Area Clearance

INTRODUCTION	A process may be under good procedural control, but yet end up in a batch failure. Common errors occurring in the manufacturing facilities, such as use of dirty equipment, cross-contamination with materials from previous batches and microbial contamination are mainly due to personnel and easily minimized by practicing stringent Area Clearance. Area Clearance is basically an activity of pre-checking and pre-approval prior to starting a process. It provides the avenue for final checking to be done by a competent person and avoid silly errors as wrong product, dirty premises, dirty equipment, etc.
OBJECTIVE	This 1-day workshop will give participants a basic understanding of Area Clearance, its importance and how best it should be conducted. Participants will also be brief on the full requirements of a good Area Clearance and actions to be taken when faced with unapproved Area Clearance.
MODULES & SYLLABUS	**01 The basic of Area Clearance** • What is Area Clearance • Requirements as per GMP guidelines • Benefits of Area Clearance **02 Important Components of Area Clearance** • Premise / facilities • Equipment • Products / Materials • Personnel • Recordings **03 Procedures** • Conduct of Area Clearance • Authorized personnel • Written SOP & records • Checklist/Form **04 Corrective actions** • When Area Clearance can fail • Corrective actions • Approval for operation to resume • Records
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
TARGET GROUPS	This course will be beneficial to the production executive, supervisor, line leaders and operators Max participants per session: 25
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:** • 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

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

Area Clearance (Course)

PROGRAMME	TIME PERIOD	METHODOLOGY
01 The basic of Area Clearance	1 hour	1. Lecture class 2. Exercises 3. Group discussion 4. Test Note: 1 hour for tests / breaks
02 Important Components of Area Clearance	2 hours	
03 Procedures	2 hours	
04 Corrective actions	2 hours	