ASEAN – EC PROGRAMME
ON SITE AUDIT FOR ASEAN NRA
Centre for Good Manufacturing Practice
National Pharmaceutical Control Bureau
Ministry of Health Malaysia
17 November 2005 – 19 November 2005

Preamble

An on-site audit for Good Manufacturing Practice for cosmetic auditors / inspectors of the National Regulatory Authority (NRA) from ASEAN member countries was conducted by the Centre for Good Manufacturing Practice, National Pharmaceutical Control Bureau Ministry of Health Malaysia, from 17 November 2005 – 19 November 2005. The ASEAN Senior Experts .were Muhammad Lukmani Ibrahim from the Centre for GMP, National Pharmaceutical Control Bureau, Ministry of Health Malaysia and Pia Rose Belarmino from Regulation II, Bureau of Food and Drug, Philippines. The training focused on preparing, conducting and reporting of inspections i.e managing a GMP inspection carried out by the National Regulatory Authority.

Background

The ASEAN cosmetic GMP task force has develop 14 training modules to supplement the ASEAN GMP Cosmetic guideline. The modules will be used by the NRA as a reference by the NRA and cosmetic industry in ASEAN for similar and consistent interpretation. The 14 modules were promulgated in consultation with the NRA and cosmetic industries in two workshops held in Indonesia (14-16 June 2005) and Malaysia (14-16 November 2005). The modules was adopted in principle by the ASEAN cosmetic GMP task force and the ACC Head of delegates at the Malaysia workshop and will be tabled at the next ACC meeting in Brunei Darussalam for endorsement by ACC.

16 cosmetic inspectors participated in the onsite audits. The team was divided into 3 groups and the live audits were conducted in 3 different site. Each group consists of 4-6 auditors / inspectors. The site selected by the host countries consist of 1 SME, 1 large local manufacturer and a multinational.

Learning points:-

- understand fundamental steps for GMP audits
  - ⇨ plan, do, check & act
- prepare audit plan
- list the differences between system & compliance audit
- established audit targets based on risk management
- importance of process review in preparing audits
- understand design & layout of a drug manufacturer's facility
- best practices that can be applied to manage the unexpected situation
- inspectors must be prepared at all times

The audits conducted during the training were classified as regular audit and an audit plan was established. The audit team had planned to work individually on site. During the on site inspection they were exposed / demonstrated to:-

- audit techniques used during audit
- gathering objective evidence in order to substantiate the non compliance identified.
  - ⇨ construct the relevant GMP questions (what if ….) and arrived at decision whether or not they are GMP issues.

The above principles may be applied during auditing GMP system for compliance. And the 14 GMP modules developed by the ASEAN GMP Task Force were used as a reference as

the basic principle during assessing GMP compliance. The inspectors' role is to evaluate the system whether it meets the objective of the modules. The guidelines tell us what to do; they do not tell us how to do it. Often, **HOW?**, comes from industry standard practice and guidelines and varies from one manufacturer to another to achieve the desired GMP compliance.

The on the job training demonstrates the necessity for inspectors to familiarize themselves and correctly interpret the Cosmetic GMP Modules and the Guideline before arriving to a logical decision. The inspectors were also required to observe time management of the audit.

Presentation of reports

On the 3rd day, each group team leader was required to present their report. They shared their experiences and learning with the participants in conducting a team audit. During the presentation, participants were encouraged to raise questions with regard to the audit team non compliances reported, while the audit team is required to corroborate the non compliance raised.

The word inadequate or insufficient used in describing non compliance must be supported with evidence found during inspection which demonstrates the inadequacy or insufficiencies.

The presentation of reports is to illustrate situations where consultations with fellow inspectors on interpretation are sometimes necessary before arriving at a decision. Issue that requires collective decision serves as a guide, and decision is made after considering the industries perspective and inspectors observation. As such, the issues of inconsistency amongst inspectors can be minimized.

Capacity

To utilize the expertise within the NRA and the available resources they may consider

- Conduct team audits, and members of the team may comprise officers from other divisions of NRA;

  technical expert in specific area, for example officers from quality control division

- A risk management approach can be used to determine audit frequency, risk factors built in into this approach may include :-

  - Type of products manufactured
  - Changes to premises or procedures
  - Classification of non compliance
    ⇨ Critical, major or minor
  - Any recalls or complaints
  - Determine the maximum time of re-audit, irrespective of the type of products

Inspection Report

The NRA may consider stating the good GMP practices that are observed at the site. All aspects of GMP system inspected and the non compliances found must be fairly evaluated. The NRA may give GMP compliance rating to the manufacturer. The GMP

compliance rating of last audit for a manufacturer can be use as tool to assess the inspection frequency for a particular manufacturer. The rating can also be the basis to

determine the next course of action on the corrective action reported to NRA by the audited organization such as:-

- whether there is a need for a follow up inspection to verify compliance base on the feedback report. (This should be done by the same lead inspector) or
- only needs to be verified at the next regular inspection

To further illustrate to the industry on the importance of the GMP guideline for cosmetic relevant provision / section of the guideline should be quoted when reporting the non compliance.

The lead inspector should be the responsible officer to communicate with the audited organization for clarification on issues raised in the report.

Conclusion

The activity, as a whole, has helped the participants in learning a various inspection techniques from fellow auditors. It paved the way for harmonizing and fostering mutual understanding on the modules that were previously adopted. Ties were made such that Networking among ASEAN GMP task force to exchange views on GMP concerns to arrive to a similar and consistent interpretation.

MUHAMMAD LUKMANI IBRAHIM **PIA ROSE A. BELARMINO**
Asean Senior Experts

List of Participants

ASEAN Experts	:	Mr Muhammad Lukmani Ibrahim Ms Pia Rose Belarmino	
			Group
NRA of Indonesia	:	Ms Hardaningsih Ms Tita Nursjarfrida	II I
NRA of Lao PDR	:	Ms Davong Oumavong	II
NRA of Philippines	:	Ms Eusebia Regodon Ms Gracia Recuenco	I III
NRA of Singapore	:	Ms Hui Foong Mei Ms Karen Ho	III II
NRA of Thailand	:	Ms Yupa Tiengthavaj Ms Somsri Preechatthaveekid	II III
NRA of Vietnam	:	Mr Nguyen Van Loi Ms Nguyen Dien Ha	I III
NRA of Malaysia	:	Sulaiman Ahmad Wan Othman Wan Ismail Norhafizah Mohd Potri Sufian Hardi Mohamed Zuhair Belinna Abu Bakar	I II III II III

Group I Site audited – SME	Best Cosmetic Private Limited
Group II Site Audited – Large local	Manufacturing Services (UNZA) Private Ltd
Group III Site audited – Multinational	Johnson & Johnson Private Limited

AGENDA FOR ON-SITE AUDIT
17-19 NOVEMBER 2005
MALAYSIA

ASEAN SENIOR EXPERTS :

Muhammad Lukmani Ibrahim and Pia Rose Belarmino

Day 1 : 17 November 2005

9.00 – 10.00	:	Audit Preparations at Centre For GMP, National Pharmaceutical Control Bureau, Ministry of Health Malaysia
10.30 – 11.00	:	Coffee Break
11.00 – 17.00	:	Depart for On site Audits : 3 Separate site will be audited The Groups will be divided into 3 groups

Day 2 : 18 November 2005

9.00 – 13.00	:	Continue Audit at Each Site
13.00– 14.45	:	Lunch Break
14.45 – 17.00	:	Reconvene at Centre For GMP, National Pharmaceutical Control Bureau, Ministry of Health Malaysia for Preparation of Audit Reports
17.00	:	Coffee Break

Day 3 : 19 November 2005

9.00 – 10.30	:	Reconvene at Subang Meeting Room, Sheraton Subang Jaya, Preparation of Audit Reports
10.30– 11.00	:	Coffee Break
11.00 – 12.00	:	Preparations of Audit Reports

Presentation and Disscussion on Audit Findings

12.00 – 13.30	:	Group I
13.00– 14.30	:	Lunch Break
14.30 – 15.30	:	Group II

15.30 – 16.30 : Group III

16.30 – 17.00 : Conclusion, Coffee Break (End of Trainning)