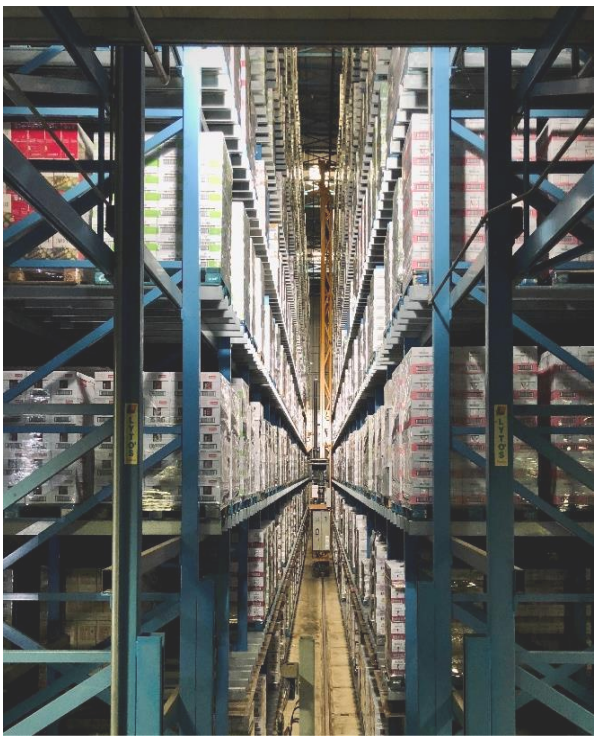
PHARMACY BOARD MALAYSIA
MINISTRY OF HEALTH MALAYSIA
2023

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

Non-Manufacturing Pharmaceutical



PERSONAL PARTICULARS *To be completed by the Provisionally Registered Pharmacist (PRP)*		
1	Full Name (as per I/C)	
2	New I/C Number	
3	Provisional Registration Number	
4	Contact Number (Mobile)	
5	Home Address	
6	E-mail Address	
7	Education Qualification Name of University Qualification Year of Graduation	
8	Contact Person Details in Case of Emergency Name Contact Number	
TRAINING PREMISE PARTICULARS *Details of which approved by Pharmacy Board Division Malaysia (PBMD)*		
9	Name of Training Premise	
10	Address of Training Premise	
11	Duration of Training	to
PRECEPTOR PARTICULARS		
12	Name of Master Preceptor (MP)	
13	Details of Principal Preceptors (PP) / Preceptors	*Please fill in Appendix I on page 3.*
By signing, I confirm that all the information provided above is true. Signature: Date:		

Appendix I

Department	*Name of Principal Preceptor(s) / Preceptor (s)	Specialisation/ Qualification	Contact Number	Email Address
Regulatory Affairs				
Pharmacovigilance				
Medical Affairs				
Clinical Research				
Sales and Marketing				
Drug Distribution				
Other Organized Activities				

*** the preceptor who assess the PRP directly**

1 INTRODUCTION

1.1 The Registration of Pharmacists Act (Amendment) 2003 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 Pharmacy Board for 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 The Pharmacy Board may extend the one-year period of employment of a PRP if the Board is not satisfied with the performance of that person as a PRP.

1.4 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 Non-Manufacturing Pharmaceutical Industries are established industries that focuses on innovation and creativity, quality, safety and efficacy of medicines with objectives to continuously improve health in human beings. These industries require dynamic sets of people with competencies to align with new discoveries, latest technologies as well as challenges faced by the industries.

2.1.2 By the end of the training, the PRP will be able to achieve key and functional competencies in various aspects, namely sales and marketing, product registration, clinical research, medical affairs, drug distribution and others related to the development and shaping of the healthcare environment. 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 Non-Manufacturing Pharmaceutical Industries aims to provide the pharmacists with sufficiently in-depth clarity in the understanding of management of innovative 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 PRP in the non-manufacturing pharmaceutical industries:

2.5.1 Regulatory Affairs
2.5.2 Pharmacovigilance
2.5.3 Medical Affairs
2.5.4 Clinical Research
2.5.5 Sales and Marketing
2.5.6 Drug Distribution

2.5.7 Others: Other Organized Activities

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 and all 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 additional attachment.)

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 the following:

2.7.1 Endorse the completion of each task with signature, name and date 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 and Appendix A or Appendix A1 shall be uploaded by PRP into Pharmacist Registration Management System (PRiSMA) for the Fully Registered Pharmacist (FRP) application. The original logbook should be kept at the premise for a minimum of three (3) years.

2.8 Criteria of Non-Manufacturing Pharmaceutical Industries for Training of PRP

2.8.1 All Non-Manufacturing Pharmaceutical Industries that enable PRPs to undergo training for the modules as mentioned in Table 1.1.

2.8.2 All companies must be a registered company with the Companies Commission of Malaysia (Suruhanjaya Syarikat Malaysia, SSM).

2.8.3 Each company will have a Master Preceptor and Principal Preceptors qualified and appointed by the respective company and approved by the Pharmacy Board.

3 DUTIES AND RESPONSIBILITIES OF A PRECEPTOR

3.1 Type of Preceptors

Master Preceptor	:	Must be a Registered Pharmacist, with at least 3 years working experience in non-manufacturing pharmaceutical industry.
Principal Preceptor	:	Not necessarily a Registered Pharmacist. Must have at least 3 years working experience in the respective function.

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 behaviours expected as a competent pharmacist in the Non-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 PRP

4.1 A Provisionally Registered Pharmacist (PRP) should:

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

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

4.1.3 Actively seek knowledge on one's initiatives using the guidance from the logbook with a positive attitude.

4.1.4 Committed to learn from the preceptor and other co-workers in the training environment.

4.1.5 To follow up on his/her training schedule and outcome with the relevant preceptor.

4.1.6 Be aware that, in addition to the daily activities, your time should be set aside to consider activities outside working/office hours.

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

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

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

4.1.10 Remember that obtaining adequate working experience is your responsibility. Others will help, but it requires a conscientious effort on your own part, not just passive acceptance.

4.1.11 Recognize that not all of the preceptor's time can by devoted to teaching, and you should therefore actively acquire knowledge and skills by observation, reading and questioning others.

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 Department/Division Head and supervised overall by 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 training.

Table 1.1: Training Timetable

COMPETENCY TRAINING MODULES	DURATION (weeks)
Regulatory Affairs	18
Pharmacovigilance	4
Drug Distribution	6
Clinical Research	1
Medical Affairs	10
Sales and Marketing of Pharmaceutical Products	12
Other Organized Activities	1
TOTAL	52

4.3 Confidentiality

PRP will be briefed on the importance of confidentiality and must sign the respective companies' Confidentiality Agreement.

ASSESSMENT

MODULE 1: REGULATORY AFFAIRS

REGULATORY REQUIREMENTS, REGISTRATION ACTIVITIES AND RELATED LICENCES OF PHARMACEUTICAL PRODUCTS

(Duration of Attachment: 18 weeks including 1 week at NPRA)

1. Knowledge and understanding of the regulatory process and requirements in Malaysia.

2. Knowledge and understanding of the structure & functions of the Regulatory Affairs Department (within the subsidiary and worldwide).

3. Knowledge of the statutory aspects of regulatory related matters.

4. Understand the role of regulatory affairs in product launches/product life cycle management in a pharmaceutical company.

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.												
4	Expose to the implementation of licensing scheme for pharmaceutical manufacturers, importers and												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
	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: REGULATORY REQUIREMENTS & PROCESSES (4 Weeks)

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 pharmacy related legislations in Malaysia.												
2	Knowledge on related regulatory guidelines of Malaysia and ASEAN.												
3	Knowledge of International Standards and Regulatory Guidelines.												
4	Understand the structure and functions of various departments within the Ministry of Health (MOH).												
5	Knowledge of the MOH online submission system e.g., QUEST. <u>Target</u>: Participate in at least 1 exercise using the system												

SECTION 3: REGISTRATION ACTIVITIES (5 Weeks)

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Understand critical aspects pertaining to preparation of a registration dossier for submission in Malaysia.												
2	Assist in preparation of variation submissions and product registration renewal in Malaysia. Target: Participate in at least 1 exercise												
3	Able to assist in the preparation of routine reports and regulatory agency communications. Target: Participate in at least 1 exercise												
4	Able to assist / support in the review/preparation of advertising and promotional items. Target: Participate in at least 1 exercise												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
5	Knowledge on regulatory issue management – tracking product events, complaints, recalls, and counterfeits. <u>Target</u>: Participate in at least 1 exercise												

SECTION 4: INFORMATION MANAGEMENT AND CONTROL IN REGULATORY AFFAIRS (4 Weeks)

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Understand and assist on internal database management and archiving of regulatory documentation to ensure compliance. Target: Participate in at least 1 exercise												
2	Understanding and assist in review of regulatory SOPs. Target: Participate in the review of at least 1 SOP												
3	Support in handling any regulatory information requests. Target: Participate in at least 1 exercise												
4	Under guidance of manager, liaise with other internal stakeholders at local level and at headquarters / regional office.												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
	Target: Participate in at least 1 exercise												

SECTION 5: RELATED LICENSING ACTIVITY (4 Weeks)

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 (eg. Clinical Trials Import License (CTIL) where applicable)												
	Able to prepare applications for regulatory related licenses/certificates/permits etc.												
2	Able to maintain records required under the licenses.												
3	Able to assist/coordinate internal audits and/or inspection.												

EVALUATION

Mark = _____ × 100%
230

= _____ %

Preceptor's Name & Signature:

Note: % mark should not be less than 60% for every unit/section.

GENERAL COMMENT ON ATTITUDE:

MODULE 2: PHARMACOVIGILANCE

PHARMACOVIGILANCE ACTIVITIES AND PRODUCT SAFETY MONITORING

(Duration of Attachment: 4 Weeks)

1. Knowledge and understanding of current regulatory requirements on pharmacovigilance.

2. Knowledge and understanding of the pharmacovigilance (PV) process in a pharmaceutical company.

SECTION 1: PHARMACOVIGILANCE ACTIVITIES

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Understand definition of and need for pharmacovigilance. Target: To complete learning on PV												
2	Exposure to the different PV activities within the pharmaceutical company. Target: Participate in at least 1 exercise												
3	Recognize the importance of adverse event reporting. Target: Participate in at least 1 exercise (if any)												

SECTION 2: PRODUCT SAFETY MONITORING

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Familiarity with and training on internal procedures and guidelines related to pharmacovigilance.												
2	Knowledge on the Malaysia Guidelines on Good Pharmacovigilance Practices (GVP) for Product Registration Holders and relevant international guidelines. Target: Support 1 local Pharmacovigilance system master file (PSMF) compilation, if applicable.												
3	Familiarity with terminology related to pharmacovigilance. Understand the different definitions of Adverse Events (AE), Adverse Drug Reactions) ADR, serious ADR, Suspected Unexpected Serious Adverse Reactions (SUSAR) etc.												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
4	Understand and assist on Periodic Benefit – Risk Evaluation Report (PBRER) submissions. Target: Prepare 1 Malaysia Annex for PBRER submission, if applicable.												
5	Aware of the different types of AE report including pregnancy reports. Target: List all available sources of AE in the company and differentiate the nature of the reports (solicited / spontaneous)												
6	Understand the role of Pharmacovigilance in market research activities, local studies, contracts and/or agreements. Target: Perform 1 source document quality check (SDQC) and 1 case transmission verification (CTV), if applicable.												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
7	Assist in reporting and submission of ADR (local/international) to Malaysia Adverse Drug Reactions Advisory Council (MADRAC). <u>Target</u>: 1. Assess at least 1 case for NPRA ADR submission qualification 2. Assess at least 1 case for NPRA SUSAR submission qualification. Note: these cases could be simulation basis depending on company.												
8	Assist in maintaining Pharmacovigilance records and database.												
9	Assist in Pharmacovigilance audit and/or understanding in Risk Management Plan. <u>Target</u>: Prepare 1 Risk Management Plan (RMP)												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
	Malaysia Specific Annex for submission, if applicable.												

If any of the tasks/assignments mentioned above do not present itself in real life during training duration, a simulation/case study or an example of a case can be conducted to promote learning.

EVALUATION

Mark = $\frac{\text{\_\_\_\_\_}}{120}$ × 100%

= _____ %

Preceptor's Name & Signature:

Note: % mark should not be less than 60% for every unit/section.

GENERAL COMMENT ON ATTITUDE:

MODULE 3: DRUG DISTRIBUTION

(Duration of Attachment: 6 Weeks)

1. Knowledge and understanding of the principles of Distribution Centre management, inventory, stock movement and control, cleanliness and sanitation and security in accordance to Procedures in Distribution Centre Management.

2. Knowledge of storage and distribution of pharmaceuticals, biologicals, handling of psychotropic and 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 preparation and documentation of disposal of pharmaceuticals and biological products.

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 materials, drugs and finished products in accordance to the respective legislations:

    - Dangerous Drugs Act 1962 & its Regulations
    - Poisons ACT 1952 & its Regulations
    - Poisons (Psychotropic Substance) Regulations 1989
    - Control of Drugs and Cosmetics Regulations 1984

SECTION 1: OVERVIEW OF DRUG DISTRIBUTION

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	<u>Organizational Structure/Chart</u> Able to understand the structure/layout and identify a pharmacist's role in the organization. <u>Target:</u> Make 1 formal presentation on Pharmacist role in Drug Distribution and explain the decisions and actions with respect to the evaluation, procurement, storage, distribution, and administration of all drug products.												
2	<u>Inventory</u> Awareness of Distribution Centre Catalogue and type of products managed.												
3	<u>Stock Movement and Control</u> Able to explain stock movement and control of drugs and non-drugs.												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
4	<u>Cleanliness</u> Able to identify requirements for cleanliness.												
5	<u>Security/Safety</u> Able to list security/safety aspects of warehouse/distribution centre.												
6	<u>Pest Control</u> Monitor pest control activities with contractor.												

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	Able to understand what is meant by inventory and its importance.												
2	Able to understand demand and supply in supply chain and procurement management for stocks. <u>Target:</u> Participate in 1 procurement management exercise												
3	Basic understanding of supply chain process integration.												
4	Able to identify the major challenges in effective supply chain strategy. <u>Target:</u> Written assignment on the challenges and recommendations to overcome it based on the legislations.												

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 requirements and key principles to storage conditions, stock discrepancies and stock disposal management. Target: Make 1 formal presentation on Pharmacist role in Good Distribution Practice (GDP)												
2	Able to conduct the following during receiving of stocks: • Weighing and counting of received stocks • Visual inspection • Verifying documents (Certificate of Analysis, Delivery Orders vs. Purchase Orders) Target: Participate in at least 1 exercise												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
3	<u>Stock Movement Management</u> • Cleaning down of stock containers prior to storage • Able to allocate stocks based on First In First Out (FIFO) or First Expiry First Out (FEFO) • Preparation of stocks for distribution need – weighing, counting, packing etc. <u>Target</u>: Participate in at least 1 exercise												
4	Knowledge on the requirement of storage and documentation relating to controlled item e.g., cytotoxic and psychotropic drugs and biologics. <u>Target</u>: Participate in at least 1 exercise												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
5	Knowledge and understanding the need of a cycle-count and stock take. <u>Target:</u> Participate in at least 1 exercise of cycle count.												
6	Able to understand the implementation of proper segregation, markings at designated areas within the warehouse – product storage in appropriate areas based on status.												
7	Knowledge on requirements of certain items with temperature and humidity control needs – temperature and humidity monitoring e.g., cold chain monitoring. <u>Target:</u> Written assignment on the objective of maintaining temperature and humidity controls for drug distribution.												

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 drugs and controlled medicines.												
2	Knowledge on documentation requirements and compliance to various legislations such as Poison Act 1952, Dangerous Drugs Act 1952, Sales of Drugs Act, and Control of Drugs and Regulations 1984. <u>Target:</u> Written assignment on the requirements and compliance that relates to Drug Distribution												
3	Product complaint and recall management including storage & disposal according to procedures and regulatory requirements. <u>Target</u>: Participate in at least 1 exercise												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
4	Handling of returned damaged, spilled products and expired stocks and their appropriate storage and disposal according to procedures and related regulatory requirements. Target: Participate in at least 1 exercise												

SECTION 5: MANAGEMENT OF TRANSPORTATION AS PER GDP REQUIREMENTS

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 understand the requirements of GDP for transportation of Pharmaceuticals and Biologics. Target: Participate in at least 1 exercise												
2	Able to conduct continuous education for transport vendors under the supervision of the preceptor. Target: To write 1 proposal and justification for continuous education for transport vendors.												

EVALUATION

Mark = _____ × 100%
230

= _____ %

Preceptor's Name & Signature:

Note: % mark should not be less than 60% for every unit/section.

GENERAL COMMENT ON ATTITUDE:

MODULE 4: CLINICAL RESEARCH

(Duration of Attachment: 1 Week)

1. To understand drug development process and phases of clinical trials.

2. Expose to the clinical research conduct terms e.g. protocol, investigational product, investigator brochure and essential documents.

3. Expose to Good Clinical Practice guideline

4. Expose to the roles played by various stakeholders in the running of a clinical trial (investigators, ethics committee, study coordinators, sponsors, regulatory authorities, institution and etc.)

5. Expose to the different stages in conducting a clinical trial (planning, implementing, monitoring and managing).

CLINICAL RESEARCH: ATTACHMENT WITH CLINICAL RESEARCH MALAYSIA (CRM)

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 drug development process and phases of clinical trials.												
2	Expose to the different terms used in clinical research e.g., new chemical entities or generic drug development, investigational new drug, new drug application.												
3	To understand Good Clinical Practice guideline and Good Documentation Practice.												
4	Appreciate the roles played by various stakeholders in the running of a clinical trial (investigators, ethics committee, study coordinators, sponsors, regulatory authorities).												
5	Appreciate the different stages in conducting a clinical trial (planning, implementing, monitoring, managing).												

Target: 1 formal presentation/ written assignment / quiz at the end of the attachment.

EVALUATION

Mark = $\frac{\qquad}{50}$ × 100%

= $\frac{\qquad}{\qquad}$ %

Preceptor's Name & Signature:

Note: % mark should not be less than 60% for every unit/section.

GENERAL COMMENT ON ATTITUDE:

MODULE 5: MEDICAL AFFAIRS

(Duration of Attachment: 10 Weeks)

Medical Affairs Roles

1. Understand the roles and responsibilities of Medical Affairs (and the different roles within), and their work nature.
2. Experience how Medical Affairs engages Key Opinion Leaders/Scientific Leaders in various settings.

Medical Affairs Activities

1. Understand the different Medical Affairs activities including:
    I. Advisory Boards
    II. Continuous Medical Education (CME) events
    III. Disease training or scientific updates to sales/marketing team
    IV. Compassionate use/pre-approval access programs
    V. Data generation activities
2. Be involved in and contribute to at least 2 of the different Medical Affairs Activities.
3. Learn how to dissect clinical papers and present key scientific information.

Medical Information:

1. Understand the company's policy in providing medical information to healthcare professionals.
2. Learn how to perform literature searches using internal/external databases.
3. Learn how to evaluate clinical papers.
4. Learn how to write responses to medical enquiries.
5. Assist in responding to medical enquiries.

Medical Review of Promotional Materials:

1. Knowledge and understanding of companies Code of Conduct.
2. Understand local laws and regulation on drug sales, advertisement, copyrights, and trademarks.
3. Apply working knowledge on medical review of promotional/marketing materials.
4. Be exposed to products of new therapeutic areas.

SECTION 1: MEDICAL AFFAIRS ROLES

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Understand the roles and responsibilities of Medical Affairs (and the different roles within), and their work nature. Target: List the core Roles & Responsibilities of Medical Affairs												
2	Experience how Medical Affairs engages Key Opinion Leaders/Scientific Leaders in various settings Target: Participate in at least 3 scientific field engagements and submit post-field visit report												

SECTION 2: MEDICAL AFFAIRS ACTIVITIES

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Understand the different Medical Affairs activities including: I. Advisory Boards II. Continuous Medical Education (CME) events III. Disease training or scientific updates to sales/marketing team IV. Compassionate use/pre-approval access programs V. Data generation activities <u>Target</u>: List the differences in the objectives and nature of the activities												
2	Be involved in and contribute to at least 2 of the different Medical Affairs Activities <u>Target</u>: Participate in at least 2 of these activities												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
3	Learn how to dissect clinical papers and present key scientific information <u>Target</u>: Dissect at least 1 clinical paper to be presented back to Medical Affairs												

SECTION 3: MEDICAL INFORMATION

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Understand the company's policy in providing medical information to healthcare professionals. Target: List key points in company SOP in addressing medical inquiries												
2	Learn how to perform literature searches using internal/external databases. Target: List key resources												
3	Learn how to evaluate a clinical paper.												
4	Learn how to write responses to medical enquiries.												
5	Assist in responding to medical enquiries. Target: Respond to at least 3 medical inquiries												

SECTION 4: MEDICAL REVIEW OF PROMOTIONAL MATERIALS

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Knowledge and understanding of companies Code of Conduct.												
2	Understand local laws and regulations on drug sales, advertisements, copyrights, and trademarks.												
3	Apply working knowledge on medical review of promotional / marketing materials. Target: Review at least 3 promotional materials accurately												
4	Be exposed to products of new therapeutic areas.												

EVALUATION

Mark = $\frac{\quad}{140}$ × 100%

= _____ %

Preceptor's Name & Signature:

Note: % mark should not be less than 60% for every unit/section.

GENERAL COMMENT ON ATTITUDE:

MODULE 6: SALES & MARKETING OF PHARMACEUTICAL PRODUCTS

(Duration of Attachment: 12 Weeks)

1. Training: Understanding the role of disease and product training of sales representatives.

2. Marketing:
   a) Marketing Planning
      i. Understand market planning, market demand and customer behaviour.
      ii. Expose to tracking and evaluating results, and forecasting/inventory management.
   b) Promotional material development
      i. Introduced to the term promotional strategy, objective, key messages.
      ii. Involved in the development of promotional materials based on evidence, promotional strategy, and market demand/customer behaviour.
   c) Marketing activities
      i. Appreciate the activities involved in managing marketing campaign.
      ii. Assist in management and organization of CME events.

3. Sales:
   a) Roles of Sales Representatives and Sales Manager
      i. Understand the roles and responsibilities of Sales Representatives and Sales Manager and their work nature.
      ii. Experience how a sales representative engages customers in various settings.
   b) Different Sales Activities
      i. Be involved in different sales activities, including Continuous Medical Education (CME) events.

4. Corporate/Government Affairs and Market Access (if available):
   a) Understand the different types of internal/external stakeholder engagement.
   b) Appreciate the roles of different stakeholders in organizing health promotions, corporate social responsibility (CSR) events, or other ongoing policy engagements.
   c) Understand the different types of health economics studies and its roles in supporting decision making.

SECTION 1: TRAINING

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Understand the role of disease and product training of sales representatives. <u>Target</u>: To be involved in conducting 1 workshop / make 1 presentation												

SECTION 2: MARKETING

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	<u>Marketing Planning</u> • Understand market planning, market demand and customer behaviour. • Exposed to tracking and evaluating results, and												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
	forecasting / inventory management. <u>Target</u>: 1 written assignment on marketing plan												
2	<u>Promotional material development</u> • Introduced to the term promotional strategy, objective, key messages. Exposed in the development of promotional materials based on evidence, promotional strategy, and market demand/customer behaviour. <u>Target</u>: Prepare 1 promotional material /mock simulation												
3	<u>Marketing activities</u> • Appreciate the activities involved in managing marketing campaign.												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
	Assist in management and organization of CME events. <u>Target</u>: Participate in at least 1 marketing project / event												

SECTION 3: SALES

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	<u>Roles of Sales Representatives and Sales Manager</u> • Understand the roles and responsibilities of Sales Representatives and Sales Managers and their work nature. • Experience how a sales representative engages customers in various settings. <u>Target</u>: To make at least 3 field visits and complete 3 daily call												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
	report (outlining the objectives and outcome of the call)												
2	<u>Sales Activities</u> • Involved in various sales activities including sales meeting and CME activities. <u>Target</u>: Involved in at least 1 CME presentation (internal /external audience)												

SECTION 4: CORPORATE/GOVERNMENT AFFAIRS AND MARKET ACCESS (if available)

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
1	Understand the different types of corporate communications (internal and external) and internal/external stakeholder engagement												

No.	Knowledge/Task	Level of Performance										Comments	Name and Signature of Preceptor
		1	2	3	4	5	6	7	8	9	10		
	Target: At least 1 training with corporate communications												
2	Appreciate the roles of different stakeholders in organizing health promotions, corporate social responsibility (CSR) events, product launches or ongoing listing initiatives Target: At least 1 training on stake holder management												
3	Understand the different types of health economics studies and its roles in supporting decision making Target: At least 1 study report/critical appraisal on health economics studies, if applicable												

EVALUATION

$$\textbf{Mark} = \frac{\qquad}{\textbf{60* or 90}} \times 100\%$$

$$= \qquad \%$$

Preceptor's Name & Signature:

**Use 60 if company is without Corporate Affairs component.*

Note: % mark should not be less than 60% for every unit/section.

GENERAL COMMENT ON ATTITUDE:

MODULE 7: OTHER ORGANIZED ACTIVITIES

(Duration: 1 Week)

1. Introduction to non-manufacturing pharmaceutical industry activities
2. Industry Code of Conduct
3. Intellectual Property Laws
4. Competition Act
5. Personal Data Protection Act (PDPA)
6. Counterfeit drugs
7. Introduction to Pharmacy Services Program in Ministry of Health
8. Good Governance in Medicine (GGM)

OTHER ORGANIZED ACTIVITIES

No.	Knowledge/Task	Attendance		Comments	Name and Signature of Preceptor
		Yes	No		
1	Introduction on non-manufacturing pharmaceutical industry activities				
2	Industry Code of Conduct				
3	Intellectual Property Law				
4	Competition Act				
5	Personal Data Protection Act (PDPA)				
6	Counterfeit drugs				
7	Introduction to Pharmacy Services Division in Ministry of Health				
8	Good Governance in Medicine (GGM)				

ATTENDANCE

$$\textbf{Mark} = \frac{\qquad}{8} \times 100\%$$

$$= \frac{\qquad}{\qquad} \%$$

Preceptor's Name & Signature:

Note: % mark should not be less than 60% for every unit/section.

RECORD OF TRAINING AND EXPERIENCES

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

MODULE 1: REGULATORY AFFAIRS

a) DURATION OF ATTACHMENT:

18 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

MODULE 1: REGULATORY AFFAIRS

SECTION 2: REGULATORY REQUIREMENTS & PROCESSES

Task: Knowledge of the MOH online submission system e.g., QUEST

Target: Participate in at least 1 exercise using the system

Date	Exercise Participated	Preceptor's Initial

SECTION 3: REGISTRATION ACTIVITIES

Task: Assist in preparation of variation submissions and product registration renewal in Malaysia.

Target: Participate in at least 1 exercise

Date	Exercise Participated	Preceptor's Initial

MODULE 1: REGULATORY AFFAIRS

Task: Able to assist in the preparation of routine reports and regulatory agency communications.

Target: Participate in at least 1 exercise

Date	Exercise Participated	Preceptor's Initial

Task: Able to assist / support in the review/preparation of advertising and promotional items.

Target: Participate in at least 1 exercise

Date	Details of Exercise	Preceptor's Initial

MODULE 1: REGULATORY AFFAIRS

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

Target: Participate in at least 1 exercise

Date	Exercise Participated	Preceptor's Initial

SECTION 4: INFORMATION MANAGEMENT AND CONTROL IN REGULATORY AFFAIRS (4 Weeks)

Task: Understand and assist on internal database management and archiving of regulatory documentation to ensure compliance.

Target: Participate in at least 1 exercise

Date	Exercise Participated	Preceptor's Initial

MODULE 1: REGULATORY AFFAIRS

Task: Understanding and assist in review of regulatory SOPs.

Target: Participate in the review of at least 1 SOP

Date	SOP Reviewed	Preceptor's Initial

Task: Support in handling any regulatory information requests.

Target: Participate in at least 1 exercise

Date	Exercise Participated	Preceptor's Initial

MODULE 1: REGULATORY AFFAIRS

Task: Under guidance of manager, liaise with other internal stakeholders at local level and at headquarters / regional office.

Target: Participate in at least 1 exercise

Date	Exercise Participated	Preceptor's Initial

MODULE 2: PHARMACOVIGILANCE

a) DURATION OF ATTACHMENT:

4 weeks

b) RECORD OF TRAINING WITH TARGET TO BE ACHIEVED:

SECTION 1: PHARMACOVIGILANCE ACTIVITIES

Task: Understand definition of and need for pharmacovigilance.

Target: To complete learning on PV

Date of Completion	Preceptor's Initial

Task: Exposure to the different PV activities within the pharmaceutical company.

Target: Participate in at least 1 exercise

Date	Exercise Participated	Preceptor's Initial

MODULE 2: PHARMACOVIGILANCE

Task: Recognize the importance of adverse event reporting.

Target: Participate in at least 1 exercise (if any)

Date	Exercise Participated	Preceptor's Initial

SECTION 2: PRODUCT SAFETY MONITORING

NOTE: If any of the tasks/assignments mentioned above do not present itself in real life during training duration, a simulation/case study or an example of a case can be conducted to promote learning.

Task: Knowledge on the Malaysia Guidelines on Good Pharmacovigilance Practices (GVP) for Product Registration Holders and relevant international guidelines.

Target: Support 1 local Pharmacovigilance system master file (PSMF) compilation, if applicable.

Date	PSMF Compiled	Preceptor's Initial

MODULE 2: PHARMACOVIGILANCE

Task: Understand and assist on Periodic Benefit – Risk Evaluation Report (PBRER) submissions.

Target: Prepare 1 Malaysia Annex for PBRER submission, if applicable.

Date	PBRER Prepared	Preceptor's Initial

Task: Aware of the different types of AE report including pregnancy reports.

Target: List all available sources of AE in the company and differentiate the nature of the reports (solicited / spontaneous)

Date of Completion	Preceptor's Initial

MODULE 2: PHARMACOVIGILANCE

Task: Understand the role of Pharmacovigilance in market research activities, local studies, contracts and/or agreements.

Target: Perform 1 source document quality check (SDQC) and 1 case transmission verification (CTV), if applicable.

Task	Date of Completion	Preceptor's Initial
SDQC		
CTV		

Task: Assist in reporting and submission of ADR (local/international) to Malaysia Adverse Drug Reactions Advisory Council (MADRAC).
Note: these cases could be simulation basis depending on company.

Target:

1. Assess at least 1 case for NPRA ADR submission qualification

Date	Case Assessed	Preceptor's Initial

MODULE 2: PHARMACOVIGILANCE

Target:

2. Assess at least 1 case for NPRA SUSAR submission qualification.

Date	Case Assessed	Preceptor's Initial

Task: Assist in Pharmacovigilance audit and/or understanding in Risk Management Plan.

Target: Prepare 1 Risk Management Plan (RMP) Malaysia Specific Annex for submission, if applicable.

Date	RMP Prepared	Preceptor's Initial

MODULE 3: DRUG DISTRIBUTION

a) DURATION OF ATTACHMENT:

6 Weeks

b) **RECORD OF TRAINING WITH TARGET TO BE ACHIEVED:**

SECTION 1: OVERVIEW OF DRUG DISTRIBUTION

Task: Organizational Structure/Chart: Able to understand the structure/layout and identify a pharmacist's role in the organization.

Target: Make 1 formal presentation on Pharmacist role in Drug Distribution and explain the decisions and actions with respect to the evaluation, procurement, storage, distribution, and administration of all drug products.

Date	Topic of Presentation	Preceptor's Initial

MODULE 3: DRUG DISTRIBUTION

SECTION 2: SUPPLY CHAIN AND INVENTORY MANAGEMENT

Task: Able to understand demand and supply in supply chain and procurement management for stocks.

Target: Participate in 1 procurement management exercise

Date	Procurement	Preceptor's Initial

Task: Able to identify the major challenges in effective supply chain strategy.

Target: Written assignment on the challenges and recommendations to overcome it based on the legislations.

Date	Topic of Written Assignment	Preceptor's Initial

MODULE 3: DRUG DISTRIBUTION

SECTION 3: STORAGE AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS

Task: Good Distribution Practice (GDP) Able-to understand GDP requirements and key principles to storage conditions, stock discrepancies and stock disposal management.

Target: Make 1 formal presentation on Pharmacist role in Good Distribution Practice (GDP)

Date	Topic of Presentation	Preceptor's Initial

Task: Able to conduct the following during receiving of stocks:

- Weighing and counting of received stocks
- Visual inspection
- Verifying documents (Certificate of Analysis, Delivery Orders vs. Purchase Orders)

Target: Participate in at least 1 exercise

Date	Stock Received	Task Performed	Preceptor's Initial

MODULE 3: DRUG DISTRIBUTION

Task: Stock Movement Management

- Cleaning down of stock containers prior to storage
- Able to allocate stocks based on First In First Out (FIFO) or First Expiry First Out (FEFO)
- Preparation of stocks for distribution need – weighing, counting, packing etc.

Target: Participate in at least 1 exercise

Date	Exercise Participated	Preceptor's Initial

Task: Knowledge on the requirement of storage and documentation relating to controlled item e.g., cytotoxic and psychotropic drugs and biologics.

Target: Participate in at least 1 exercise

Date	Exercise Participated	Preceptor's Initial

MODULE 3: DRUG DISTRIBUTION

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

Target: Participate in at least 1 exercise of cycle count

Date	Exercise Participated	Preceptor's Initial

Task: Knowledge on requirements of certain items with temperature and humidity control needs – temperature and humidity monitoring e.g., cold chain monitoring.

Target: Written assignment on the objective of maintaining temperature and humidity controls for drug distribution

Date	Topic of Written Assignment	Preceptor's Initial

MODULE 3: DRUG DISTRIBUTION

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

Task: Knowledge on documentation requirements and compliance to various legislations such as Poison Act 1952, Dangerous Drugs Act 1952, Sales of Drugs Act, and Control of Drugs and Regulations 1984.

Target: Written assignment on the requirements and compliance that relates to Drug Distribution.

Date	Topic of Written Assignment	Preceptor's Initial

Task: Product complaint and recall management including storage & disposal according to procedures and regulatory requirements

Target: Participate in at least 1 exercise

Date	Product Name	Exercise Participated	Preceptor's Initial

MODULE 3: DRUG DISTRIBUTION

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

Target: Participate in at least 1 exercise

Date	Product Name	Exercise Participated	Preceptor's Initial

SECTION 5: MANAGEMENT OF TRANSPORTATION AS PER GDP REQUIREMENTS

Task: Able to understand the requirements of GDP for transportation of Pharmaceuticals and Biologics

Target: Participate in at least 1 exercise

Date	Exercise Participated	Preceptor's Initial

MODULE 3: DRUG DISTRIBUTION

Task: Able to conduct continuous education for transport vendors under the supervision of the preceptor.

Target: To write 1 proposal and justification for continuous education for transport vendors.

Date	Topic of Written Proposal	Preceptor's Initial

MODULE 4: CLINICAL RESEARCH

a) **DURATION OF ATTACHMENT**:

1 Weeks

b) **RECORD OF TRAINING WITH TARGET TO BE ACHIEVED:**

Target: 1 formal presentation/ written assignment / quiz at the end of the attachment.

Date	Topic of Presentation/ Written Assignment / Quiz	Preceptor's Initial

MODULE 5: MEDICAL AFFAIRS

a) **DURATION OF ATTACHMENT**:

10 Weeks

b) **RECORD OF TRAINING WITH TARGET TO BE ACHIEVED:**

SECTION 1: MEDICAL AFFAIRS ROLES

Task: Understand the roles and responsibilities of Medical Affairs (and the different roles within), and their work nature.

Target: List the core Roles & Responsibilities of Medical Affairs

Date of Completion	Preceptor's Initial

Task: Experience how Medical Affairs engages Key Opinion Leaders/Scientific Leaders in various settings

Target: Participate in at least 3 scientific field engagements and submit post-field visit report

Date of Participation	Preceptor's Initial

MODULE 5: MEDICAL AFFAIRS

SECTION 2: MEDICAL AFFAIRS ACTIVITIES

Task: Understand the different Medical Affairs activities including:

I. Advisory Boards
II. Continuous Medical Education (CME) events
III. Disease training or scientific updates to sales/marketing team
IV. Compassionate use/pre-approval access programs
V. Data generation activities

Target: List the differences in the objectives and nature of the activities

Date of Completion	Preceptor's Initial

Task: Be involved in and contribute to at least 2 of the different Medical Affairs Activities

Target: Participate in at least 2 of these activities

Date	Activities Participated	Preceptor's Initial

MODULE 5: MEDICAL AFFAIRS

Task: Learn how to dissect clinical papers and present key scientific information

Target: Dissect at least 1 clinical paper to be presented back to Medical Affairs

Date	Topic of Clinic Paper	Preceptor's Initial

SECTION 3: MEDICAL INFORMATION

Task: Understand the company's policy in providing medical information to healthcare professionals.

Target: List key points in company SOP in addressing medical inquiries

Date of Completion	Preceptor's Initial

MODULE 5: MEDICAL AFFAIRS

Task: Learn how to perform literature searches using internal / external databases.

Target: List key resources

Date of Completion	Preceptor's Initial

Task: Assist in responding to medical enquiries.

Target: Respond to at least 3 medical inquiries

Date	Inquiries Responded	Preceptor's Initial

MODULE 5: MEDICAL AFFAIRS

SECTION 4: MEDICAL REVIEW OF PROMOTIONAL MATERIALS

Task: Apply working knowledge on medical review of promotional / marketing materials.

Target: Review at least 3 promotional materials accurately

Date	Material Reviewed	Preceptor's Initial

MODULE 6: SALES & MARKETING OF PHARMACEUTICAL PRODUCTS

a) **DURATION OF ATTACHMENT**:

12 Weeks

b) **RECORD OF TRAINING WITH TARGET TO BE ACHIEVED:**

SECTION 1: TRAINING

Task: Understand the role of disease and product training of sales representatives.

Target: To be involved in conducting 1 workshop / make 1 presentation

Date	Topic	Involved in Conducting Workshop / Make Presentation (please specify)	Preceptor's Initial

MODULE 6: SALES & MARKETING OF PHARMACEUTICAL PRODUCTS

SECTION 2: MARKETING

Task: Marketing Planning

- Understand market planning, market demand and customer behaviour.
- Exposed to tracking and evaluating results, and forecasting / inventory management.

Target: 1 written assignment on marketing plan

Date of Completion	Preceptor's Initial

Task: Promotional material development

- Introduced to the term promotional strategy, objective, key messages.
  Exposed in the development of promotional materials based on evidence, promotional strategy, and market demand/customer behaviour.

Target: Prepare 1 promotional material /mock simulation

Date of Completion	Material Prepared	Preceptor's Initial

MODULE 6: SALES & MARKETING OF PHARMACEUTICAL PRODUCTS

Task: Marketing activities

- Appreciate the activities involved in managing marketing campaign.
- Assist in management and organization of CME events.

Target: Participate in at least 1 marketing project / event

Date of Completion	Project Participated	Preceptor's Initial

SECTION 3: SALES

Task: Roles of Sales Representatives and Sales Manager

- Understand the roles and responsibilities of Sales Representatives and Sales Managers and their work nature.
- Experience how a sales representative engages customers in various settings.

Target: To make at least 3 field visits and complete 3 daily call report (outlining the objectives and outcome of the call)

MODULE 6: SALES & MARKETING OF PHARMACEUTICAL PRODUCTS

Field Visits

Date	Objectives	Outcome	Preceptor's Initial

Daily Call:

Date	Objectives	Outcome	Preceptor's Initial

MODULE 6: SALES & MARKETING OF PHARMACEUTICAL PRODUCTS

Task: Sales Activities

- Involved in various sales activities including sales meeting and CME activities.

Target: Involved in at least 1 CME presentation (internal /external audience)

Date	CME Topic	Preceptor's Initial

SECTION 4: CORPORATE/GOVERNMENT AFFAIRS AND MARKET ACCESS (if available)

Task: Understand the different types of corporate communications (internal and external) and internal/external stakeholder engagement

Target: At least 1 training with corporate communications

Date	Training Topic	Preceptor's Initial

MODULE 6: SALES & MARKETING OF PHARMACEUTICAL PRODUCTS

Task: Appreciate the roles of different stakeholders in organizing health promotions, corporate social responsibility (CSR) events, product launches or ongoing listing initiatives

Target: At least 1 training on stake holder management

Date	Training Topic	Preceptor's Initial

Task: Understand the different types of health economics studies and its roles in supporting decision making

Target: At least 1 study report/critical appraisal on health economics studies, if applicable

Date	Study Topic	Preceptor's Initial

TRAINING LOG

Date	Task Assignment	Description of Task	Remarks*	Name & Signature of Preceptor

**This may include key learnings of the day, challenges faced when performing the job, follow up action for the next day and/or PRP or preceptor's comments.*
***Please print as many copies of this page as needed during the duration of PRP training.*

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												

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** **=____%**											

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 receive in a positive manner												
TOTAL MARKS (SECTION 2)													
MARKS (%)(SECTION 2)		**Marks = _____X 100** **30** **=____%**											

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 =___%**											

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 necessaryinformation 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 =____%**											

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 MODULE

MARKS (%) FOR EACH MODULE		
No.	**Module**	**Marks (%)**
1	Regulatory Affairs	
2	Pharmacovigilance	
3	Drug Distribution	
4	Clinical Research	
5	Medical Affairs	
6	Sales and Marketing of Pharmaceutical Products	
7	Other Organized Activities	
AVERAGE MARKS		
PERSONAL ASSESSMENT		
1	Demonstrate a Professional Approach	
2	Teamwork	
3	Undertake Personal and Professional Development	
4	Communication Skills	
5	Integrity	
AVERAGE MARKS		

Preceptor's Name, Signature & Stamp: Date:

Appendix A1

(To be filled by Principal Preceptor for those extended)

SUMMARY OF PERFORMANCE (%) FOR EACH MODULE

MARKS (%) FOR EACH MODULE				
No.	**Module**	**Marks (%) prior to extension period**	**Marks (%) after extension period**	**Actual extension period**
1	Regulatory Affairs			
2	Pharmacovigilance			
3	Drug Distribution			
4	Clinical Research			
5	Medical Affairs			
6	Sales and Marketing of Pharmaceutical Products			
7	Other Organized Activities			
AVERAGE MARKS				
PERSONAL ASSESSMENT				
1	Demonstrate a Professional Approach			
2	Teamwork			
3	Undertake Personal and Professional Development			
4	Communication Skills			
5	Integrity			
AVERAGE MARKS				

Preceptor's Name, Signature & Stamp: Date:

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		

APPRAISAL BY PRP OF PRECEPTOR

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											

Note: This appraisal is optional and is to be sent directly by PRP to Pharmacy Board Malaysia Division.