

EFfCI

GMP GUIDE FOR COSMETIC INGREDIENTS



TARGET ORGANISATIONS

The service is aimed at all companies that produce ingredients for the production of cosmetics.

THE CONTEXT

The quality of cosmetic ingredients is essential when it comes to ensuring the safety and effectiveness of cosmetic products that must be placed on the market in accordance with the requirements of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009. For this reason, EFfCI - the European Federation for Cosmetic Ingredients,

the European association that represents the chemical industries that produce raw materials for the cosmetic sector, has developed a guideline for applying Good Manufacturing Practices (GMP) in the production of cosmetic ingredients.

THE SERVICE

Drawing on its extensive experience in assessing management systems in companies in the cosmetic sector and related sectors such as pharmaceuticals and medical devices, Certiquality offers companies that produce ingredients for the cosmetic industry services to attest compliance with the requirements of the guideline for applying Good Manufacturing Practices in the production of cosmetic ingredients.

The guideline adopts a quality management system in compliance with ISO 9001 integrated with additional requirements regarding Good Manufacturing Practices (GMP) as a reference model.

Specific GMP requirements include, for example:

- quality controls on cosmetic ingredients;
- the expansion of the responsibilities of the 'Quality Unit' in the review and approval of quality documents and in the release of the production batch;
- the definition of specific responsibilities, for example, for the approval of suppliers, for the approval of raw materials and packaging materials;
- the obligation to issue procedures for the management of the most critical activities such as laboratory analysis, control and release of cosmetic ingredients;
- records, which must include the identification of the personnel who carried out each activity;
- the adoption of a 'change control' system;
- the definition of methods and behaviours for the management, cleaning and maintenance of work environments such as to reduce the risks of contamination of cosmetic ingredients.

BENEFITS

With the certificate of compliance with the EffCI Guideline - GMP Guide for Cosmetic Ingredients, companies have the opportunity to:

- ensure compliance with the guidelines on Good Manufacturing Practices for raw materials intended for the production of cosmetic products;
- give confidence to the manufacturers of cosmetic products that the production of raw materials has been carried out in accordance with Good Manufacturing Practices;
- demonstrate that the production of cosmetic ingredients is carried out under conditions such as to guarantee the compliance of the product with the specifications agreed with the customer, the reduction of the risks of contamination and the availability of records regarding the activities and controls carried out;
- integrate a pre-existing ISO 9001 certification with a more specific sectoral certificate.

CERTIFICATION PROCESS

The main phases of the certification process include:

- the preliminary audit, carried out exclusively on request, which makes it possible to assess the state of the business management system in relation to what is required by the EFFci - GMP Guide for Cosmetic Ingredients. Areas for improvement and strengths (gap analysis) are identified;
- the audit for the certificate of compliance, with the objective of assessing the compliance of the management system with the requirements of the EFFCI - GMP Guide for Cosmetic Ingredients, through the analysis of documents and field observations;
- the issuance of the certificate of conformity;
- the annual surveillance audits and the three-year renewal.

For companies already certified according to the ISO 9001 standard by Certiquality, the audit for the certificate of compliance and subsequent periodic audits can be carried out in conjunction with the activities already planned, such as surveillance and renewal.

ADDITIONAL DOCUMENTATION

The following documents are available on request

(see: <http://www.effci.org>):

- EFFCI GMP GUIDE FOR COSMETIC INGREDIENTS, which includes the standard against which the certification is carried out;
- EFFCI-GMP-Audit-Checklist .

