Basic of Validation

INTRODUCTION	The quality of a particular batch is determined at final stage by quality tests done on random samples. Together with a complete batch document /record, and a final FPQC, a batch will be evaluated for release to the market. It is impractical to have 100% assurance on the batch by having FPQC tests done on every single unit produced. This leaves nothing for sale to the market. In order to assure that the batch produced has meet the required criteria, it is thus crucial that the equipment, facilities, utilities and process used has been qualified and validated to meet the required specifications. Qualification and validation may seem a laborious task, but it will definitely assure that the batch produced will consistently meet the desired requirements. Where products' integrity, safety and efficacy are crucial, such as sterile products or products with small therapeutic index, the local drug authority will require such qualification and validation be done and completed before the product can be release to the market.
OBJECTIVE	This two days (or one day) workshop will give participants an in-depth understanding of the qualification and validation requirements and activities. Participants will be able to differentiate the various stages of qualification and able to identify critical equipment and processes for validation. He or she will also be able to understand a qualification / validation master plans and protocols for the critical processes.
MODULES & SYLLABUS	**01 General points on Qualification and Validation** • Definition & concept • Legal requirement • Scope / coverage – critical equipment & processes • Why qualify / validate • Impact assessment & risk analysis • Whose responsibilities • Benefits **02 Qualification** • Identifying critical equipment / utilities / facilities • The V-approach • URS, DQ, IQ & commissioning • OQ & PQ **03 Installation Qualification** • FAT • Verify against Design Specification • Scope / coverage • Output

	04 Operational Qualification • SAT & Verify against Functional Specification • Scope / coverage • Calibration • Training • Output **05 Performance Qualification** • Verify against User Specification • Scope / coverage • Output **06 Process Validation** • Application: critical processes e.g. sterilization, cleaning, aseptic filling • Objective / purpose • Challenged parameters • Three approaches **07 Qualification / Validation Master Plans** • What is a master plan? • Purposes • Work schedule **08 Documentation in Qualification / Validation** • Documents prior to initiation • VMP • Protocols • Reports • Change control • Deviation reports • Investigation documents
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 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 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. of pharmaceutical or cosmetic manufacturing environment. Max participants per session: 25

DATE & VENUE	To be decided by client.
DAYS OF COURSE	2 Days (session can be reduced to 1day upon request)
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 Experience and CV can be downloaded from **www.acissb.com**
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
CONTACT PERSON	Azman Abdul Jalil, Tel: 06 – 3178158 H/P: 016- 663 6688 E-mail: azmanaj@acissb.com

Annex 1

PROGRAM SCHEDULE

Basic of Qualification & Validation

PROGRAMME	TIME PERIOD	METHODOLOGY
01 General points on Qualification and Validation	2 hours	1. Lecture class 2. Exercises 3. Group discussion 4. Test
02 Qualification	2 hours	
03 Installation Qualification	1.5 hour	
04 Operational Qualification	1.5 hour	
05 Performance Qualification	2 hour	
06 Process Validation	3 hours	
07 Qualification / Validation Master Plans	1 hour	
08 Documentation in Qualification / Validation	1 hour	