



Basic Hygiene in cGMP

INTRODUCTION	<p>The need for hygiene is vital to ensure compliance to GMP. Most contamination occurs due to microbial contamination rather than particulate contamination.</p> <p>It is also well known within the pharmaceutical industry that human is the main source of microbial contamination as compared to environment, materials, equipments and source of water.</p> <p>A good control on hygiene practice will definitely provide added assurance on product quality.</p>
OBJECTIVE	<p>This 1 day workshop will address the fundamental of hygiene control in a pharmaceutical manufacturing environment.</p> <p>Participants will be briefed on importance of hygiene to an individual's health as well as to the product he is processing.</p> <p>The main activities in hygiene control will be dealt with. Basic good hygiene practise will be taught. Supporting activities as environmental control, HVAC system, source of water and monitoring program will also be discussed.</p>
MODULES & SYLLABUS	<p>01 General</p> <ul style="list-style-type: none">• What is hygiene control?• Why need hygiene control?• Impact of bad hygiene practice to individual• Impact of bad hygiene practice to manufacturers & consumers <p>02 Activities in hygiene control</p> <ul style="list-style-type: none">• Good Hygiene Policy and guidelines• Training and briefing to all operational personnel• Good hygiene practice• Cleaning & sanitation• Medical examination <p>03 Good hygiene practice for operator</p> <ul style="list-style-type: none">• Gowning & Hand washing• Discipline in production areas• Observing compliance to GMP <p>04 Supporting activities in hygiene control</p> <ul style="list-style-type: none">• Environmental control: dedusting• HVAC: pressure differential• Water: use of purified water as per specifications• Monitoring program periodic 'finger prints' tests, settle plates, air microbial monitoring <p>05 Cleaning & Sanitation</p> <ul style="list-style-type: none">• For processing areas (rooms)• For equipment & utensils• For utilities (water system, steam, gases)



	<p>06 The Do's and Don'ts in Hygiene practices</p> <ul style="list-style-type: none">• Before, during and after work• Actions to be taken in cases of emergencies (eg. power cut-off). <p>07 Ensuring effectiveness of a hygiene control system</p> <ul style="list-style-type: none">• Management supervision• Recordings• Trainings• Internal audits• Corrective actions and follow-up• Why need documents?
SCHEME	<ol style="list-style-type: none">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	<p>To qualify the certificate of attendance, participants need to:</p> <ol style="list-style-type: none">1. PASS the entire test given. Note: Passing mark is 50%2. To attend at least 75% of the course
TARGET GROUPS	<p>This course will be beneficial to operational staff that is involved in any part of the manufacturing processes and quality controls. It is vital to key personnel such as the Managers, executives and supervisors in the Production, Quality Assurance, Quality Control and warehousing activities.</p> <p>Max participants per session: 25</p>
DATE & VENUE	To be decided
DAYS OF COURSE	1 Day
COURSE FEE	<p>RM4,000.00 per day for training conducted in-house, inclusive of travelling and accommodation expenses.</p> <p>Additional participants (up to a maximum number of 35) will be chargeable at RM100 per pax.</p>
FACILITATOR	<p>Facilitator : Azman bin Abdul Jalil</p> <p>Qualification: B.Pharm (Hons), University Of El-Mansourah, Egypt, 1983.</p> <p>Experience:</p> <ul style="list-style-type: none">• 8 years in government



	<ul style="list-style-type: none">- Hospital Pharmacist: 4 years- Pharmacy Enforcement Officer: 4 years• 19 years in private sectors<ul style="list-style-type: none">- Pharmacist/Logistic Officer: 3 years- Quality Assurance Manager: 5 years- Plant Manager: 2 years- Consultant & trainer: since year 2004• Others<ul style="list-style-type: none">- 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 <p>CV of trainers are available at our website www.acissb.com</p>
TRAINING PROVIDER	<p>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</p> <p>Ref. No. Ministry of Finance (Bumiputra status): 357-02063111 Register under code 220502 (Training) and 221709 (Audit and Certification)</p>
SCHEDULE	As attached; Annex 1
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Annex 1

PROGRAM SCHEDULE *Basic Hygiene in cGMP (Course)*

PROGRAMME	TIME PERIOD	METHODOLOGY
01 General	1 hour	<ol style="list-style-type: none">1. Lecture class2. Q & A3. Test <p>Note: 1 hour for tests / breaks</p>
02 Activities in hygiene control	1 hour	
03 Good hygiene practice for operator	0.5 hour	
04 Supporting activities in hygiene control	0.5 hour	
05 Cleaning & Sanitation	2 hours	
06 The Do's and Don'ts in Hygiene practices	1 hour	
07 Ensuring effectiveness of a hygiene control system	1 hour	