European Cosmetics Responsible Person Association

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Good Manufacturing Practices (GMP) compliance verification by the Responsible Person (RP)

ERPA POSITION PAPER

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A. *Current legislation-References*

1. Regulation 1223/2009/EC

- Article 5 - Obligations of responsible persons
  - "*Responsible persons shall ensure compliance with Articles 3, **8**, 10, **11**, 12, 13, 14, 15, 16, 17, 18, Article 19(1),(2)and (5), as well as Articles 20, 21, 23 and 24.*"
- Article 8 - Good manufacturing practice
  - *"1. The manufacture of cosmetic products shall comply with good manufacturing practice with a view to ensuring the objectives of Article 1."*
  - *"2. Compliance with good manufacturing practice shall be presumed where the manufacture is in accordance with the relevant harmonised standards, the references of which have been published in the Official Journal of the European Union."*
- Article 11 - Product information file
  - "*2. The product information file shall contain the following information and data which shall be updated as necessary:*
    - *…*
    - *(c) a description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 8;*"

2. Commission communication in the framework of the implementation of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, Official Journal of the European Union (2011/C 123/04)

- Reference and title of the harmonised standard (and reference document)
  - *EN ISO 22716:2007 Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices (ISO 22716:2007)*

B. *Issues arising from the above articles*

Since the compliance to the GMP is one of the obligations of the Responsible Person (Article 5) and since the declaration of conformity of the RP is one of the documents listed in the PIF requirements (Article 11), it is clear that the RP needs to verify the manufacturer compliance to the GMP.

The purpose of this position paper is to provide tools for the RP or his experts in charge, for the evaluation and monitoring of compliance with GMP, especially in case of outsourced productions (subcontracting, imports or contract manufacturing).

C. Proposal for compliance verification by the RP

ERPA considers that a simple declaration of the manufacturer stating that complies with GMP should not be accepted as an evidence of GMP compliance. The guideline ISO 22716:2007 is recommended as a reference to the RP to verify the manufacturer compliance with GMP, but a "certification" according with this standard is not mandatory. Different approaches/strategies can be used by the RP or his experts in charge to evaluate and ensure the manufacturer(s) compliance with GMP, such us:

- **GMP Pre-Audit Questionnaire**

  A pre-audit request for information can be a valuable tool for an expert to evaluate how far the manufacturer complies with GMP, allowing RP to collect evidence of this compliance even at long-distance. The questionnaire for analysis might include the following questions:

  1. Quality Management System
  - Are you ISO 9001 certified? If yes, provide ISO 9001 certificate.
  - Is there a manager responsible for Quality Assurance?

  2. Personnel
  - Do you have an organization chart? Provide it if available.
  - Do all personnel have written procedures for their responsibilities and operations?
  - Do all departments conduct training relevant to their requirements? Is there documented evidence to support this?
  - Is protective clothing worn in the manufacturing area? Upload a photograph of area & type of clothing worn.
  - Is there a hygiene program to be followed by the personnel?

  3. Premises
  - Do you have separate or defined areas for storage, production, quality control, ancillary, washing and toilets? Provide manufacture plant.
  - Are there housekeeping procedures readily available for all areas of the factory? Provide the hygiene procedures & photographic evidence for Manufacturing, filling and packing.
  - Do you have a pest control program?

  4. Equipment
  - Is there a preventative maintenance procedure with a schedule for all manufacturing equipment? Provide this procedure if available.
  - Is there a preventative maintenance procedure with a schedule for all filling equipment? Provide this procedure if available.
  - Are the scales calibrated regularly? Can you provide evidence of it?
  - Are the equipment within the laboratory calibrated? Can you provide evidence of it?

  5. Raw materials and packaging materials
  - Are all raw materials and packaging components purchased according to a specification that has been agreed with the supplier? Provide the list of minimum information/documentation requested for raw materials and packaging components.

- Is there an approved list of suppliers?
- Are procedures for the receipt, identification storage and handling of incoming raw materials, packaging or other products available?
- Are raw material records maintained including:
    - Supplier lot number?
    - Quantity?
    - Material Safety Data Sheet?
    - Technical Specifications Data Sheet?
    - Certificates of analysis?
- Do you use sub-contractors? If yes, why and are they validated and/or audited prior to commencement of work?
- Are there written procedures for the operation and maintenance of the process water supply system? Supply these procedures, if available.
- Is the water tested in accordance with the specified requirement and are the records maintained? Supply water specifications and an example of test record.
- Who has the authority and responsibility to approve or reject all materials purchased?

4. Production

- Are formulations and manufacturing instructions provided to the operators? Provide example of the method of manufacturing.
- Is all the necessary batch information recorded for:
    - Raw material batch numbers?
    - Raw material quantities?
    - Temperature & mixing time controls?
    - Corrections/additions?
- Provide an example of a completed batch record
- Is the fill weight checked and maintained within the specified limits? Which limits do you use?
- Does the quality unit have the authority and responsibility to approve or reject all materials, labelling, bulk and finished goods?

6. Laboratory Control

- Do you have Quality Control laboratory?
- Are their copies of the procedures/test methods readily available? Supply copies of the most relevant procedures/test methods if available.
- Are the following tested in the Quality Control laboratory:
    - Process water?
    - Raw materials?
    - Packaging?
    - Bulk products?
    - Finished products?
- Provide an example of a quality control record of a finished product.
- Is there a system for detecting and tracking non-conformances and out-of specification results? If available, supply this procedure.

7. Complaints & Recalls

- Are there written procedures in place for dealing with all customer complaints? Please detail what your procedure is for notifying the RP of any relevant complaints

- Are records of complaints maintained?
- Do you have a Recall/Withdrawal procedure? Provide the procedure if available.

9. Documentation

- Do you have a procedure for documentation control?
- Do all files have up to date back up copies?
- How long are files stored?

10. Wastes

- Do you have a procedure for waste material and rubbish control and disposal? Provide it if available

11. Audit

- Do you perform internal audits? If yes, provide copy of the latest audit report.
- Do you perform external audits? If yes, provide copy of the latest audit report.

The provided answers shall be assessed by the RP experts in GMP. The lack of some important pieces of information/documentation might evidence immediately the non-compliance with GMP. The acceptance of a declaration of the manufacturer stating GMP compliance or the decision to proceed for an audit shall de decided on a case-by-case basis, considering all the information and documentation assessed by the RP experts.

- **Audit**

Whenever possible, audits carried out by experts of the RP or subcontracted by the RP are the best tool to check and document the compliance of processes and the organization of the manufacturer. Preferably audits should be conducted by a team that is aware of the critical production parameters for the product specifically designed for the RP.

Moreover the verification of the manufacturer GMP compliance, regardless the strategy used for it, should be conducted periodically, preferably annually.

About ERPA

ERPA is the European Cosmetics Responsible Persons Association. More information: http://www.erpacosmetics.org/