
8	Knowledge on production process flow in sterile production area: Washing, Dispensing, Compounding, Filtration, Filling, Leak testing, Inspection, Labeling and Cartoning.												
9	Knowledge on the technology used in each process step.												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
10	Knowledge on different sterilization methods, advantages and disadvantagesof each sterilization method and validation of the process.												
11	Knowledge on de-pyrogenation and validation of the process												
12	Knowledge on specific requirement for utilities used in clean room: pure steam, WFI, compressed air, pharmaceutical gasses, HVAC system												
13	Knowledge on sterility testing												
14	Knowledge on microbiological environmental monitoring												
15	Knowledge on media fill run												

EVALUATION

Mark = _____ x 100%
380

=_____%

NOTE:

1. % Mark should not less than 60% for every units / sections.

GENERAL COMMENT ON ATTITUDE:

Preceptor's Name & Signature:

Date:

LOGISTICS, WAREHOUSING AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

(Duration of Attachment: 4-6 weeks)

1. Knowledge and understanding of the principles of store management,inventory, stock movement and control, cleanliness and sanitation and security in accordance to procedures in store management.

2. Knowledge of storage and distribution of biological, handling of cytotoxic drugs, refrigerated items, inflammables and corrosive items, safety measures, maintenance of cold chain on transit and storage in accordance to Good Distribution Practice (GDP).

3. Knowledge of disposal procedures and its documentation.

4. Knowledge of recall management according to procedures and regulatory requirements.

5. Knowledge on handling of returned, damaged, spilled products and expired stocks according to procedures and regulatory requirements.

6. Knowledge of the statutory aspect related to storage and distribution of scheduled poison and finished products in accordance to the respective legislations:

    - Dangerous Drugs Act 1952 & its Regulations
    - Poisons Act 1952 & its Regulations
    - Poisons (Psychotropic Substance) Regulations 1989

7. Knowledge and understanding the management of goods transportation.

SECTION 1: OVERVIEW OF LOGISTIC, WAREHOUSING AND DISTRIBUTION

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	**Organization Workflow** Able to understand the workflow in the warehouse												
2	**Inventory Movement and Control** Able to explain stock movement and control of poison and non-poison												
3	**Housekeeping** Understand the needs for housekeeping and maintaining the area in a clean and orderly manner												
4	**Security/ Safety** Understand the safety needs while working in a warehouse • knowledge of the system to maintain a safe and secure environment												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature ofPreceptor
		1	2	3	4	5	6	7	8	9	10		
5	**Pest Control** Understand the requirement of pest control program in the warehouse - Target: 1 report on the requirement on the pest control												

SECTION 2: SUPPLY CHAIN AND INVENTORY MANAGEMENT

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Knowledge on supply chain business process integration												
2	Awareness on the major challenges to effective supply chain strategy												
3	Basic understanding on quantitative inventory management												

SECTION 3: STORAGE AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	**Good Distribution Practice (GDP)** Able to understand GDP**/**GDPMD requirements and key principles to storage conditions, stock discrepancies and stock disposal management - Target: Provide 1 training on GDP to warehouse personal												
2	Able to conduct the following • Weighing and counting of received stocks • Visual inspection • Verifying documents(COA, DO vs PO) - Target: Perform the following task at least 3 times: o Weighing and counting of received stocks o Visual inspection o Verifying of documents (COA, DO vs PO)												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
3	**Stock Movement Management** • Able to allocate stocks basedon FIFO and FEFO • Preparation of stocks for production need – weighing/counting/ packing/etc • Cleaning down of stock containers prior to entrance into production buffer area												
4	Knowledge on the requirement of storage and documentation relating to: i. Specially controlled items ii. Printed Packaging Materials iii. Holograms												
5	Knowledge and understand the need of a cycle-count and stock take - Target: Conduct at least 1 actual exercise from involvement in preparatory work to involvement in generation of final report												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
6	Able to understand the implementation of proper segregation, markings at designatedareas within the warehouse • Product storage in appropriate areas based on status												
7	Knowledge on requirements of Warehouse Environmental Control such as temperature/RH mapping and certain special storage condition such as light sensitivity, corrosive, flammable etc. - <u>Target:</u> • Manually take temperature and RH recording of the warehouse / store area for at least 1 week (*even if the company already has an automated system*) • 1 report on the review of the trending data of the temperature/RH for the warehouse environment												

SECTION 4: STOCK MANAGEMENT ACCORDING TO STATUTORY REQUIREMENTS AND STANDARD PROCEDURES

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Knowledge on the relevant legislation in the effective management of scheduled poisons and controlled medicines												
2	Knowledge on documentation requirements and compliance to various legislation such as Poison Act, Dangerous Drugs Act, and Sale of Drugs Act and Control of Drugs and Cosmetic Regulations												
3	Knowledge of recall management including storage & disposal according to procedures and regulatory requirements												
4	Handling of returned, damaged, spilled products and expired stocks and their appropriate storage & disposal according to procedures and related regulatory requirements - Target: Take part at least 3 times in any of the activities of returned or disposal												

SECTION 5: MANAGEMENT OF GOODS TRANSPORTATION

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Knowledge of transport validation that covers • Transport Validation Process Design • Transporter Qualification												
2	Able to understand the selection of vendor for transportation of finished goods based on: i. Storage requirements. ii. Capacity requirement iii. Route Requirement												
3	Understand the needs of continuous GDP training for transport vendors - Target: Perform a simple audit of the current GDP training program and report to the preceptor with action plans if needed.												
4	Understand the significance of stacking orientation during uploading of goods onto transport												

EVALUATION

Mark = _____ x 100%
230

= _____ %

NOTE:

1. % Mark should not less than 60% for every units / sections.

GENERAL COMMENT ON ATTITUDE:

Preceptor's Name & Signature:

Date:

REGULATORY AFFAIRS: REGISTRATION PROCEDURES, POST REGISTRATION ACTIVITIES AND RELATED LICENCES OF PHARMACEUTICAL PRODUCTS

(Duration of Attachment: 4-6 weeks)

1. Knowledge and understanding the essential functions and core activities of the Regulatory Affairs Department.

2. Knowledge of the statutory aspect relating to registration, clinical testing, post registration and document controls.

3. Knowledge on the importance of being updated on ever- changing legislation in all the regions in which the organization wishes to distribute its products.

4. Knowledge and understanding on the legal and scientific restraint and requirement.

SECTION 1: ATTACHMENT AT NPRA (1 WEEK)

Target: Prepare a written summary after every briefing session

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	To understand the roles and function of NPRA as the only pharmaceutical and cosmetic regulatory agency in Malaysia.												
2	Expose to the process of the implementation of drug registration / cosmetic notification scheme through evaluation of technical data, latest research and up to date guidelines from NPRA and international regulatory agencies (ASEAN, ICH, WHO, EMA & USFDA, etc.)												
3	Expose to the chemical and microbiological test in NPRA on drugs and cosmetics to determine quality and safety of such products.												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
4	Expose to the implementation of licensing scheme for pharmaceutical manufacturers, importers and wholesalers including a licensing scheme for clinical trial.												
5	Expose to the roles of inspectorate (GMP/GCPGLP/GDP/BEEC) and different post-marketing activities (Surveillance/ Pharmacovigilance).												

SECTION 2: REGISTRATION DOSSIER PREPARATION

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Able to identify the latest version of legislation, regulation and guidelines												
2	Assist in Dossier Compilation • Able to assist in interaction with outside experts, partners and regulatory agencies, as requested • Able to assist in preparation for technical meetings with regulatory agencies. • Participate in product and/or regulatory teams to coordinate documentation												
3	Labeling, Package Insert, Patient Information Leaflet (PIL) requirements • Able to review the labeling, package insert and PIL based on references(such as DRGD, labelling requirement, reference product info) - Target: Review at least 3 of each label, PI and PIL against the requirements												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
4	Knowledge on requirement of Hologram												
5	Exposure in dossier submission through Quest system												
6	Knowledge on database management of submitted dossiers to the authority												
7	Able to assist in responding to Regulatory Agency information requests												

SECTION 3: POST REGISTRATION ACTIVITIES

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Knowledge on transfer information of registered product to the manufacturing facility												
2	Able to understand the product variations requirements in Malaysia - Target: Assist with at least 1 variation application preparation												
3	Knowledge in product renewal procedure in Malaysia												
4	Able to assist in the preparation of internal routine reports												
5	Able to assist in the preparation of post- market surveillance and submission to regulatory agency												
6	Knowledge on regulatory issue management - tracking product events, complaints, recalls, and counterfeits. - Target: Participate in at least 1 Initiating Investigation report												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
7	Pharmacovigilance Activities • Understand definition of and need for pharmacovigilance • Exposure to the different PV activities within the pharmaceutical company • Recognize the importance of adverse event reporting												
8	Product Safety Monitoring • Familiarity with and training on internal procedures and guidelines related to pharmacovigilance • Knowledge on the Malaysian Guidelines for good Pharmacovigilance Practices (GVP) for product registration holders and relevantinternational guidelines • Understand the role of Pharmacovigilance in market research activities, localstudies, contracts and/or agreements Assist in reporting and submission of ADR (local / international) to MADRAC (Malaysia Adverse Drug Reactions												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
	Advisory Council).												
9	Able to assist in the review of advertising and promotional materials Target: Review at least 3 materials (if applicable)												

SECTION 4: RELATED LICENSING ACTIVITY

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Able to demonstrate understanding of the functions and activities of the RA department in application for Manufacturer's License, Import License and other required licenses												

EVALUATION

Mark = _____ x 100%

220

= _____ %

NOTE:

1. % Mark should not less than 60% for every units / sections.

GENERAL COMMENT ON ATTITUDE:

Preceptor's Name & Signature:

Date:

RESEARCH & DEVELOPMENT / TECHNICAL SERVICES OF PHARMACEUTICAL PRODUCT

(Duration of Attachment: 4-8 weeks)

1. Understanding of Research & Development or technical functions in the company
2. Understanding on Patent / Intellectual Properties / Data Exclusivity in Pharmaceutical Industry.
3. Understanding of pre-formulation, formulation, development and product improvement of various pharmaceutical dosageforms.
4. Understanding on Bioequivalence Study / Bioavailability study design.
5. Understanding on method development and validation for new formulation.
6. Understanding the importance of stability study in drug development process.
7. Understand the requirements and importance of PharmaceuticalDevelopment and data analysis
8. Activities involve in this department are:

    - Conduct literature search
    - Conduct laboratory batch experiments
    - Conduct pilot batch experiments (optional)

ASSESSMENT

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Understanding of R&D or technical service function												
2	Ability to conduct search on Patent / Intellectual Properties/ Data Exclusivity in Pharmaceutical Industry - Target: List down the patent expiry of 1 product to be determine by the preceptor.												
3	Ability to conduct pre-formulation study by evaluating data of API, excipients and reference product formulation												
4	Participate in laboratory scale (Trial Batch) study												
5	Understanding of pilot scale batch study												
6	Understanding the design and conduct of BE/BA study - Target: List down the BE centres accredited by NPRA and the list of references products for at least 1 compound to be determined by the preceptor												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
7	Understanding of method development and method validation												
8	Ability to identify parameters to monitor for stability study in new formulation												
9	Understanding the requirement of pharmaceutical product development and data analysis												

EVALUATION

$$\text{Mark} = \frac{\qquad\qquad}{90} \times 100\%$$

$$= \underline{\qquad}\%$$

NOTE:

1. *% Mark should not less than 60% for every units / sections.*

GENERAL COMMENT ON ATTITUDE:

Preceptor's Name & Signature:

Date:

QUALITY ASSURANCE / QUALITY CONTROL

(Duration of Attachment: 4- 12 weeks)

1. Knowledge and understanding of roles and activities of QA / QC / Stability / Validation in pharmaceutical manufacturing.

2. Knowledge on key QA system e.g., CAPA system, Quality RiskManagement (QRM), deviation management, handling of non- conformity, OOS investigation, quality audits, change control management, principle of validation and qualification,documentation control, product complaint handling, annual product review etc.

3. Knowledge and understanding of Quality Control activities like testing, sampling, specifications monitoring, method validation, validation analysis, microbiological testing, environmentalmonitoring, standardization etc.

4. Knowledge in product stability studies.

5. Knowledge of the various qualification & validation requirements in pharmaceutical industry

SECTION 1: QUALITY ASSURANCE FUNCTION

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Knowledge on roles & responsibilities of QA												
2	Comprehend the key areas in QA system:												
2.1	• Quality System & Manual • Site Master File • Principle of Good Documentation Practice • Essential documents and records in Quality Management System according to GMP e.g., Specifications, Manufacturing formula, processing and packaging instructions, records and procedure etc.												
2.2	• Vendor qualification and performance monitoring • Annual product review												
2.3	• Quality / Internal audits, Quality Risk Management (QRM), Change Control and Deviation Management inclusive of CAPA system												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
2.4	• Sterility Assurance Program (SAP)												
2.5	• Product release and reject & handling of non-conforming products investigation												
3	Able to assist or participate in internal audits and inspection												
4	Able to handle product complaints and investigations												
5	Knowledge in Qualification & validation principles & programs: i. Validation Master Plan (VMP): • Validation on analytical methods • Process Validation • Cleaning Validation • Computer System Validation ii. Qualification on facilities, utilities & equipment (URS, DQ, IQ, OQ, PQ) iii. Revalidation & Requalification iv. Knowledge on "V" model and its application in validation v. Knowledge on the differences												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
	and application of prospective, retrospective and concurrent validation.												
6	Able to assist in preparation of cleaning validation analysis & method validation analysis												

SECTION 2: QUALITY CONTROL FUNCTIONS

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Knowledge on roles and responsibilities in the various QC facilities: • Chemical Laboratory • Microbiological Laboratory • Retention Sample Storage • Reference Standard Storage • QC Waste Management • Sampling Facilities etc.												
2	Knowledge on testing and releasing of incoming raw & packaging materials, finished products, In-process QC - <u>Target:</u> • List down test require for at least 3 raw materials specified by the preceptor • List down difference between in process QC and finished product testing.												
3	Understand specifications and various compendia standards such as BP, USP, EP etc.												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
4	Knowledge on environmental monitoring, water monitoring & waste water monitoring - Target: List down monitoring parameters for environment, water and waste water												
5	Comprehend Good Laboratory Practice (GLP) & Laboratory Quality Management System												
6	Documentation system like preparation of SOPs, protocol of analysis, worksheets, preparation of CoA etc. - Target: Assist in preparing certificate of analysis for 1 product												
7	Able to assist in preparing specifications for raw materials, packaging & finished products												
8	Able to assist in preparation of: • protocol of analysis • worksheets • training manuals • etc.												

SECTION 3: CHEMICAL ANALYSIS LABORATORY

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Knowledge of theory and fundamental of analysis (chemical & physical) in pharmaceutical industry												
2	Knowledge on sampling plans, how to set sampling plans and sampling procedure - Target: Prepare draft sampling plans for 1 product												
3	Knowledge on analysis employed in the laboratory (Assays, dissolution, disintegration, pH,viscosity, identification, impurities,etc.) Able to conduct basic testing.												
4	Able to handle of out-of- specifications (OOS) and out-of-trend (OOT) investigations												
5	Exposure to laboratory equipment qualification, calibration & maintenance and the control of consumables in the laboratory												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
6	Knowledge on laboratory safety & chemical safety in chemical laboratory including chemical spillage												

SECTION 4: MICROBIOLOGICAL ANALYSIS LABORATORY

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Knowledge on theory and fundamental of microbiological analysis in Pharmaceutical Industry												
2	Exposure to all testing in Microbiological laboratory • Microbiological Assay, Sterility Test, Endotoxin test, Microbial limit test (MLT), Microbial contamination test (MCT), Preservative Efficacy Test (PET), environmental monitoring and water system monitoring • Able to conduct basic testing												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
	- Target: Assist in preparing data for microb testing for 1 product												

SECTION 5: STABILITY STUDIES

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Comprehend stability studies requirements and guidelines: Product Stability studies – accelerated,real time and simulation stability studies, various testing requirements. - Target: Review at least 1 stability report based on the requirement by NPRA guidelines												

EVALUATION

$$\text{Mark} = \frac{\text{\_\_\_\_\_}}{270} \times 100\%$$

$$= \text{\_\_\_\_\_}\%$$

NOTE:

1. *% Mark should not less than 60% for every units / sections.*

GENERAL COMMENT ON ATTITUDE:

Preceptor's Name & Signature:

Date:

SALES & MARKETING OF PHARMACEUTICAL PRODUCTS

(Duration of Attachment: 2-6 weeks)

1. Knowledge and understanding of the role and responsibilities of sales and marketing.

2. Knowledge and understanding of the principles of Good Governance of Medicines (GGM) and Good PharmaceuticalTrade Practice (GPTP).

3. Knowledge on the selling process, meeting and getting customers feedback, understanding the concept of ethical marketing practices, andthe concept of good and effective marketing material design.

ASSESSMENT

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Understanding the concept of ethical marketing practices (Code of Ethics and related legislation)												
2	Understanding the principles of Good Governance of Medicines (GGM) and Good Pharmaceutical Trade Practice (GPTP).												
3	Understanding the role of Sales and Marketing - Target: Prepare a list of activities to differentiate the role of Sales vs Marketing												
4	Knowledge on marketing strategy and implementation												
5	Monitoring / review of the marketing strategy and program												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
6	Able to provide healthcare professionals with details on the company's product information. - Target: Perform mock detailing for 1 product; to be evaluated by the preceptor												
7	Understanding the fundamental of good and effective marketing material design												

EVALUATION

$$\text{Mark} = \frac{\text{\_\_\_\_\_}}{70} \times 100\%$$

$$= \text{\_\_\_\_\_}\%$$

NOTE:

1. *% Mark should not less than 60% for every units / sections.*

GENERAL COMMENT ON ATTITUDE:

Preceptor's Name & Signature:

Date:

RECORD OF TRAINING AND EXPERIENCES

(Note: Please make an attachment if the space provided is not sufficient)

PRODUCTION PROCESSES: THE MANUFACTURING AND PACKAGING OF PHARMACEUTICAL PRODUCTS

a) DURATION OF ATTACHMENT:

22 – 30 weeks

b) RECORD OF TRAINING WITH TARGET TO BE ACHIEVED:

SECTION 1: DOCUMENTATIONS IN MANUFACTURING

Task: Understanding of guidelines and specifications related to manufacturing according to PIC/S GMP, ISO & ICH guidelines

Target: 1 presentation / written assignment (topic: guideline / protocol)

Date	Topic	Presentation (√)	Written Assignment (√)	Preceptor's Initial

PRODUCTION PROCESSES: THE MANUFACTURING AND PACKAGING OF PHARMACEUTICAL PRODUCTS

Task: Knowledge on preparingdocumentation - BMR / BPR, SOP, Status Labels

- Drafting new document
- Reviewing SOP and BMR

Target: Review 6 manufacturing SOPs throughout the duration of this module

Date	SOP Reviewed	Preceptor's Initial

PRODUCTION PROCESSES: THE MANUFACTURING AND PACKAGING OF PHARMACEUTICAL PRODUCTS

Task: Knowledge of the content and importance of BMR/BPR: traceability etc and status labels(examples: on hold, reject etc.) and its usage.

Target: Review 15 BMRs

Date	BMR/BPR Reviewed	Preceptor's Initial

PRODUCTION PROCESSES: THE MANUFACTURING AND PACKAGING OF PHARMACEUTICAL PRODUCTS

Task: Knowledge on the role of pharmacist in handling of Controlled Drugs including documentation and management of Import / Export Permit. (Referring to Poison Act etc.)

Target: 1 presentation / written assignment

Date	Topic	Presentation (√)	Written Assignment (√)	Preceptor's Initial

Task:

1) Able to explain the objectives of manufacturing function and processes, knowledge on the differences of sterile and non-sterile products, describe the meaning of the main terms used in production
2) Knowledge on the role of Production Planning and terminologies
3) Able to understand the basic component of ERP systems, how it works and the benefits, including demand and supply as well as procurement management for manufacturing needs.

Target: *Minimum 1 discussion session with preceptor/team

Date	Topic of Discussion	Preceptor's Initial

PRODUCTION PROCESSES: THE MANUFACTURING AND PACKAGING OF PHARMACEUTICAL PRODUCTS

Task: Knowledge on different types of cleaning agents used: detergent, solvent cleaners, acid cleaners and abrasive cleaners.

- Able to prepare cleaning agents.

Target: Prepare cleaning agents at least 3 times (preferably different type)

Date	Name of Cleaning Agent Prepared	Preceptor's Initial

Task: Knowledge on facility and equipment management

- Perform replacement for consumable parts

Target: Perform replacements for at least 3 consumable parts related to utilities and equipment (example: filter)

Date	Utility / Equipment	Consumable Parts	Preceptor's Initial

PRODUCTION PROCESSES: THE MANUFACTURING AND PACKAGING OF PHARMACEUTICAL PRODUCTS

Task: Knowledge of role of production in validation

- Assist in validation / qualification process and report preparation

Target: Prepare at least 2 sets of documentation

Date	Validation / Qualification Process Assisted	Title of Report	Preceptor's Initial

Task: Knowledge and skill on preparing User Requirement Specification (URS)

Target: Prepare at least 1 URS on simple equipment or tools

Date	Name of Simple Equipment / Tool	Preceptor's Initial

PRODUCTION PROCESSES: THE MANUFACTURING AND PACKAGING OF PHARMACEUTICAL PRODUCTS

Task: Knowledge on process flow for

- Formula calculation inBMR
- pH adjustment
- Perform IPQC checking

Target: Perform the following task for at least 3 times:

- pH adjustment (if applicable)
- IPQC testing

Date	Task Performed	Preceptor's Initial

Task: Knowledge on the technology and functionality of each machine/ equipment used in each process, such as: Mixer, Granulator/Oscillator, FBD, Oven, IBC, One-Pot Process, Compression machine, etc**.**

Target: Provide at least 1 training session to the production workers on any of this machine/equipment

Date of Training session	Topic	Preceptor's Initial

PRODUCTION PROCESSES: THE MANUFACTURING AND PACKAGING OF PHARMACEUTICAL PRODUCTS

Task: Knowledge on essential & critical utilities used in manufacturing plant: plant steam, pure steam, HVAC system, compressed air, vacuum system, waste water treatment plant, dust extractor and water system.

Target:

1) Manually take daily recording of any two utilities for at least 1 week (*even if the company already has an automated system*)

Name of Utility	Date of recording	Preceptor's Initial

2) 1 report on the review of the trending data of the chosen utility

Date	Title of Report	Preceptor's Initial

PRODUCTION PROCESSES: THE MANUFACTURING AND PACKAGING OF PHARMACEUTICAL PRODUCTS

Sterile Production

Task: Knowledge on different grade of cleanroom, its specification and qualification ofclean room

Target: Make1 formal presentation to the team on this subject

Date of Presentation	Topic	Preceptor's Initial

Task: Knowledge on gowning procedure and able to demonstrate adherence toprocedure

Target: Perform the gowning qualification successfully

Date of demonstration	Successful (Yes / No)	Preceptor's Initial

LOGISTICS, WAREHOUSING AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

a) DURATION OF ATTACHMENT:

4-6weeks

b) RECORD OF TRAINING WITH TARGET TO BE ACHIEVED:

SECTION 1: OVERVIEW OF LOGISTIC, WAREHOUSING AND DISTRIBUTION

Task: Understand the requirement of pest control program in the warehouse

Target: 1 report on the requirement on the pest control

Date	Title of Report	Preceptor's Initial

LOGISTICS, WAREHOUSING AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

SECTION 3: STORAGE AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

Task: Able to understand GDP**/**GDPMD requirements and key principles to storage conditions, stock discrepancies and stock disposal management

Target: Provide 1 training on GDP to warehouse personal

Date of Training	Topic	Preceptor's Initial

LOGISTICS, WAREHOUSING AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

Task: Able to conduct the following

- Weighing and counting of received stocks
- Visual inspection
- Verifying documents(COA, DO vs PO)

Target: Perform the following task at least 3 times:

- Weighing and counting of received stocks
- Visual inspection
- Verifying of documents (COA, DO vs PO)

Date	Task Performed	Preceptor's Initial

LOGISTICS, WAREHOUSING AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

Task: Knowledge and understand the need of a cycle-count and stock take

Target: Conduct at least 1 actual exercise from involvement in preparatory work to involvement in generation of final report

Date	Summary of the Exercise	Preceptor's Initial

Task: Knowledge on requirements of Warehouse Environmental Control such as temperature/RH mapping and certain special storage condition such as light sensitivity, corrosive, flammable etc.

Target:

1) Manually take temperature and RH recording of the warehouse / store area for at least 1 week (*even if the company already has an automated system*)

Type of Control	Date of Recording	Preceptor's Initial
Temperature		
RH		

LOGISTICS, WAREHOUSING AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

Target:
2) 1 report on the review of the trending data of the temperature/RH for the warehouse environment

Date	Title of Report	Preceptor's Initial

SECTION 4: STOCK MANAGEMENT ACCORDING TO STATUTORY REQUIREMENTS AND STANDARD PROCEDURES

Task: Handling of returned, damaged, spilled products and expired stocks and their appropriate storage & disposal according to procedures and related regulatory requirements

Target: Take part at least 3 times in any of the activities of returned or disposal

Date	Activity Performed	Product Involved	Preceptor's Initial

LOGISTICS, WAREHOUSING AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

SECTION 5: MANAGEMENT OF GOODS TRANSPORTATION

Task: Understand the needs of continuous GDP training for transport vendors

Target: Perform a simple audit of the current GDP training program and report to the preceptor with action plans if needed.

Date of Audit	Program Audited	Preceptor's Initial

REGULATORY AFFAIRS: REGISTRATION PROCEDURES, POST REGISTRATION ACTIVITIES AND RELATED LICENCES OF PHARMACEUTICAL PRODUCTS

a) DURATION OF ATTACHMENT:

4-6 weeks

b) RECORD OF TRAINING WITH TARGET TO BE ACHIEVED:

SECTION 1: ATTACHMENT AT NPRA (1 week)

Target: Prepare a written summary after every briefing session

Date of Attachment	Summary of Briefing Session	Preceptor's Initial

REGULATORY AFFAIRS: REGISTRATION PROCEDURES, POST REGISTRATION ACTIVITIES AND RELATED LICENCES OF PHARMACEUTICAL PRODUCTS

SECTION 2: REGISTRATION DOSSIER PREPARATION

Task: Labeling, Package Insert, Patient Information Leaflet (PIL) requirements

- Able to review the labeling, package insert and PIL based on references(such as DRGD, labelling requirement, reference product info)

Target: Review at least 3 of each label, PI and PIL against the requirements

Date	Product Name	Requirement Reviewed			Preceptor's Initial
		Labeling (√)	Package Insert (√)	PIL (√)	

REGULATORY AFFAIRS: REGISTRATION PROCEDURES, POST REGISTRATION ACTIVITIES AND RELATED LICENCES OF PHARMACEUTICAL PRODUCTS

SECTION 3: POST REGISTRATION ACTIVITIES

Task: Able to understand the product variations requirements in Malaysia

Target: Assist with at least 1 variation application preparation

Date	Product Name	Type of Application	Preceptor's Initial

Task: Knowledge on regulatory issue management - tracking product events, complaints, recalls, and counterfeits.

Target: Participate in at least 1 Initiating Investigation report

Date	Issue Managed	Title of Investigation Report	Preceptor's Initial

REGULATORY AFFAIRS: REGISTRATION PROCEDURES, POST REGISTRATION ACTIVITIES AND RELATED LICENCES OF PHARMACEUTICAL PRODUCTS

Task: Able to assist in the review of advertising and promotional materials

Target: Review at least 3 materials (if applicable)

Date	Materials Reviewed	Preceptor's Initial

RESEARCH & DEVELOPMENT / TECHNICAL SERVICES OFPHARMACEUTICAL PRODUCT

a) DURATION OF ATTACHMENT:

4-8 weeks

b) RECORD OF TRAINING WITH TARGET TO BE ACHIEVED:

Task: Ability to conduct search on Patent / Intellectual Properties/ Data Exclusivity in Pharmaceutical Industry

Target: List down the patent expiry of 1 product to be determine by the preceptor.

Date	Product Name	Patent Expiry Date	Preceptor's Initial

Task: Understanding the design and conduct of BE/BA study

Target: List down the BE centers accredited by NPRA and the list of references products for at least 1 compound to be determined by the preceptor

Date	Compound Name	BE Centers	Reference Products	Preceptor's Initial

QUALITY ASSURANCE / QUALITY CONTROL

a) DURATION OF ATTACHMENT:

4- 12 weeks

b) RECORD OF TRAINING WITH TARGET TO BE ACHIEVED:

SECTION 2: QUALITY ASSURANCE FUNCTION

Task: Knowledge on testing and releasing of incoming raw & packaging materials, finished products, In-process QC

Target:
1) List down test require for at least 3 raw materials specified by the preceptor

Date	Name of the Raw Material and Batch / Production Number	Test Required	Preceptor's Initial

QUALITY ASSURANCE / QUALITY CONTROL

Target:

2) List down difference between in process QC and finished product testing

Date	Product Name	List of Differences	Preceptor's Initial

QUALITY ASSURANCE / QUALITY CONTROL

Task: Knowledge on environmental monitoring, water monitoring & waste water monitoring

Target: List down monitoring parameters for environment, water and waste water

Date	Area of Monitoring (environmental / Water / Wastewater)	List of Monitoring Parameters	Preceptor's Initial
	Environmental		
	Water		
	Waste water		

QUALITY ASSURANCE / QUALITY CONTROL

Task: Documentation system like preparationof SOPs, protocol of analysis, worksheets, preparation of CoA etc.

Target: Assist in preparing certificate of analysis for 1 product

Date	Product Name and Batch / Production Number	Preceptor's Initial

SECTION 3: CHEMICAL ANALYSIS LABORATORY

Task: Knowledge on sampling plans, how to set sampling plans and sampling procedure

Target: Prepare draft sampling plans for 1 product

Date	Product Name and Batch / Production Number	Preceptor's Initial

QUALITY ASSURANCE / QUALITY CONTROL

SECTION 4: MICROBIOLOGICAL ANALYSIS LABORATORY

Task: Exposure to all testing in Microbiological laboratory

- Microbiological Assay, Sterility Test, Endotoxin test, Microbial limit test (MLT), Microbial contamination test (MCT),Preservative Efficacy Test (PET),environmental monitoring andwater system monitoring
- Able to conduct basic testing

Target: Assist in preparing data for microbe testing for 1 product

Date	Product Name and Batch / Production Number	Test Conducted	Preceptor's Initial

SECTION 5: STABILITY STUDIES

Task: Comprehend stability studies requirements and guidelines: Product Stability studies – accelerated,real time and simulation stability studies, various testing requirements.

Target: Review at least 1 stability report based on the requirement by NPRA guidelines

Date	Product Name and Batch / Production Number Reviewed	Preceptor's Initial

SALES & MARKETING OF PHARMACEUTICAL PRODUCTS

Task : Understanding the role of Sales and Marketing

Target : Prepare a list of activities to differentiate the role of Sales vs Marketing

Date	List of Activities	Preceptor's Initial

Task : Able to provide healthcare professionals with details on the company's product information.

Target : Perform mock detailing for 1 product; to be evaluated by the preceptor

Date	Product Name	Details of the Product	Preceptor's Initial

MONTHLY SUMMARY REPORT / END OF SESSION SUMMARY REPORT

Date	Task/Assignment	Job Performed	Remarks	Name & Signature Preceptor

MONTHLY SUMMARY REPORT/END OF SESSION SUMMARY REPORT

Date	Task/Assignment	Job Performed	Remarks	Name & Signature Preceptor

APPRAISALS

PRP PERSONAL ASSESSMENT BY MASTER PRECEPTOR / PRECEPTOR

(Note: Personal assessment can be done upon consensus decision by preceptors from various department)

SECTION 1: DEMONSTRATE A PROFESSIONAL APPROACH

No.	Assessment	Level of Performance											Comments
		1	2	3	4	5	6	7	8	9	10	NA	
1.	A commitment to provide quality pharmaceutical care of patients is demonstrated												
2.	A polite and helpful manner is demonstrated												
3.	Dress code and behavior meet the requirements of the organization												
4.	Reliability is demonstrated												
5.	Initiative is demonstrated												
6	Adaptability, flexibility and willingness are demonstrated in new situations												
7.	Understanding of personal limitation is demonstrated												
8.	Work is carried out in an organized and systematic manner with attention to detail so that the desired result is achieved												

PRP PERSONAL ASSESSMENT BY MASTER PRECEPTOR / PRECEPTOR

SECTION 1: DEMONSTRATE A PROFESSIONAL APPROACH

No.	Assessment	Level of Performance											Comments
		1	2	3	4	5	6	7	8	9	10	NA	
9.	Work is prioritized effectively												
10.	Tasks are pursued to completion and within agreed time limits												
11.	Problems or potential problems are identified and the appropriate corrective action taken or solution found												
12.	Stressful situations are handled effectively												
13.	Use professional judgement in a decision making												
TOTAL MARKS (SECTION 1)													
MARKS (%)(SECTION 1)		**Marks = _____X 100** **130** **=____%**											

PRP PERSONAL ASSESSMENT BY MASTER PRECEPTOR / PRECEPTOR

SECTION 2: TEAMWORK

No.	Assessment	Level of Performance											Comments
		1	2	3	4	5	6	7	8	9	10	NA	
1.	Able to collaborate with other team members to achieve organizational goals												
2.	Able to provide constructive feedback to colleagues in a respect manner												
3.	Constructive criticism is received in a positive manner												
TOTAL MARKS (SECTION 2)													
MARKS (%)(SECTION 2)		**Marks = _____X 100** **30** **=____%**											

PRP PERSONAL ASSESSMENT BY MASTER PRECEPTOR / PRECEPTOR

SECTION 3: UNDERTAKE PERSONAL AND PROFESSIONAL DEVELOPMENT

No.	Assessment	Level of Performance											Comments
		1	2	3	4	5	6	7	8	9	10	NA	
1.	The ability to self-evaluate and reflect onexperiences is demonstrated												
2.	Feedback on performance is used effectively to improved competence												
3.	The ability to take responsibility to meet own development needs and to achieve targets is demonstrated												
TOTAL MARKS (SECTION 3)													
MARKS (%)(SECTION 3)		**Marks = _____X 100 30 =___%**											

PRP PERSONAL ASSESSMENT BY MASTER PRECEPTOR / PRECEPTOR

SECTION 4: COMMUNICATION SKILLS

No.	Assessment	Level of Performance											Comments
		1	2	3	4	5	6	7	8	9	10	NA	
1.	A sufficient command of the *Bahasa Malaysia* and English Language is demonstrated												
2.	Conversations are conducted confidentially and with empathy												
3.	Questioning is used effectively to elicit necessary information and increase understanding												
4.	Responses in conversation are helpful and clear												
5.	Body language is appropriate to the situation												
6.	Clear, concise and well-structured written material isprovided when required												
7.	All responses are tailored to the needs of the recipient												
8.	Complaints or demands are responded to in a professional manner												
TOTAL MARKS (SECTION 4)													
MARKS (%)(SECTION 4)		**Marks = _____X 100** **80** **=____%**											

PRP PERSONAL ASSESSMENT BY MASTER PRECEPTOR / PRECEPTOR

SECTION 5: INTEGRITY

No.	Assessment	Level of Performance											Comments
		1	2	3	4	5	6	7	8	9	10	NA	
1.	Subscribes to the organization's core values												
2.	Tasksand situation are approached with compliance to organizational policy and legalities												
3.	Accountable, follows the rule of law and guidelines to prevent corruption												
4.	Honest, being open and not taking advantage of others												
TOTAL MARKS (SECTION 5)													
MARKS (%)(SECTION 5)		**Marks = _____X 100 40 =____%**											
MARKS (%)(SECTION 1 – SECTION 5)		**Marks = _____X 100 310 =_____%**											

Appendix A

SUMMARY OF PERFORMANCE (%) FOR EACH SECTION

MARK (%) FOR EACH SECTION		
No.	**Section**	**Mark (%)**
1.	*Production Processes: The Manufacturing and Packaging of Pharmaceutical Products*	
2.	*Logistics, Warehousing and Distribution of Pharmaceutical Products*	
3.	*Regulatory Affair: Registration Procedures, Post Registration Activities and Related Licences of Pharmaceutical Products (Including one week attachment at NPRA)*	
4.	*Research & Development of Pharmaceutical Products*	
5.	*Quality Assurance / Quality Control*	
6.	*Sales & Marketing of Pharmaceutical Products*	
	AVERAGE MARK (%)	

PRP PERSONAL ASSESSMENT AVERAGE PERFORMANCE

No.	**Section**	**Mark (%)**
1.	*Demonstrate a Professional Approach*	
2.	*Team Work*	
3.	*Undertake Personal and Professional Development*	
4.	*Communication Skills*	
5.	*Integrity*	
	AVERAGE MARK (%)	

Preceptor's Name, Signature & Stamp: Date:

Appendix A1

(TO BE FILLED BY PRINCIPAL PRECEPTOR FOR THOSE EXTENDED)SUMMARY OF PERFORMANCE (%) FOR EACH SECTION

MARK (%) FOR EACH SECTION				
No.	**Section**	**Mark % prior to extension period**	**Mark % after extension period**	**Actual extension period**
1.	*Production Processes: The Manufacturing andPackaging of Pharmaceutical Products*			
2.	*Logistics, Warehousing and Distribution of Pharmaceutical Products*			
3.	*Regulatory Affair: Registration Procedures, PostRegistration Activities and Related Licences of Pharmaceutical Products (Including one week attachment at NPRA)*			
4.	*Research & Development of PharmaceuticalProducts*			
5.	*Quality Assurance / Quality Control*			
6.	*Sales & Marketing of Pharmaceutical Products*			
AVERAGE MARK (%)				

PRP PERSONAL ASSESSMENT AVERAGE PERFORMANCE

No.	**Section**	**Mark % priorto extension period**	**Mark % after extension period**	**Actual extension period**
1.	*Demonstrate a Professional Approach*			
2.	*Team Work*			
3.	*Undertake Personal and Professional Development*			
4.	*Communication Skills*			
5.	*Integrity*			

APPRAISAL BY MASTER PRECEPTOR		
Setiausaha Lembaga Farmasi Malaysia Bahagian Perkhidmatan Farmasi Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor.		
PROVISIONALLY REGISTERED PHARMACIST'S DETAILS		
Name of Provisionally Registered Pharmacist		*Insert photo*
I/C Number		
Provisional Registration Number		
Place of Training		
Duration of Training	to	
I certify that the above PRP has completed his/her training as required under subsection 6A(2) of the Registration of Pharmacist Act 1951.		
PROPOSAL *Tick where appropriate*		
A ☐	Certificate of satisfactory experience in accordance to sub-regulation 7(1) Registration of Pharmacists Regulations 2004 is **recommended** to be given to him/her.	
B ☐	Certificate of satisfactory experience in accordance to sub-regulation 7(1) Registration of Pharmacists Regulations 2004 is **not recommended** to be given to him/her.	
MASTER PRECEPTOR'S DETAILS		
Name		
Address of Training Premise		
Master Preceptor's Signature		
Date		

Preceptor's Name, Signature & Stamp: Date:

APPRAISAL BY PRP OF PRECEPTOR (Optional)												
Setiausaha Lembaga Farmasi Malaysia Bahagian Perkhidmatan Farmasi Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor.												
Name of Provisionally Registered Pharmacist												
I/C Number												
PRP Registration Number												
Place of Training												
Duration of Training												to
Name of Master Preceptor												
No.	**Subject**	**Grade**										**Comments**
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	
1	Facilities of Training Place											
2	Professional Exposure by the Preceptors											
3	Professional Guidance by the Preceptors											
4	Training Skills of the Preceptors											