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The EFfCI GMP Certification Scheme: celebrating 15 years of improving Quality and safety of cosmetic ingredients

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Abstract

Cosmetic ingredients are a fundamental link in the cosmetic supply chain, not only with regard to Quality management but also to the safety of the finished cosmetic products.

EFfCI GMP is today the only certifiable Quality Standard for the production and the distribution of cosmetic ingredients, and it will soon include a substantial add-on focused on sustainability with the introduction of the Industrial Ecology principles.

Keywords:

- Quality Standard
- EFfCI GMP
- Good Manufacturing Practice
- Cosmetic Ingredients
- Industrial Ecology
- Green Engineering
- Green Chemistry
- Regulation

The EFfCI GMP Certification Scheme celebrates 10 years of providing cosmetic ingredient suppliers with GMP Certificates to show the suitability of their materials for use in cosmetics. In those 10 years it has steadily grown from being a "good idea" to becoming an instrumental, effective, and successful part of the assurance of cosmetic ingredient Quality chain. With over 220 certificates it is now also a truly global Standard with certificate holders in more than 30 countries.

The current scheme traced its ancestry to the original EFfCI GMP Guide for cosmetic ingredients which was first published in 2005. This was inspired on the very well-known and adopted IPEC-PQG Good Manufacturing Practice Guide for Pharmaceutical Excipients, as many cosmetic ingredients are used in both sectors. But as a Guide its purpose was purely educational, informing cosmetic ingredient suppliers how to adopt the well-known principles of GMP to their operations. By basing the Guide pharmaceutical GMPs the highest assurance of product Quality was in-built, and one that had as its prime focus on consumer safety. That's what differentiates it from other guides, the aim is to solely assure cosmetic ingredient Quality, but to make sure the cosmetic ingredient when put in use as a cosmetic does no harm to the consumer, provided that the formulation is correctly designed.

The Guide itself, was prepared because the early drafts of what was to become the European Cosmetic Regulation 1223/2009 included the requirement to apply the principles of GMP to cosmetic manufacturing and packaging. Early drafts of the associated GMP Guide for cosmetics included cosmetic ingredients in scope as well. Whereas this would secure consumer safety along the whole supply chain, the detailed GMP rules for cosmetics are different to those for cosmetic ingredients and there was then a risk that cosmetic ingredient suppliers would be implementing GMP rules for no benefit. Against this backdrop EFfCI took the responsible view that there should be a GMP for cosmetic ingredients and established the first GMP Guide accordingly.

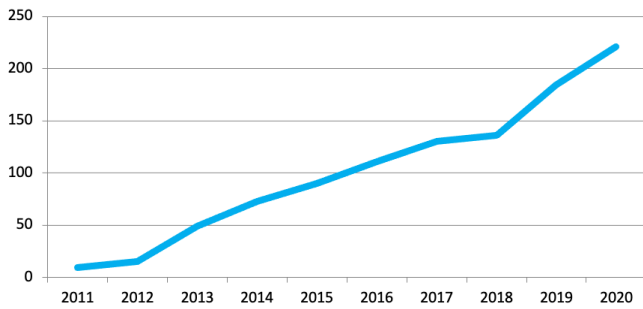
As cosmetic ingredients are often manufactured by chemical synthesis, and this industry had already implemented Quality management systems based on ISO 9001, it was decided to align the EFfCI GMP Guide to the ISO 9001 clause structure to aid implementation. Through all the subsequent revisions of the Guide that alignment has remained even when ISO 9001 was itself updated in 2015, in specific under the ISO Annex SL framework.

The approach and petition to the legislators drafting 1223/2209 were successful and cosmetic ingredients were removed from the scope of the regulation. That initial GMP for cosmetics transitioned in the well-known ISO 22716, which is still limited to cosmetics, without, however, this specific Standard being officially mentioned by the legislators in the European Cosmetic Regulation.

Once issued the Guide was well received and many suppliers soon started asking for certification by independent third parties to demonstrate they had adopted the GMPs in their operations. Hence the issue of the EFfCI Certification Scheme in 2010 which utilized a revision of the Guide where the requirements were converted into an auditable Standard. Whereas the Guide is informative and tells suppliers how to implement the GMPs, the Standard just sets out what has to be done and guaranteed as a requirement. This allows for objective and more importantly consistent auditing by different Auditors around the world, and also reduces subjective findings which are due to the Auditor's opinions.

The EFfCI GMP Guide and Standard is free to use and access (see www.effci.org). The EFfCI GMP Certification Scheme is globally recognized and used. Growth in certification has been very steady throughout the past 10 years with excellent certificate retention. Once suppliers have certification, they only tend to stop being certified when there is a major change to their organization, such as a takeover or site closure. In the early days uptake was slow, not least because suppliers had to implement the GMPs in their systems.

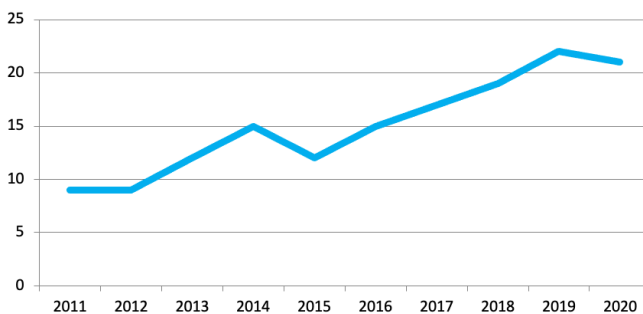
EFFCI GMP Certificates



Since then, as the graph illustrates, growth has been consistent but is now showing signs of acceleration. More and more cosmetic manufacturers are recognizing the value of a certified EFFCI GMP supplier and are requiring this certification as part of their supplier approval processes.

Not surprisingly the number of registered Certifying Bodies has risen in the last 10 years too, with an increasingly global coverage.

EFFCI Registered Certifying Bodies



For cosmetics manufacturers the benefits of choosing a supplier with EFFCI GMP certification include:

- The supplier meets an independently audited and world-wide Quality Standard;
- A common Standard of Quality Management Systems (QMS) and operations across all suppliers with EFFCI GMP;
- Knowing that end-user requirements and expectations are addressed.

For cosmetics ingredients manufacturers (suppliers), the benefits of certification to EFFCI GMP include:

- Operating to a Standard that addresses risks and controls specific to cosmetics ingredients and their markets with relevant requirements;

- Operating to a common Standard that adds onto ISO 9001:2015 and so requires little change to the QMS because its development is on synoptic basis;
- Being scalable to suppliers of all sizes and types of manufacturing processes;
- Operating to a Standard that is widely accepted by cosmetics manufacturers;
- Operating to a Standard that ensures consistent and objective Auditor interpretations.

The EFFCI Certification Scheme Audits are conducted by well-known 3rd party Certification Bodies (CBs), often the same ones that issue ISO 9001 certificates. These CBs sign a legal agreement with EFFCI to implement the rules behind the Certification Scheme which includes training the Auditors in EFFCI GMPs. Once they have agreed to conform to the scheme rules and have a trained Auditor, they can then perform Audits on cosmetic ingredient suppliers and issue GMP Certificates and EFFCI GMP Audit reports.

A cosmetic ingredient supplier desiring to be certified should directly contact an EFFCI registered Certifying Body among those listed on the EFFCI website.

It is the main purpose of EFFCI GMP to have independent, fair, objective, and well-experienced Auditors for the certification process. Therefore, EFFCI established a Registration Scheme for Auditors and Trainers. Only Auditors and Trainers approved by EFFCI combined with recognized and approved Certifying Bodies are authorized to certify organizations as EFFCI GMP compliant.

All recognized Certifying Bodies and registered Auditors are listed on www.effci.com. This allows the cosmetic manufacturer to validate the Certificate and or Audit report as being compliant to the EFFCI GMP Scheme rules.

Increasingly today cosmetic ingredient suppliers are not only sharing their EFFCI GMP Certificates with their customers, namely the cosmetic manufacturers, but also sharing the Audit reports, findings and all associated actions.

With 10 years of successful Certificates, we can now see other benefits from certification. In the intervening time the need for a customer to physical Audit the supplier has grown exponentially with more and more Audits being requested. By sharing EFFCI GMP Certificates and Audit reports, suppliers are able to use these instead of a physical Audit.





And customers too are increasingly willing to accept these instead of performing the Audit. This is to both parties' immediate benefit and has other environmental benefits such as a reduction in travel.

The EffCI GMP Certification Scheme will undoubtedly continue to evolve and adopt to include contemporary Quality approaches. It is already fully integrated with Quality risk-based thinking, which places the duty on the supplier to identify and manage the risks to product Quality.

Until the COVID-19 pandemic, the growing crisis was an environmental one, and there was the acute need to develop a circular economy with a minimal impact on the planet and its critical ecosystems. Therefore, EffCI has started work on a complementary and fully aligned Standard alongside the GMPs one on Industrial Ecology, a modern and complex subject which consists of Green Engineering and Green Chemistry, ensuring to drive towards more and more sustainable chemical transformations and processes. The development of this new Standard will also provide functional connections with the Life Cycle Assessment and with the Responsible Care program.

At the time of the pandemic, with travel so restricted or impossible, have a credible reliable and high-quality Certification Scheme in place has been essential to the continued supply of cosmetic ingredients which are safe for consumers. The EffCI GMP Certification scheme has certainly come of age in 2020. ■

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