INDUSTRIAL TRAINING AWARDING CERTIFICATE OF MANUFACTURING EXECUTIVE

BACKGROUND

Pharmaceutical industry is a well-regulated industry. It is a major source of pharmaceutical products supplying various types of medicines to the public. This industry is required to be operated by following stringent Good Manufacturing Practice in order for the medicines to be manufactured, registered and commercialised. Having a well-trained manufacturing executive is an added advantage to this industry complimenting its aggressive nature.

OBJECTIVES

1. To expose the trainee to the fundamental aspects of Good Manufacturing Practice (GMP) of pharmaceutical industry.
2. To train the trainee on manufacturing and In-Process Quality Control (IPQC) of pharmaceutical dosage forms abiding Good Manufacturing Practice (GMP).
3. To train the trainee on development of performance qualification protocol of an equipment.
4. To train the trainee on development of process validation protocol.
5. To train the trainee on relevant statistical tools and analysis for process validation.

ENTRY REQUIREMENT

DEGREE level of any science-based and not limited to mechanical, chemical and pharmaceutical engineering.

MAXIMUM NO. OF PARTICIPANTS PER INTAKE & DURATION OF TRAINING

Seven (7) participants per intake. Intake is on middle of April, June, August, October, December. Duration per intake is 60 days.

CONTACT INFORMATION

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DETAIL COST OF ACTIVITIES

As depicted in the next page.

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IKOP (614589-A) **SDN. BHD.**

Activities	Materials	Equipments	Trainer's Fees	Student's allowance
1. 10 hr lectures on : a. Personnel and material flow in a pharmaceutical industry b. Introduction to GMP c. Fundamental aspects of Standard Operating Procedure for manufacturing & IPQC test d. Basic information on SOPs of manufacturing equipment e. Basic information on IPQC equipments and testing f. Fundamental aspects of performance qualification (PQ) of an equipment. g. Fundamental aspects of process validation (PV) h. Statistical tools for PQ and PV i. Development of PQ protocol. j. Development of PV protocol. **2. Dispensing of raw materials** **3. Manufacturing & IPQC test of solid dosage forms (tablet/capsule)** 4. **Manufacturing & IPQC test of semi-solid or liquid for external use** **5. PQ & PV protocol development** **6. Analysis of real data**	**Training materials=** 1. 10 hrs Lectures notes = RM500 2. Assessment post-lectures = RM500 3. Hands-on training modules = RM600 **Sub-total = RM1600** **Raw materials =** 1. For manufacturing of solid dosage forms = RM500 2. For manufacturing of semisolid = RM400 **Sub-total = RM900**	1. For solid line equipment = RM800 (4 weeks) 2. For Semisolid equipment= RM400 (2 weeks) **Sub-total = RM1200**	**10 hrs lectures + assessment time + protocol development for PQ & PV + analysis of real data =** RM 250 x 10 hrs = 2500 **Sub-total =RM2500** **Hands-on instructions and briefings =** 1. For solid line = RM200 (4 weeks) 2. For semisolid line = RM100 (2 weeks) **Sub-total= RM 300**	RM20/day = 20 x **60days** = RM1200 **Sub-total = RM1200**
Sub-total fees per pax	RM2,500	RM1,200	RM 2,800	RM1200
GRAND TOTAL FEES/pax	**RM 7,700**			

A GMP Manufacturer of Shari'ah-Compliant Pharmaceuticals

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