# GMP Training Program

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| **INTRODUCTION** | A good system depends highly on the capability and efficiency of its personnel to execute all the plans and procedures that have been developed . Thus, training is an effective tool in ensuring the developed system will functions as per its requirement. Training is not a *'one-off'* job. It must be pre-planned, structured and executed well to be beneficial to the organization. Training efficiency must also be evaluated through a comprehensive evaluation procedure.<br><br>Most organization tends to take training lightly as training do not seems to directly contribute to the organization productivity. Training is never given the priority it deserves.<br><br>However, when evaluated from the benefits that training can provide, organization should instead place training as one of the top priority activities and be more than willing to invest in having a well structured training program in place. |
| **OBJECTIVE** | This one day training session will address the fundamental cGMP requirements for training, its benefits, planning, execution and evaluation on its efficacy. This module will also cover the various stages in developing a good and comprehensive GMP Training Program and providing tips on how an efficient Training Plan should be developed.<br>The rationale and importance of a good Training Plan in ensuring the effectiveness of a GMP and quality system will also be addressed. |
| **MODULES & SYLLABUS** | **01 General**<br>• What is training?<br>• Training & Education<br>• Why need training?<br>• ISO perspective<br>• GMP perspective<br>• Manufacturer's role & perspective<br>• Employer's role & perspective<br><br>**02 Training Needs Analysis**<br>• Collection of data<br>• Sources of data.<br>• Criteria for assessment<br>• Techniques & Tools<br>• Interpretation of findings<br>• Prioritization<br><br>**03 Types of training**<br>• Factors to consider<br>• In-house or external |

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| | **04 Evaluation**<br>▪ Why evaluate?<br>▪ Evaluation methods<br>▪ Short term<br>▪ Long term<br>▪ Criteria of evaluator<br><br>**05 Records**<br>• Attendance<br>• Training materials<br>• Training log record<br>• SOPs<br>• Schedule |
| **SCHEME** | **1. Attendance:** At least 75% of the course.<br>**2. Workshop:** Lectures, exercises, case study or group discussion will be conducted in between the session.<br>**3. Test:** Short tests will be given to evaluate the understanding of participants of the subjects given and to qualify the certificate of attendance.<br>**4. Q&A session:** A forum with the facilitator will be provided at the end to provide participants to put forward any doubts and questions. |
| **CERTIFICATE** | To qualify the certificate of attendance, participants need to:<br>1. **PASS** the entire test given. Note: Passing mark is 50%<br>2. To attend at **least 75%** of the course |
| **TARGET GROUPS** | This course will be beneficial to personnel involves in developing a training program for their staff. It is vital to key personnel such as the Human Resource personnel, Managers, executives and supervisors in the Production, Quality Assurance, Quality Control and Engineering dept. of pharmaceutical or cosmetic manufacturing environment.<br>Max participants per session: 25 |
| **DATE & VENUE** | To be decided |
| **DAYS OF COURSE** | 1 Day |
| **REGISTRATION & COURSE FEE** | **RM4,000.00** per day for training conducted in-house, inclusive of travelling and accommodation expenses.<br>Additional participants (up to a maximum number of 35) will be chargeable at RM100 per pax. |

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| **FACILITATOR** | **Facilitator : Azman bin Abdul Jalil**<br><br>**Qualification:** B.Pharm (Hons), University Of El-Mansourah, Egypt, 1983.<br><br>**Experience:**<br>• 8 years in government<br>- Hospital Pharmacist: 4 years<br>- Pharmacy Enforcement Officer: 4 years<br><br>• 19 years in private sectors<br>- Pharmacist/Logistic Officer: 3 years<br>- Quality Assurance Manager: 5 years<br>- Plant Manager: 2 years<br>- Consultant & trainer: since year 2004<br><br>• Others<br>- Member of Malaysian Pharmaceutical Society since year 1984<br>- Member of PDA (Parenteral Drug Association) since year 2002<br>- Member of ISPE (International Society of Pharmaceutical Engineering) since year 2002<br>- Qualified trainer as per HRDF Scheme |
| **TRAINING PROVIDER** | **A1 Consultancy & Integrated Services Sdn Bhd**<br>No. 8670, Jalan Seri Wangsa 7, Taman Seri Wangsa, Batu Berendam,<br>75350 Melaka, Malaysia.<br>Tel: (606) 3178158 Fax: (606) 3176929<br>Email: azmanaj@acissb.com<br><br>Ref. No. Ministry of Finance (Bumiputra status): 357-02063111<br>Register under code 220502 (Training) and 221709 (Audit and Certification) |
| **SCHEDULE** | As attached; Annex 1 |
| **CONTACT PERSON** | Azman Abdul Jalil,<br>Tel: 06 – 3178158 H/P: 016- 663 6688 E-mail: azmanaj@acissb.com |

## Annex 1

# PROGRAM SCHEDULE

*GMP Training Program (Course)*

| PROGRAMME | TIME PERIOD | METHODOLOGY |
|---|---|---|
| 01 General? | 1 hour | 1. Lecture class<br>2. Exercises<br>3. Group discussion<br>4. Test<br><br>Note: 1 hour for tests / breaks |
| 02 Training Needs Analysis | 2 hours | |
| 03 Types of training | 1 hour | |
| 04 Evaluation | 1 hour | |
| 05 Records | 1 hour | |
| 06 Exercise & Tests | 1 hour | |