PROVISIONALLY REGISTERED PHARMACIST (PRP)

PROGRAM @ KOTRA PHARMA

INTRODUCTION

- 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 a period of not less than one year.

- The engagement as a PRP must be in any premises listed in the *Second Schedule (can be obtain in the Minister of Health website) in* order to be entitled to apply for full registration.

- Kotra Pharma is one of the manufacturers in the pharmaceutical industry gazetted by the Minister of Health (MOH) and thus can offer placement for PRP in manufacturing sector.

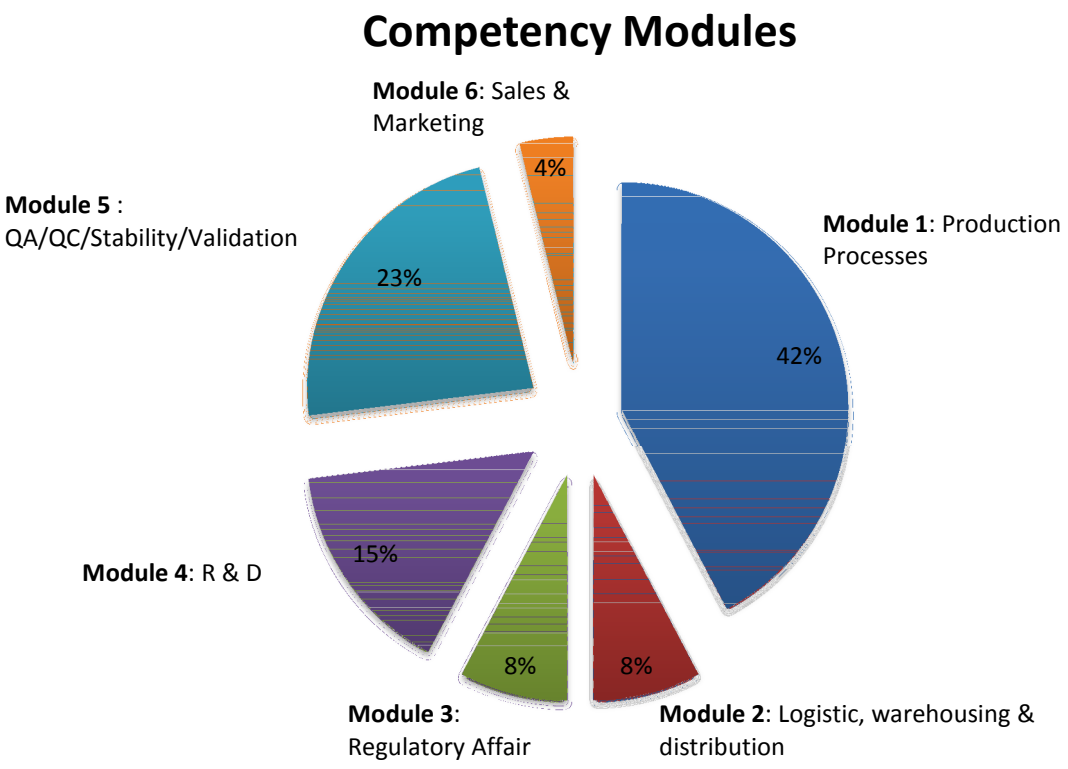
OBJECTIVE

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

There are 6 main competency modules of training for the PRP in the pharmaceutical industry. Modules are regulated by Pharmacy Board Malaysia of Ministry of Health Malaysia.

Table 1: Competency Modules of Training

Module No.	Competency Modules Title	Duration (weeks)
Module 1	Production Process: Manufacturing and Packaging of Pharmaceutical Products	**22**
Module 2	Logistics, Warehousing and Distribution of Pharmaceutical Products	**4**
Module 3	Regulatory Affairs	**4**
Module 4	Research & Development/ Technical Services of Pharmaceutical Products	**8**
Module 5	Quality Assurance / Quality Control / Stability / Validation of Pharmaceutical Products	**12**
Module 6	Sales & Marketing of Pharmaceutical Products	**2**
	Total	**52**



MODULE 1:

PRODUCTION PROCESSES: THE MANUFACTURING AND PACKAGING OF PHARMACEUTICAL PRODUCTS
(Duration of Attachment: 22 weeks)

1. Knowledge and the understanding of the principle of production process planning and structure of the organization.

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

3. Knowledge of Standard Operating Procedures (SOPs) and ability to adhere to the SOP during operation.

4. Knowledge of master formula, production record and their contents, manufacturing techniques, use and selection of appropriate equipment, shelf sample, and product release procedures etc.

5. Knowledge and understanding cleaning, sanitization, safety and security in production process.

6. Knowledge of the manufacturing of various dosage forms of products either sterile 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 and storage requirements;
    - understanding of the principles of Good Manufacturing Practices (GMP)

7. Knowledge on master planned preventive maintenance, risk management in controlling cross contamination and the implications.

8. Knowledge on validation in production process.

MODULE 2:

LOGISTICS, WAREHOUSING AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS
(Duration of Attachment: 4 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 Storage Practice (GSP) and 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 materials, drugs 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.

MODULE 3:

REGULATORY AFFAIRS: REGISTRATION PROCEDURES, POST REGISTRATION ACTIVITIES AND RELATED LICENCES OF PHARMACEUTICAL PRODUCTS
(Duration of Attachment: 4 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.

MODULE 4:

RESEARCH & DEVELOPMENT/TECHNICAL SERVICES OF PHARMACEUTICAL PRODUCT
(Duration of Attachment: 8 weeks)

1. Understanding of Research & Development 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 dosage forms.
4. Ability to conduct Experimental Formulation Development.
5. Understanding on Bioequivalence Study design and overall conduct of study.
6. Understanding on method development and validation for new formulation.
7. Ability to design and conduct stability study in drug development process.
8. Ability to write a Pharmaceutical Development Report.
9. Activities' involves in this department are:
    - Mini project on new product/product improvement formulation
    - Conduct literature search
    - Excipient incompatibility study in formulation
    - Conduct laboratory batch experiments
    - Conduct pilot batch experiments(optional)
    - Conduct Physical/Chemical/Microbiology analysis
    - Data analysis reporting

MODULE 5:

QUALITY ASSURANCE / QUALITY CONTROL / STABILITY / VALIDATION OF PHARMACEUTICAL PRODUCTS
(Duration of Attachment: 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 Risk Management (QRM), deviation management, handling of non-conformity, OOS investigation, quality audits, change control and 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, method validation, validation analysis, microbiological testing, environmental monitoring, standardization etc.
4. Knowledge in product stability studies.
5. Knowledge of the various qualification & validation requirements in pharmaceutical industry

MODULE 6:

SALES & MARKETING OF PHARMACEUTICAL PRODUCTS
(Duration of Attachment: 12 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).
3. Knowledge on the selling process, meeting and getting customers feedback, understanding the concept of ethical marketing practices, and the concept of good marketing material design.

For more information on PRP, go to http://www.pharmacy.gov.my

HOW TO APPLY

Program based in Melaka and Sales and Marketing Office in Bangsar South. Interested candidates are invited to send your full resume to the following address.

PRP – Recruitment
Human Resource Department
Kotra Pharma (M) Sdn Bhd
No. 1, 2 & 3 Jalan TTC 12
Cheng Industrial Estate
75250 Melaka
Malaysia

Or e-mail: hr@kotrapharma.com

PRP – Recruitment
Human Resource Department
Sales & Marketing Office
Kotra Pharma (M) Sdn Bhd
Vertical Business Suite
Unit 35-01, Level 35, Tower A
Avenue 3, Bangsar South
No: 8, Jalan Kerinchi
59200 Kuala Lumpur

Or e-mail: smohr@kotrapharma.com