Internal (Self) GMP Audit

INTRODUCTION	Every manufacturer is required to conduct their internal GMP audit on a regular basis, preferable at least once a year. Internal audit is also known as self-GMP audit. This will enable a manufacturer to evaluate their quality system, ability to comply to cGMP and identifying weak areas for subsequent corrective actions. With a good handling of a GMP Audit, this self-internal audit can also be used as a very powerful tool for further improvement. However, GMP audit is always a stressful exercise for both the auditee and auditors. Matters of relevant to GMP need to be well understood for good evaluation during audit and for a meaningful investigation to be carried out. When the relevant personnel is not knowledgeable, has no full understanding of the subject, and do not handle the situation well, the audit may not only be worthless, but results in various misunderstanding amongst personnel. It must be noted that in self (internal) GMP audit, the auditors will at some time also be the auditee, and vice-versa. However, when being an auditor, he/she will always be at the upper hand during the audit. In conducting audit, auditors require full cooperation and understanding from the auditee. If the auditee feel stress out by the audit, and fail in contributing to the needs of the auditors, the auditors too will feel stress out in conducting the audit. When these happen, both parties will not be getting the fruits from the audit exercise, thus jeopardizing the audit activity. In view of this scenario, this module was proposed and designed in such a way that the participants will be made know of expectations from the audit exercise, the role and responsibilities of an auditor and an auditee, and how to portray an acceptable response which benefits both the auditors and auditee during the audit. Participants will be made to understand the standard procedure in auditing, the needs in understanding cGMP needs and the needs for a good relationship and environment during audit. A smooth and trouble free audit will always benefits an organization.
OBJECTIVE	This is a 2-days (or 1-day) workshop that will give participants an in-depth understanding of a self (internal) GMP audit activities. Participants will be able to realize the importance of a GMP audit. He or she will also be able to prepare well for the audit and able to plan and conduct a smooth audit. Participants will be able to identify critical areas requiring attention and behave accordingly during the audit and able to reap the benefits from a self-GMP audit.
MODULES & SYLLABUS	**Part I** • Objective & purpose of a self or internal audit • Scope/Types of audit • Criteria of audit • Setting up an audit team

Part 2

- Pre-audit evaluation & preparation
  - Review of GMP audit procedures
  - Review all internal and/or 3rd part audits
  - Review all raised corrective actions. Ensure they are done or scheduled to be done.
  - Review complaints record. Ensure all complaint logged in and acted upon
  - Review deviation records and raised corrective or preventive actions.
  - Review OOS reports on QC tests
  - Review OOS reports on utilities and Environmental monitoring
  - Pre-audit discussion
- Audit Plan
- Preparation of check-lists

Part 3

- Conduct of an audit
  - Importance of opening brief
  - Availability of a recorder during audit
  - Presence of a capable guide (auditee)
  - Auditor-auditee communication
  - Good Auditing Practise
    - Be observant and impartial
    - Record findings & evidence
    - Handling discrepancies during audit
    - Always well composed and calm
    - Be factual. Avoid giving comments
    - Etc.
  - Importance of closing brief
- Auditors' requirements
- Requirements of a good auditee

Part 4

- Collection of all audit reports
- GMP Audit reporting
- Typical problem areas in performing self audit
- Follow-up of GMP Audit
  - List all non-compliances found during audit by sections
  - Responding to GMP Audit report
  - Submission of proposed corrective and preventive actions
  - Always denote time frame and responsible person/dept.
  - Follow-up of corrective and preventive actions

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. To 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
DATE & VENUE	To be decided
DAYS OF COURSE	2 Days. However, session can be shorten to 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. CV is available and can be downloaded from our website at 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
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Annex 1

PROGRAM SCHEDULE

Internal (Self) GMP Audit (Course)

PROGRAMME	TIME PERIOD	METHODOLOGY
Part 1	**2 hours**	**1. Lecture classes** **2. Exercises** **3. Test**
Part 2	**1 hour**	
Part 3	**2 hours**	
Part 4	**1 hour**	
Tests	**1 hour**	

The following program is thus proposed:

9:00 – 9:15am : 1- Introduction and short briefing
9:15 – 10:15am : 2- Basis of audit
10:15 – 10:30am : Break
10:30 – 11:30am : 3- Audit in GMP
11:30 – 12:15am : 4- Preparing an Audit
12:15 – 12:45pm : Test No 1
12:45 – 1:45pm : Lunch break
1:45 – 2:45pm : 5- Conduct of Audit
2:45 – 3:45pm : 6- Case Study
3:45 – 4:00pm : Break
4:00 – 5:00pm : 7- Reporting and Follow-up
5:00 – 5:30pm : Test No. 2
5:30pm : End