Handling & Control of Materials

INTRODUCTION	GIGO in computer field is garbage-in-garbage-out. It means, whatever data entered will produce bad results. Similarly in a pharmaceutical industry, the starting materials is given due importance. Materials with qualities not meeting the pre-determined specifications will produce final products that will not meet the Finished Product Quality Specifications. The adverse implications from materials used may not arise immediately, but it may show signs of defects well before end of its shelf-life period. Materials include raw materials, labels and packaging materials.
OBJECTIVE	This 1-day workshop will address the importance of good handling and control of materials in a pharmaceutical manufacturing environment. Participants will be briefed on the critical procedures involved and look into documents involve in handling and controlling materials.
MODULES & SYLLABUS	**01 General** • Normal process flow • Where starting materials come in. • Impact of bad materials being used. **02 Quality control** • Knowing your materials: Materials specification & test methods • Control in procurement • Giving GMP Status • Control during receiving • Requirement of pre-approval prior to use • Inventory control **03 Recordings** • Receiving details • QC activities • Stock movements • Approval for use • In-process usage (BM **04 In-process control** • Effect of environmental variations • Potential risk of cross contaminations • Effect of process variations
SCHEME	1. **Attendance:** At least 75% of the course. 2. **Workshop:** Lectures, will be conducted for all the required subjects. 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.
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 QC staff and production mid-management personnel such as supervisors or line leaders. It is also vital to key personnel such as the QC & Production. Executives, materials / purchasing officers and warehouse supervisors. Max participants per session: 25
DATE & VENUE	To be decided by client
DAYS OF COURSE	1 Day
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

Handling & Control of Materials (Course)

PROGRAMME	TIME PERIOD	METHODOLOGY
01 Requirements as per GMP guidance	1 hour	1. Lecture class 2. Q & A 3. Test Note: 1 hour for tests / breaks
02 Procurement & Specifications	1 hours	
03 Receiving & Recordings	1 hours	
03 Issuing & Storage	1 hours	
03 In-process control	1 hours	
04 Product handling and release	2 hours	