GMP Basic For Beginners

INTRODUCTION	GMP is a set of guidelines that ensures product safety, quality & efficacy are constantly being met, which all pharmaceutical and food manufacturers are required to comply. The factors covering GMP are numerous and all personnel are required to have some basic understanding of each components affecting GMP. With high staff turnover, the needs to instill quality and importance of GMP to every staff become more pressing and require tremendous continuous effort. Although training in this aspect is time consuming and troublesome, manufacturers have no choice but to carry it out as it forms a basis for GMP compliance and understanding of the importance of producing quality products.
OBJECTIVE	This programme will give participants a basic understanding of GMP. Participants will know in brief all the requirements for quality products, concept of GMP, different basic components to GMP, and identify scope or areas to be covered. There will be a brief overview of the documentation system as required by GMP.
MODULES & SYLLABUS	**01 What is Quality** • Introduction to scope of quality • Requirement by customer • Requirement by manufacture **02 Concept of GMP** • Other Good Practices; GSP, GLP, GDP • Why GMP • Concept of GMP, cGMP • Implication of GMP **03 Quality Assurance & Quality control** • The function and responsibilities • The needs for Separation of functions **04 Legal requirements pertaining to GMP** • GMP Guidelines • Standards • Regulatory agencies & related industries **05 Basic components of GMP** • Facilities ▪ Design ▪ Materials ▪ Flow ▪ Environment Control ▪ Prevention of Cross Contamination

	• Utilities
	  ▪ Qualification
	  ▪ Materials used
	  ▪ Monitoring & Records
	• Equipment (Machineries)
	  ▪ Design & materials of construction
	  ▪ Qualification & Records
	• Personal
	  ▪ Qualified
	  ▪ Sufficient in numbers
	  ▪ Skilled & trained
	  ▪ Hygiene
	• Materials
	  ▪ Specifications
	  ▪ Vendor evaluation
	  ▪ Tracking
	• Processes: Monitoring & Records
	• QA/QC: Quarantine release
	06 Importance of Training
	• Why Training required
	• Scope of training
	• Monitoring & Evaluation
	07 Self-Audit
	• The importance of Self-Audit
	• Scope of Audit

SCHEME	1. **Attendance:** At least 75% of the course. 2. **Workshop:** Lectures and exercises will be conducted in between the session. 3. **Test:** Short tests will be given to evaluate the understanding of participants of the subjects given and to qualify the certificate of attendance. 4. **Q&A session:** A forum with the facilitator will be provided at the end of each session to provide participants to put forward any doubts and questions.
CERTIFICATE	To qualify the certificate of attendance, participants need to: 1. **PASS** the entire test given. Note: Passing mark is 50% 2. To attend at **least 75%** of the course
TARGET GROUPS	This course will be beneficial to young execs, new recruits and down liners such as supervisors, line leaders and operators. No of 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. Additional participants (up to a maximum number of 35) will be chargeable at RM100 per pax.
FACILITATOR	**Facilitator : Azman bin Abdul Jalil** **Qualification:** B.Pharm (Hons), University Of El-Mansourah, Egypt, 1983. **Experience:** • 8 years in government - Hospital Pharmacist: 4 years - Pharmacy Enforcement Officer: 4 years • 19 years in private sectors - Pharmacist/Logistic Officer: 3 years - Quality Assurance Manager: 5 years - Plant Manager: 2 years - Consultant & trainer: since year 2004 • Others - Member of Malaysian Pharmaceutical Society since year 1984 - Member of PDA (Parenteral Drug Association) since year 2002 - Member of ISPE (International Society of Pharmaceutical Engineering) since year 2002 - Qualified trainer as per HRDF Scheme
TRAINING PROVIDER	**A1 Consultancy & Integrated Services Sdn Bhd** No. 8670, Jalan Seri Wangsa 7, taman Seri Wangsa, Batu Berendam, 75350 Melaka, Malaysia. Tel: (606) 3178158 Fax: (606) 3176929 Email: azmanaj@acissb.com Ref. No. Ministry of Finance (Bumiputra status): 357-02063111 Register under code 220502 (Training) and 221709 (Audit and Certification)
SCHEDULE	As attached; Annex 1
CONTACT PERSON	Azman Abdul Jalil, Tel: 06 – 3178158 H/P: 016- 663 6688 E-mail: azmanaj@acissb.com

Annex 1

PROGRAM SCHEDULE

GMP Basic For Beginners (Course)

PROGRAMME	TIME PERIOD	METHODOLOGY
01- What is quality	1 hour	1. Lecture classes 2. Questions and Answers 3. Test Note: 1 hour for tests / breaks
02- Concept & Introduction to GMP	1 hour	
03- Quality Assurance & Quality Control	1 hour	
04- Basic components of GMP	2 hours	
05- Basic documentation in GMP	1 hour	
06- Importance of Training	½ hour	
07- Importance of Audit	½ hour	