Documentation Basics For cGMP

INTRODUCTION	A good documentation system is the basis for a systematic and effective operation of any corporation. It also forms a vital link for communication amongst workers at all levels and presents an only common platform for sharing of information. Its proper structure, design and implementation will directly influence the effectiveness of a particular quality management system; in this case is cGMP. As documentation is an important tool for internal as well as external communication, its system must be effectively designed for it to be proactive, and flexible to improvement and changes within the corporation.
OBJECTIVE	This 2 days workshop will address the fundamental cGMP requirements for documentation, its content, usage and control in a pharmaceutical, traditional and cosmetic manufacturing environment. The similarities with ISO 9001:2000 requirements will be dealt with. This module will also cover the various category levels of documents from Manuals, Policies, SOPs, WIs, Records, Checklists, Forms and other supporting documents for the implementation of cGMP. Participants will be introduced to the various types of documents used in the manufacturing, in-process control, quality control, warehousing and other activities. The importance of an internal audit and training in ensuring the effectiveness of a particular document system will also be addressed.
MODULES & SYLLABUS	**01 General** • Why need documents? • ISO requirements • cGMP requirements • What is document and records? **02 Numbering and coding system** • Batch numbering • QC lot nos. & Product codes • Documents and Records numbering **03 Essential requirements in cGMP** • Key elements & Language • Identify Critical process • Traceability • Certification & Authority • Electronic records **04 Different types of documents (and samples)** • Policies • Quality & Master Plans (include VMPs) • Batch manufacturing records • SOPs • Checklist and schedules

	• Specifications • WIs & Records **05 Documents from Validation & Qualification exercise** • Master Plans and schedules • Operation and Cleaning SOPs • PM : SOPs, checklist and schedules • Cleaning VMP • Training requisitions **06 Document Control** • Indexes of document & records • Numbering • Standardizing document formats • Comprehensive procedure for control • Responsibilities • Master copies • Distribution • Change requirements • Filing • Review & Archives **07 The Do's and Don'ts in documentation** • Format • Recording • Filing & Distribution • Soft copies **08 Ensuring effectiveness of documentation system** • Training • Evaluation of training • Exercise in training of a document • Internal audits • Corrective actions and follow-up • Exercise in auditing a document
SCHEME	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.
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
DATE & VENUE	To be decided

TARGET GROUPS	This course will be beneficial to operational staff involved in any part of the document controls. It is vital to key personnel such as the Managers, executives and supervisors in the Production, Quality Assurance, Quality Control and warehousing activities. Max participants per session: 25
DAYS OF COURSE	2 Days
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

Documentation Basics For cGMP (Course)

PROGRAMME	TIME PERIOD	METHODOLOGY
01 General	1 hour	1. Lecture class 2. Case study 3. Exercises 4. Group discussion 5. Test
02 Numbering and coding system	1 hour	
03 Essential requirements in cGMP	1 hour	
04 Different types of documents (and samples)	3 hours	
05 Documents from validation & qualification exercise	2 hours	
06 Document Control	3 hours	
07 The Do's and Don'ts in documentation	1 hour	
08 Ensuring effectiveness of documentation system	2 hours	