Questions and Answers on the interpretation of ASEAN GMP Guideline for Cosmetic

The advice given here should serve as guidance only. You should always make reference to the ASEAN Cosmetic Directive.

I. Quality Management System

1. Is the ISO9001:2000 Quality Manual acceptable?

Yes, it is acceptable if the Quality Manual has covered all the GMP elements as specified in the ASEAN GMP Cosmetic Guideline.

II. Sanitation and Hygiene

2. Should the hand-washing tap be of any other particular design e.g. with press button or sensor? Is there any particular requirement with regard to this?

There is no specific requirement with regard to the design of the tap. The objective of hand-washing is to prevent contamination of the products. As such, there should be procedures in place to ensure operators' hands are properly cleaned and sanitized before entering the production area.

3. Is there a list of pest control agents which are safe for use?

The pest control agent should not contaminate equipments, raw materials, packaging materials, in process materials or finished products and should be safe to the persons who are exposed to it. You may obtain the safety information from the pest control company.
Please note that pest control agents should not be used in the production area.

III. Production

4. If several batches of the same product are produced continuously, must the processing equipment be cleaned after the production of each batch?

The objective of cleaning between batches is to prevent contamination. Continuous manufacturing without cleaning and sanitization can be allowed as long as there is proof to show that there is no contamination.

5. Can paper carton/ boxes be allowed in the processing areas?

This may be allowed only if there is no risk of contamination to the products.

6. Can the same transfer hose be used for different products or materials?

Yes, provided there is effective cleaning and sanitization of the transfer hose between products.

7. What is the water quality standard required?

The minimum requirement is the national drinking water standard. However, further purification/treatment of water may be required depending on the formulation of your product.

8. If microbial limit testing was carried on the finished product for each and every batch of the product manufactured, is it justifiable for the company to reduce the frequency of water testing? What should be the recommended frequency of water testing?

Water is an important starting material and its quality in terms of chemical as well as microbiological aspect should be monitored frequently so that any problem can be detected as early as possible. Finished product testing should only serve as a final check and can not replace the need for regular water testing at the pre-defined frequency.
Water testing should be carried out frequently before one can decide on a suitable reduced frequency. The chosen frequency should be supported/justified with relevant data such as trend analysis.

9. What should be the frequency of D.I. water system regeneration? Can yearly frequency be considered appropriate? How do we verify the water quality after the regeneration process? How do we regenerate the D.I. water system?

The frequency of water system regeneration should be based on the conductivity and other relevant test results obtained. The water quality should be verified in accordance with the water quality specification established for its intended use. For regeneration method, you are advised to refer to the operation manual of the equipment vendor.

10. In the training modules, it is mentioned that the raw materials are required to be weighed and checked before they are dispensed for use in production. If the raw material is a liquid, can the material be charged directly into the mixing tank via the volume control gauge?

Yes. However, the volume control gauge, like the scales, should be calibrated against a reference standard which is traceable to the national standard.

11. Must I check and verify all the parameters included in the CoA of packaging materials e.g. bottles and jars?

Packaging materials should be checked for compliance with the specifications established internally.

IV. Quality Control

12. Is it a requirement for environmental monitoring to be carried out?

The objective is to prevent product contamination from environmental pollution (microbiological as well as physical). Environmental monitoring should be implemented, where appropriate, to demonstrate that the manufacturing environment is not contributing to contamination.

V. Contract Analysis and Manufacture

13. Who should ensure that a contract is established for contract manufacture/analysis - the contract giver or the contract acceptor?

The contract giver should ensure that the contract is established and there should be provisions in the contract to allow any ASEAN National Regulatory Authority to inspect the contract acceptor.

14. If the manufacturer and distributor is the same person operating in two different companies, is there a need for a contract?

Yes, a contract is required to be put in place so that there is no ambiguity of the respective GMP responsibilities undertaken by the two companies.

VI. Storage

15. When the recommended storage condition is not stated on the label of the imported products. What should be the appropriate storage conditions provided by the warehouse?

Importers are required to find out from the suppliers/manufacturers the right storage conditions for the products. The recommended storage conditions should be based on the results of the stability studies conducted.

VII. Premise

16. Can raw material sampling be conducted in the weighing/dispensing area? Must there be a designated area for the sampling activity?

The objective of recommending a separate area is to prevent cross-contamination. The company must demonstrate that there are adequate

processes in place to prevent cross contamination if the areas are not separated.

17. Is false ceiling required for the production area?

The objective is to prevent environmental contamination (microbiological or physical). The manufacturer should demonstrate that they have ways to clean and sanitize the ceiling effectively.

18. Can ceramic tiles be allowed for floor or wall?

Ceramic tiles can be allowed provided the company can ensure that the gaps between the tiles can be properly cleaned and sanitized to prevent microbial contamination.

19. Can restrooms which are already separated from the manufacturing areas be in the same building?

Yes.

20. What type of filter should be used in the air intake system? What should be the appropriate air exchange rate and direction of air flow?

The need for air filters and, if so, the air exchange rate as well as the direction of air flow will depend on the desired air quality needed for the manufacture of your products. This should take into account the prevention of contamination from the surrounding environment.

VIII. Personnel

21. Are there a minimum number of personnel that a company must have for the manufacturing activities?

No but there must be sufficient personnel to carry out the work effectively. Additionally, the QC and Production functions should be independent from each other.

22. Are personnel working at the mixing or filling areas required to put on long sleeved gown?

Personnel can potentially introduce contamination to the environment, equipment and materials/product with which they come into contact. Staff should put on appropriate garments which are suitable to the operation in a manner that can ensure protection against contamination.

IX. Equipment

23. Is it possible to use plastic mixing tank in production?

Production equipment should be constructed of material which is compatible with products and materials which they will come into contact with. It should be non reactive, non adsorptive and non additive in nature. In addition, the production equipment should be easy to clean and sanitize.

24. Is it appropriate to calibrate all balances once a year?

Yes, at least once a year.

25. Can PVC pipes be used for delivering water and other materials for use in the manufacturing process?

To prevent contamination and facilitate cleaning and sanitization, stainless steel pipes are preferred. Should PVC pipes be used, you have to ensure that you have effective cleaning and sanitization procedures in place.
Please refer to the ASEAN Cosmetic GMP Training Module on "Equipment" for more information.

26. If they are free can the QC staff help in production work and vice versa?

The Head of Production can enlist the help of QC staff provided these staff are qualified and trained in the area of work that they help out and that there are no conflict of interest involved. The production head should also take note that his responsibility can not be delegated and he will be held responsible for the work performed by the helpers and vice versa.

X. Documentation

27. Is computer validation required?

Data should be controlled and secured with adequate audit trails whether a computerised or manual system is used.

XI. General issues

28. What is the GMP requirement for manufacturers which are located outside the ASEAN region?

The overseas manufacturers should comply with the requirements of the ASEAN Guideline on Cosmetic GMP or the equivalent GMP Guidelines/Requirements as approved by the ACC.

29. Is there a need to have filtered air in a soap manufacturing facility?

The need for air filters and, if so, the air exchange rate as well as the direction of air flow will depend on the desired air quality needed for the manufacture of your products. This should take into account the prevention of contamination from the surrounding environment.

30. Can wooden floor or wall be allowed when concrete cement flooring is not suitable e.g. in swamp area?

The company should take note that it is necessary to put in place an effective cleaning and sanitation programme to ensure that the material used for flooring or wall will not become the potential source of contamination (microbial or physical).

31. Some SMEs feedback that they lack knowledge on how to set up raw material, packaging materials or finished product specifications

SMEs should send their staff for training in this area of concern. They may approach the cosmetic association or engage a suitable consultant for assistance.

32. Is it possible to house a number of pieces of equipment in one production room and to carry out the manufacturing of different products concurrently? Some SMEs have limited manufacturing space and they have to carry out many activities in one room.

Yes but there should be measures in place to prevent mix-up and cross contamination.

33. Window Air conditioners or spilt air conditioners are commonly used by SME's as the air handling system, is this acceptable?

It is acceptable if they are fitted with proper filters and subject to proper monitoring and maintenance at appropriate interval.

34. Some SMEs expressed that they lack technical persons who can understand the GMP requirements

These SMEs should send their personnel for the relevant training or/and engage technically competent staff. They can also engage a suitable consultant for assistance.

35. Some SMEs expressed that they lack qualified personnel to provide staff training

These SMEs should send their personnel for the relevant training or/and engage technically competent staff. They can also engage a suitable consultant for assistance.

36. Some SMEs are concerned about the required qualification that their key personnel should possess.

Qualified key personnel should have knowledge, experience, skills and capabilities to perform their job functions. There is no requirement about University degrees.

37. Some SMEs are concerned about the number of key personnel required.

There should be adequate number of key personnel to ensure work is carried out properly according to the GMP requirements. The QC and Production functions should be independent from each other.

38. Can I reduce the frequency of finished product testing?

Reduced testing of certain parameters can be considered if it is supported with scientific, rationale and relevant data or through the use of innovative technology e.g. Process Analytical Technology (PAT).

39. Some SMEs have expressed difficulty with documentation control and development of SOPs.

Companies which are facing these problems should attend training on documentation control e.g. ISO courses. Depending on the preference of the company, bracketing of procedures or activities in one SOP can be adopted. For e.g. a general cleaning procedure can be used for a few areas such as the dispensing area, mixing room, etc.

40. Some SMEs feedback that they have limited number of personnel to conduct internal audits.

All manufacturers should fully understand that internal audit is one of the important requirements of GMP. Internal audit is required as it allows the company to assess whether the quality management system which the company has put in place is effective. Internal audit is a planned activity and it can be conducted at a time that is convenient to the company as long as it is carried out periodically. Alternatively, the company can also approach a suitable external party to audit the company.

41. What if accredited testing laboratories are not available or inaccessible?

Companies that do not have any QC facility may outsource the testing to an external accredited laboratory. If external accredited laboratories are

not available or inaccessible, the company can go for an external testing laboratory which has been qualified to be technically competent and would perform testing using methods that comply with the international requirements/standards.