Basics in Cleaning Validation

INTRODUCTION	Every manufacturer is required to take all precautionary measures in eliminating risk of product contamination and cross contamination within the processing facility. Such risk is inherent in conditions where there is no effective cleaning procedure. The risk is further compounded in multi-product facility. Residues from product may later be detected in subsequent batches. Worst, residue from cleaning and disinfectants may also find ways into the final finished products. Thus, in order to meet cGMP, auditors always demand evidence of the effectiveness of the currently employed cleaning procedures. It is also the responsibilities of pharmaceutical manufacturers to provided documented evidence that the critical cleaning procedures have been successfully validated to eliminate any risk of cross-contaminations. In view of this scenario, this module was proposed and designed in such a way that the participants will be made know of the importance and basis of cleaning validations, the pre-requisites, planning, execution and monitoring.
OBJECTIVE	This is a 1-day workshop that will present an overview of all elements in cleaning validation. However, participants will not be able to single-handedly develop their own cleaning validation exercise as this requires experience and on-the-job training. Participants will be able to realize the importance and the intricacies involved in a Cleaning Validation, and prepare them for active participation in a cleaning validation program in the future.

MODULES & SYLLABUS	**Part I**
	• Objective & purpose of Cleaning
	• Importance of Cleaning Validation
	• Scopes and coverage
	
	Part 2
	• Preparation for Cleaning Validation
	  o Review of cleaning policy and procedures
	  o Review all critical equipment
	  o Review all capabilities of operators.
	  o Review sampling techniques and recovery capability
	  o Review analysis procedure
	
	• Training of operators in various related activities.
	• Development of Cleaning Validation Plan
	• Calculation of Maximum allowable contamination limits
	
	Part 3
	• Conduct of cleaning validation
	  o Selection of product (active material)
	  o Selection of equipment
	  o Development of a suitable validation protocol

	o Development of validation schedule o Good communication among team members - Be observant and impartial - Record findings & evidence - Handling deviations and interventions - Be factual. Avoid giving comments - Etc. o Importance of compiling all relevant information (data) • Validation's requirements • Requirements of a successful cleaning validation **Part 4** • Collection of all data and reports • Final reporting • Typical problem areas in performing cleaning validation • Follow-up of Cleaning Validation o Change procedure o Change of cleaning agents or procedures o Monitoring of cleaning effectiveness (trend analysis) o Re-validation requirements
SCHEME	1. **Attendance:** At least 75% of the course. 2. **Workshop:** Lectures and short exercise 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. Participate in exercise and attend at **least 75%** of the course
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. No additional participants allowed to ensure the effectiveness of this training program.
DATE & VENUE	To be decided. Training date to be confirmed 4 weeks in advance to enable preparation of training notes.
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	1. Azman Abdul Jalil, Tel: 016-663 6688 E-mail: azmanaj@acissb.com 2. Kartini Dahlan, Tel: 06-317 8918 E-mail: kartini@acissb.com

Annex 1

PROPOSED SCHEDULE:

9:00am – 9:15am	:	1- Introduction and short briefing
9:15am – 10:15am	:	2- Basis of cleaning validation
10:15am – 10:30am	:	Break
10:30am – 11:30am	:	3- Cleaning Validation Plan
11:30am – 12:30pm	:	4- Preparing for Cleaning validation
12:30pm – 1:00pm	:	Test No 1
1:00pm – 2:00pm	:	Lunch break
2:00pm – 3:00pm	:	5- Conduct of Cleaning Validation
3:00pm – 4:15pm	:	6- Exercise
4:15pm – 4:30pm	:	Break
4:30pm – 5:15pm	:	7- Reporting and Follow-up
5:15pm – 5:30pm	:	Review of exercise
5:30pm	:	End

PROGRAM SCHEDULE

Basic in Cleaning Validation (one-day Course)

PROGRAMME	TIME PERIOD	METHODOLOGY
Part 1	**1 hour**	**1. Lecture classes** **2. Exercises** **3. Test** **Note: 1 hour for tests / breaks**
Part 2	**2 hours**	
Part 3	**1 hour**	
Part 4	**1 hour**	
Exercise (extension of Part 3)	**1.5 hour**	
Tests	**0.5 hour**	