



Basic of Good Distribution Practise (GDP)

INTRODUCTION	<p>GDP is a set of guidelines that ensures storage; transportation and distribution of goods are such that the product quality is preserved (maintained) when it reaches the destination (customers). GDP also encompass the receiving, storage and handling of materials.</p> <p>GDP is part of GMP. Together with GMP, GDP will further assure that products supplied are of good quality, and safe for consumption.</p> <p>The factors covering GDP are numerous and all personnel relating to the handling of materials and goods are required to have some basic understanding of each components affecting GDP.</p> <p>With high staff turnover, the needs to instill quality and importance of GDP to every staff become more pressing and require tremendous continuous effort. Although training in this aspect is time consuming and troublesome, manufacturers and distributors 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.</p>
OBJECTIVE	<p>This 8 hours session will give participants a basic understanding of GDP and GMP.</p> <p>Participants will know in brief all the requirements for quality products, concept of GDP, different basic components to GDP, and identify scope or areas to be covered.</p> <p>There will be a brief overview of the documentation system as required by GDP.</p>
MODULES & SYLLABUS	<p>01 What are materials and finished goods?</p> <ul style="list-style-type: none">• Quality requirements• Requirement by authority• Requirement by manufacture <p>02 Concept of GDP</p> <ul style="list-style-type: none">• Why need GDP• Difference of GDP and GMP• Implication of GDP to manufacturers, customers and law enforcers <p>03 Legal requirements pertaining to GDP</p> <ul style="list-style-type: none">• GDP Guidelines• Other laws regulating store activities• License required: Basic requirements for license holders <p>04 Basic components of GDP</p> <ul style="list-style-type: none">• Facilities<ul style="list-style-type: none">▪ <i>Design, Materials of construction & Process Flow</i>▪ <i>Environment Control</i>▪ <i>Monitoring</i>▪ <i>Pest Control</i>



	<ul style="list-style-type: none"> • Stock control <ul style="list-style-type: none"> ▪ <i>Storage conditions and control</i> ▪ <i>FIFO</i> ▪ <i>Product segregation</i> ▪ <i>Stock records</i> ▪ <i>Tracking and Lot numbering</i> • Personal <ul style="list-style-type: none"> ▪ <i>Qualified</i> ▪ <i>Sufficient in numbers</i> ▪ <i>Skilled & trained</i> • Quality activities <ul style="list-style-type: none"> ▪ <i>The function and responsibilities</i> ▪ <i>The needs for separation of functions</i> ▪ <i>Quarantine release</i> <p>05 Importance of Training</p> <ul style="list-style-type: none"> • Why continuous training required • Scope of training • Monitoring & Evaluation <p>06 Documentation</p> <ul style="list-style-type: none"> • Stock control / inventories • Stock movements: Packing Lists, DOs, Invoices • Monitoring records <p>07 Handling of Rejects</p> <ul style="list-style-type: none"> • Storage and segregation • Movements and records • Disposals
<p>SCHEME</p>	<ol style="list-style-type: none"> 1. Attendance: At least 75% of the course. 2. Workshop: Lectures, exercises, case study or group discussion 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 to provide participants to put forward any doubts and questions.
<p>CERTIFICATE</p>	<p>To qualify the certificate of attendance, participants need to:</p> <ol style="list-style-type: none"> 1. PASS the entire test given. Note: Passing mark is 50% 2. To attend at least 75% of the course
<p>TARGET GROUPS</p>	<p>This course will be beneficial to operational staff that is on the field. It is vital to key personnel such as the Managers, executives and supervisors in the Production, Quality Assurance, Quality Control and Engineering dept.</p> <p>Max participants per session: 25</p>



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: <ul style="list-style-type: none">• 8 years in government<ul style="list-style-type: none">- Hospital Pharmacist: 4 years- Pharmacy Enforcement Officer: 4 years• 19 years in private sectors<ul style="list-style-type: none">- Pharmacist/Logistic Officer: 3 years- Quality Assurance Manager: 5 years- Plant Manager: 2 years- Consultant & trainer: since year 2004• Others<ul style="list-style-type: none">- 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
ORGANIZER	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
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Annex 1

PROGRAM SCHEDULE *Basic of Good Store Practise-GDP (Course)*

PROGRAMME	TIME PERIOD	METHODOLOGY
01 What are materials and finished goods?	0.5 hour	1. Lecture classes 2. Questions and Answers 3. Test Note: 1 hour for tests / breaks
02 Concept of GDP	0.5 hour	
03 Legal requirements pertaining to GDP	1 hour	
04 Basic components of GDP	2 hours	
05 Importance of Training	1 hour	
06 Documentation	1 hour	
07 Handling of Rejects	1 hour	