

GMP

(A) An Introduction to the ASEAN Cosmetic GMP Guidelines

Under the Agreement on **ASEAN Harmonised Cosmetic Regulatory Scheme (AHCRS)** which was signed by the ASEAN Trade Ministers on 2nd September 2003, a common set of regulations is applicable to all cosmetics placed in the ASEAN market regardless of whether they are manufactured within or outside ASEAN. The objectives of the AHCRS are:

- To enhance cooperation among Member States in ensuring the safety, quality and claimed benefits of all cosmetic products marketed in ASEAN, and
- To eliminate trade restrictions by harmonizing all technical requirements

Singapore will start implementing the ASEAN Cosmetic Directive before Jan 2008.

 These regulations are found in **Schedule B: The ASEAN Cosmetic Directive (ACD)**. The ACD is closely aligned with the European Cosmetic Directive (6th amendment) as well as with most of the Annexes and Appendices.

 The **ASEAN Cosmetic GMP Guidelines** is found in *Appendix VI*. It consists of the general requirements for developing a quality management system to manufacture cosmetics of consistent quality and ensure that the cosmetics are suitable for their intended use(s). The guidelines consists of thirteen elements outlined below:

- (1) *Quality Management System*
- (2) *Personnel*
- (3) *Premises*
- (4) *Equipment*
- (5) *Sanitation & Hygiene*
- (6) *Production*
- (7) *Quality Control*
- (8) *Documentation*
- (9) *Internal Quality Audit*
- (10) *Storage*
- (11) *Contract Manufacturing & Analysis*
- (12) *Complaints*
- (13) *Product Recalls*

References:

1. http://www.hsa.gov.sg/html/business/cda_cosmetics_overview.html

2. <http://eur-lex.europa.eu/LexUriServ/site/en/consleg/1976/L/01976L0768-20051125-en.pdf>.gov.sg/docs/Appendix_VI_Asean_Guidelines_for_Cosmetic_Good_Manufacturing_Practices.pdf

(B) Past GMP Training Workshop Held in Singapore

- CTFAS, jointly with the Health Sciences Authority (HSA) of Singapore, had held a two-day workshop on ASEAN Guidelines for Cosmetic GMP at Le Meridien (Orchard) hotel on 4th & 5th May 2006.
- The workshop was organised with the objectives to familiarise the industry with the requirements stipulated in the ASEAN Guidelines for Cosmetic GMP as well as to consult the industry in particular the small-medium enterprises (SMEs) on the challenges which they may face with the implementation of ASEAN Cosmetic GMP requirements.
- The trainers' panel comprised of regulatory officers from HSA and GMP experts from the academic institution as well as industry. Responses from the industries were overwhelming as the workshop was well attended by a total of 71 participants who came from the different sectors. Among them are the importers, manufacturers, assemblers, and academia as well as GMP consultants.
- The workshop covered all the 13 ASEAN Cosmetic GMP training modules as well as the key requirements of the ASEAN Cosmetic Directive. It was very well received by the participants as 93% expressed that the workshop was beneficial in providing them the understanding of GMP requirements. In addition, majority of them (about 73%) claimed that they could be ready to comply with the GMP guidelines by 2007 or 2008.

- From the feedback received during the workshop, the challenges that are faced by the industry include a lack of trained personnel; lack of time due to busy work schedule; financial issues; ensuring overseas manufacturers comply with the ASEAN Cosmetic GMP requirements, having equivalent GMP standards etc. The manufacturers commented that they may need to outsource their works to those who are able to comply with the ASEAN Cosmetic GMP Guidelines; to source for materials from GMP compliant companies; engaging GMP consultants; setting up of new facilities etc.

(C) Coming Events

- To assist the industry in the implementation of the ASEAN Cosmetic GMP Guidelines, a second run of the workshop will held around February or March 2007. In addition to the speakers from regulatory authority as well as GMP experts from academic institution and industry, CTFAS may invite GMP compliant cosmetic companies to share their experiences.
- CTFAS will collaborate with HSA in exploring the feasibility of running in-depth training courses on specific topics such as water treatment processes; batch manufacturing records; sampling, quality assurance of analytical instruments; control of air quality etc. These are some of the topics highlighted by the companies which had attended the first GMP workshop organised in May 2006.
- In addition, HSA may conduct visits to the local cosmetic manufacturers in the next two years to assess the progress made by the industry in complying with the ASEAN Cosmetic Directive (ACD) as well as the Cosmetic GMP Guidelines.