UPDATE ON STATUS OF ECHO SEMINAR ON GMP AT NATIONAL LEVEL - SINGAPORE

Echo Workshop on GMP :
Background

An obligation under the ASEAN Cosmetic GMP Programme to conduct a GMP training workshop for the industry, using the standard training modules developed by the ASEAN Cosmetic GMP Taskforce.

Highlights of GMP Workshop

(4th - 5th May 2006)

Jointly organised by HSA and CTFAS *(i.e Cosmetic, Toiletry and Fragrance Association of Singapore*)

Highlights of GMP Workshop

Objectives

1) **To familiarise the cosmetic manufacturers with the ASEAN Cosmetic GMP requirements so that they can be GMP compliant fully by 2011 as required under ASEAN Cosmetic Directive.**

2) **To consult the industry in particular SMEs on the challenges which they may face with the implementation of GMP**

Highlights of GMP Workshop:

Opening Address

Keynotes:

- **Overview of the ASEAN Harmonised Cosmetic Regulatory Scheme**
- **Important elements in quality assurance : product formulation, process design/ control and quality of starting materials and GMP**
- **Forthcoming plans and changes.**

Highlights of GMP Workshop:
Trainers

The panel of trainers comprises Regulatory Officers from HSA , GMP experts from academic institution & industry.

-Ms Hui Foong Mei (HSA), Ms Suzie Quek (HSA),

-Mr Lam Kok Seng (Lecturer, Singapore Polytechnics),
Ms Stephanie Chan (Senior Lecturer, Singapore Polytechnics, CTFAS Committee Member),

-Mr Ronald Goon (Franchise Director (Asia Pacific), Quality and Compliance Worldwide, Johnson and Johnson)

Highlights of GMP Workshop:
Programme & Participants

Topics covered:

- **Key requirements of ASEAN Cosmetic Directives**
- **All the 13 ASEAN Cosmetic Training Modules**

The workshop was attended by a total of 71 participants who came from various sectors :

Manufacturers, Assemblers, Importers, Consultants as well as Lecturers.

Highlights of GMP Workshop:
Q & A session

Major concerns with GMP requirements:

- **What should be the appropriate storage conditions for products that were not labelled with recommended storage conditions?**
- **What should be the required chemical and microbiological properties of water? Should the water quality be different for the manufacture of different types of cosmetic products?**
- **Under what conditions should environmental monitoring be considered necessary?**

Highlights of GMP Workshop:
Survey

A survey was conducted during the workshop with the intent to assess :

- **Readiness of the industry to comply with ASEAN Cosmetic GMP requirements**
- **Challenges faced by industry in the implementation of GMP**
- **Current GMP compliance level of industry**
- **Importance of GMP from industry's perspective**

Highlights of GMP Workshop:
Survey Questionnaires

SURVEY FORM

WORKSHOP ON ASEAN GUIDELINES FOR COSMETIC GOOD MANUFACTURING PRACTICE
4TH & 5TH MAY 2006

Dear Participants,
Please provide your valuable feedback to the questions below by ticking the appropriate boxes. Your inputs will be strictly confidential. Thank you!

Participant's Name (Optional): _____

Organisation (Optional):_____

Job Designation: _____

Type of business that your company is involved in (please tick):

☐ Manufacture ☐ Assembly ☐ Import ☐ Export
☐ Wholesale ☐ Retail ☐ Warehousing ☐ Education
☐ Consultancy ☐ Others (Please specify):_____

Type of cosmetic products that your company is manufacturing/handling (if applicable):

_____

_____

1. How beneficial is this workshop in providing you with the understanding of the GMP requirements for the manufacture of cosmetics?

   A. ☐ Very B. ☐ Quite C. ☐ Somewhat D. ☐ Not At All

2. Would you recommend others to attend this workshop?

   A. ☐ Yes B. ☐ No (Please specify reason:_____)

3 How do you rate the GMP compliance of your manufacturing plant now?

   A. ☐ Exceeds basic requirements (proceed to Q5)
   B. ☐ Meets basic requirements (proceed to Q5)
   C. ☐ Complies with some of the basic requirements only (proceed to Q4)
   D. ☐ Does not comply with most of the basic requirements (proceed to Q4)
   E. ☐ Not applicable (proceed to Q5)

4. If the answer for the above question is C or D, what would be the reasonable timeframe you require to comply fully with the basic requirement of the ASEAN Guidelines for Cosmetic Good Manufacturing Practice? By:

   A. ☐ April 2007 B. ☐ January 2008
   C. ☐ January 2011 D. ☐ Others (Please Specify:_____)

5. Do you think GMP is important for the manufacture of cosmetic?

   A. ☐ Very B. ☐ Quite C. ☐ Somewhat
   D. ☐ Not At All (Please provide reason:_____)

6. What is the best means do you think you could obtain the required knowledge for meeting the GMP requirements?

   A. ☐ Engaging the service of consultant
   B. ☐ Attending training /workshops
   C. ☐ Employing the qualified and knowledgeable staff
   F. ☐ Others (Please Specify:_____)

7. List 3 main challenges that your company would face in complying with the guideline ASEAN Cosmetic Good Manufacturing Practice (eg. lack of competent and trained staff, busy work schedule, etc)

   _____

   _____

   _____

   _____

   _____

8. Does the company have any immediate plans to comply with the GMP guidelines? Please provide details:

   _____

   _____

   _____

   _____

   _____

Highlights of GMP Workshop:
Survey Questionnaires

Appendix I – To complete this Form if your company is a local Manufacturer/Assembler/Contract Manufacturer
For the following questions, please respond with a tick (✓) in the "Yes" or "No" column. You may use "NA" (Not Applicable) if the question does not apply to your situation

Name of Company:

No	Question	Yes	No	Comments
1.	For assemblers, please tick the type of assembly activities involved: (a) Primary assembly only (b) Secondary assembly only (c) Both Primary and Secondary Assembly			
2.	Is your company ISO certified? If Yes, please specify the standard in the comments column			
3.	Do you currently manufacture: Category I cosmetic products? Category II cosmetic products?			
4.	Did any other regulatory authorities other than HSA audit your company? If Yes, please specify the authorities and date of last inspection.			
5.	Do you export your products to other countries? If Yes, please specify the countries			
6.	No of products (sku) manufactured/assembled			
7.	No of staff engaged for production, QC and warehousing? 1. < 10 2. <20 3. <30 4. <40 5. <50 6. Others. Please specify the number in the comment column			
8.	Do you have defined areas for the following? 1. Materials receiving 2. Material sampling 3. Weighing and Dispensing of starting material 4. Starting Materials Quarantine 5. Area for Processing 6. Area for Packaging 7. Quarantine area before final release of finished products 8. Laboratory			
9.	Do you monitor the store for: 1. Temperature			

Highlights of GMP Workshop:
Survey Questionnaires

	2. Relative Humidity			
10.	Do you have a system to clean and maintain your equipment			
11.	Do you calibrate your equipment			
12.	Do your production staff wear protective attire			
13.	Do you have a Pest Control program in place			
14.	What type of water do you use for production – please specify the grade (portable or purified water etc.)			
15.	Do you have a batch numbering system			
16.	Do you have a dust extraction system for handling of dry products			
17.	Do you practice line clearance prior to operation (i.e. all materials from previous operation are removed)			
18.	Do you test the following: (if yes, please state the tests done) 1. Starting material 2. In process material 3. Finished product			
19.	Do you have a system for handling Returned Products			
20.	Do you have a system for handling Recalled Products			
21.	Do you have a system for handling Complaints			
22.	Do you have Standard Operating Procedures (SOP) that bear step by step instructions			
23.	Do you have specifications for 1. Starting Materials 2. Finished Products			
24.	Do you have Batch Manufacturing Records			
25.	Do you have Quality Control Records			
26.	Do you have a Master Formula for each product			
27.	Do you conduct your own Internal Audits			
28.	Do you have written contracts establishing the duties and responsibilities of the contract giver and contract acceptor			
29.	Has anyone in your company gone for GMP related training in the past? If Yes, please provide their designations			

Highlights of GMP Workshop:
Summary of Survey Findings

1. **The workshop was well received.**

   93% expressed that the workshop was either very or quite beneficial in providing them the understanding of GMP requirements

   98% indicated that they would recommend others to attend this work if held again.

2.. **None opined that GMP was not important.**

   60% opined that GMP was very important and 38% opined that GMP was quite important whilst 2% opined that GMP was somewhat important.

Highlights of GMP Workshop:
Survey Findings

3. **Manufacturers are at varying level of GMP compliance**
   - **39% of the manufacturers being survey opined that their manufacturing plants met more than the basic GMP requirements;**
   - **22% opined that their plants just met the basic requirements;**
   - **44% opined that their plants met some of the basic requirements only;**
   - **22% opined that their plants did not meet basic requirements.**

4. **Majority (73%) opined that they could be ready by 2007/2008 but the remaining indicated that they can only be ready in 2009/2011/ 2015.**

Highlights of GMP Workshop:
Survey Findings

5. Challenges which were <u>widely</u> cited by the industry :

- **Lack of trained personnel**
- **Lack of time due to busy work schedule**
- **Costly investment and lack of financial resources**

Other challenges include :

- **Need to source from overseas manufacturers which adopt the same GMP standard**
- **Uncertainty with the GMP standard of overseas manufacturers**
- **Small market**
- **Low profit margin**
- **Need to convert the labelling into English (as part of product labelling requirements for Singapore)**

Highlights of GMP Workshop:
Survey Findings

6. Immediate plans cited by the companies :

- **To set up a new plant**
- **To source from GMP compliant manufacturers and OEM**
- **To engage the help from consultants**
- **To contract the manufacture out to other companies**

Highlights of GMP Workshop:
Follow-up plans

- **Another round of echo seminar depending on industry's need**
- **To explore feasibility to work with academic institutions to provide training on specific topics.**
- **To look into the feasibility to visit SMEs manufacturers in 2007/2008 to assess the progress made**

Thank you