Quality Assurance – Our services for Cosmetic GMP

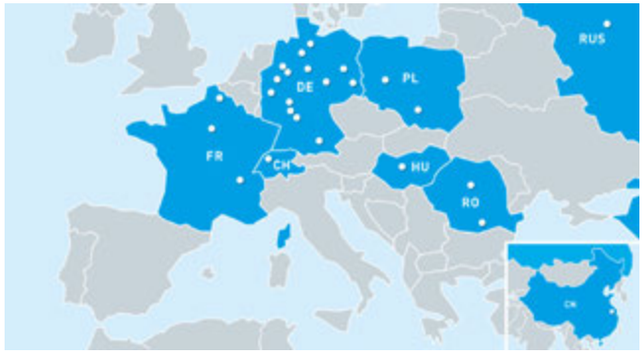
At WESSLING we provide you with a network of efficient accredited laboratories which include a vast range of analytical services. Our experts advise you in a knowledgeable and targeted manner on all issues concerning Good Manufacturing Practice:

- First inspection and auditing of a production site
- Inspections and control of existing GMP concept
- Advice on issues concerning GMP-compliant manufacturing
- Advice on DIN EN ISO 22716
- Training courses for employees
- Inspections and advice on industrial hygiene

Other services

- Product Information File (PIF)
- Analytical tests of your finished product and tests of raw materials and packaging materials
- WESSLING Quality Seal denoting above-average safety and quality standards

WESSLING
Quality of Life



WESSLING is an international and independent analytical, testing and consulting company represented at 25 locations in Europe and China. More than 1,400 employees work on the continuous improvement of quality and safety of products and processes of environmental and health protection. We examine, analyse, assess, survey, plan and implement projects - for the sustainable improvement of the quality of life.

WESSLING GmbH
Impexstraße 5
D-69190 Walldorf

Your contact
Winfried Rämisch
Tel. +49 6227 8209-42
cosmetics@wessling.de

WWW.WESSLING-GROUP.COM

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Quality and Safety Clearance for Cosmetic Products

GMP stands for Good Manufacturing Practice and provides guidelines for the quality assessment of production processes and production environment. The guidelines are also applied when producing cosmetic products and contain the practical development and implementation of quality assurance.

The requirements for producing cosmetic products in compliance with cosmetic GMP have existed in the cosmetic industry for many years. These requirements ensure constant quality and safety of your products in relation to health.

Legal Requirements

For cosmetic products, consumer safety is most important. The European Regulation 1223/2009 requires cosmetic products to be manufactured in compliance with Cosmetic GMP (Section 8). By publication of norm DIN EN ISO 22716 (Guidelines for Good Manufacturing Practice) in the Official Journal of the European Union and adherence to it, the principles of Good Manufacturing Practice are regarded as duly taken into consideration. Therefore, this norm serves as the central guideline both on a national as well as EU-wide scale.

A public declaration on production in compliance with GMP (Section 11, EU Cosmetics Ordinance 1223/2009) also has to be a part of the product information file (PIF) which has to be created for every product brought into the market.

It is legally binding for all manufacturers (responsible person) to produce cosmetic products in compliance with the guidelines of GMP.

All EU member states are encouraged to monitor compliance with the principles of Good Manufacturing Practice, by the individual producers, or responsible persons, respectively (Section 22).

Essentials of DIN EN ISO 22716

The norm deals with the following aspects and advises on organisation and practical implementation:

1. **Personnel:**
   Employees should be trained accordingly to produce, monitor and store cosmetic products in the quality defined. A corresponding organisational structure, adjusted to the company's size and product range, should be created. In addition, hygiene programmes are to be set up.
2. **Production site and equipment:**
   The production site should be designed in a way that product protection, thorough cleansing and effective disinfection can be carried out. The different areas of the production site must meet with certain spatial requirements laid down beforehand. Equipment should also be suitable for its designed usage.
3. **Raw materials and packaging materials:**
   All raw materials and packaging materials that are utilised should correspond to previously aligned quality criteria for cosmetic end products. This includes, for example, that materials with an earlier release date should be used first (first in – first out).
4. **Production and end product:**
   In every production phase measures should be taken to ensure that the end product corresponds to certain criteria. This applies to the production phase (including intermediate products) as well as any packaging materials used.
5. **Quality control lab and off-spec products:**
   The quality control lab should use suitable testing methods to prove the product's compliance with defined acceptance criteria. Moreover, it regulates how to handle off-spec results and sampling.
6. **Subcontracting:**
   Here customer and contractor should negotiate a written contract or similar agreement to administer duties and responsibilities.
7. **Deviations, claims, and recalls:**
   It is defined how to deal with deviations, claims and recalls. Tests, analysis and ways of tracing are described in detail.
8. **Change control and internal audit:**
   The audit serves to monitor the principles of Good Manufacturing Practice and should be conducted regularly by authorised personnel.
9. **Documentation:**
   Every manufacturer should set and implement one's own system of documentation which is adjusted for individual production and products.