



# UNDERSTANDING AND IMPLEMENTING THE REQUIREMENTS OF THE **ISO 22716 GOOD MANUFACTURING PRACTICES (GMP) CERTIFICATION STANDARD FOR COSMETIC PRODUCTS**

**A DISCUSSION ABOUT THE CHALLENGES, IMPACTS AND OPPORTUNITIES FOR THE PRODUCTION, CONTROL, STORAGE, AND SHIPMENT OF SAFE COSMETIC PRODUCTS**

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# ABSTRACT

The purpose of this document is to provide an introduction to the ISO 22716:2007 standard on Good Manufacturing Practices (GMP) for cosmetic products. It aims to promote the understanding of GMP across the entire cosmetics product supply chain as well as to discuss the legislative precursors to the

development of the Standard. In addition, it provides a resource for those organisations interested in implementing the specific requirements of the standard in order to support their business at a domestic or international level within the cosmetics industry.

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# I. EXECUTIVE SUMMARY

The safety of cosmetic products is an issue often on the minds of manufacturers, suppliers, and regulators alike. Numerous regional and international standards have been created over the years in order to enhance the quality and safety of cosmetic products, in many instances specifically addressing requirements for manufacturers, suppliers, wholesalers, and retailers.

Recently the International Standardization Organisation (ISO) published new guidance on the safe manufacturing of cosmetic products under a Good Manufacturing Practices (GMP) regime. Developed in response to the recently updated EU Cosmetics Regulation, the ISO 22716 also has direct links to many other cosmetic regulations in place around the world. As such regulators in several countries and regions have adopted this standard, ISO 22716, effectively replacing existing guidance and standards.

ISO 22716 provides a comprehensive approach for a quality management system for those engaged in the manufacturing, packaging, testing, storage, and transportation of cosmetic finished products. The standard has its basis in other quality management systems, ensuring a smooth integration with those quality management systems such as ISO 9001 or the British Retail Consortium (BRC) standard for consumer products.

The beauty and simplicity of ISO 22716 is that it combines the benefits of GMP, linking cosmetic product safety with overall business improvement tools that enable organisations to meet global consumer demand for cosmetic product safety certification.

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**ISO 22716  
WAS DEVELOPED  
TO RESPOND TO  
UPDATED COSMETICS  
REGULATIONS.**

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# II. GLOBAL COSMETIC PRODUCTS SAFETY

Consumers are becoming more and more concerned about the safety of the cosmetic products they are using. Fears of allergies and dermatitis caused by tainted or poisoned cosmetics have been ever-present in recent years.

Certain ingredients used in cosmetics, such as fragrances and preservatives, can trigger an allergic reaction. Obviously, these ingredients play a pivotal role in the cosmetic products of our choice and correct dosing of these substances therefore is of key importance to avoid irritation of the skin through over-exposure.

Over-exposure to preservatives has frequently been observed in historic cases, one example being beauty creams that contained mercury. Beauty creams occasionally were reported to contain excess amounts of mercury, with poisoned consumers exhibiting clear toxic neurological symptoms.

Incidents such as this have always impacted the public and therefore have forced regulators to take action to ensure consumer safety. Examples of these are the requirements manufacturers have to adhere to in terms of pre-defined and approved product specifications and by putting systematic guidance on the organisation of the manufacturing and distribution supply chains.

The recent growth of extended and complex global supply chains occurring in combination with the lack of proper control and oversight have made concerns over quality and safety even more serious.

Manufacturers and retailers are urged to address deficiencies in their supply chains, and several quality standards have been proposed to deliver assistance in ensuring global cosmetic products safety.

The introduction of ISO 22716 marks a major step in the realisation of a globally recognised standard for cosmetic products safety. This

standard was prepared by ISO Technical Committee (TC) 217 Working Group (WG) 6 between 2002 and 2006.

The final document was published in November 2007.

The result is an international, auditable standard that specifies the requirements for cosmetic products safety management systems by incorporating the elements of GMP and risk assessment in combination with a comprehensive quality management system.

**MANUFACTURERS AND RETAILERS ARE KEEN TO ENHANCE THE LEVEL OF QUALITY IN THEIR SUPPLY CHAINS.**

## The Origins of a Global Standard

<b>1938</b>	GMP are enforced by the FDA as a result of the 1938 Food, Drug, and Cosmetic Act
<b>1950s</b>	GMP are established for the pharmaceutical industry in US and Europe
<b>1976</b>	Establishment of the European Cosmetic Regulation 76/768 EWG
<b>1992</b>	Establishment of FDA Cosmetic GMP Guidelines under The Federal Food, Drug and Cosmetic Act emphasising the prohibition of bringing into commerce cosmetics that are adulterated or misbranded
<b>1994</b>	Publication of European (Colipa) Guidelines on Cosmetic GMP
<b>1995</b>	Publication of GMP Guidelines by the Council of Europe
<b>2002</b>	ISO WG 6 is activated to develop a GMP guidelines standard for cosmetics
<b>2003</b>	ASEAN Guidelines for Cosmetic GMP published in compliance with the provisions of the ASEAN Cosmetic Directive
<b>2007</b>	Introduction of ISO 22716 on the GMP for Cosmetic Products
<b>2009</b>	Regulation EC 1223/2009 on cosmetic product consumer safety passes the European parliament
<b>2011</b>	Reference to ISO 22716:2007 as a harmonised standard for GMP in the European Union (publication 2011/C 123/04)
<b>2012</b>	Publication of the Cosmetic Safety Amendments Act to modernise federal oversight of cosmetics and personal care products (HR 4395)
<b>2013</b>	Draft guidance published by US FDA Cosmetic GMP guidelines and inspection checklist, considering ISO 22716:2007

# III. THE ISO 22716 AND INTERNATIONAL REGULATIONS

The content of ISO 22716:2007 Guidelines on Good Manufacturing Practices for Cosmetic Products has been approved and accepted by a number of regulatory bodies around the world. For example the International Cooperation on Cosmetic Regulation (ICCR) – a joint effort by the USA, the European Union, Japan and Canada – agreed in their July 2008 meeting to implement ISO 22716 in their respective regions, wherever possible.

Regulators of several of these ICCR regions have decided to act accordingly. In the USA, it was proposed that the Food & Drug Administration (FDA) modify its current guidance. In addition, the EU is amending its existing European Committee for Standardisation (CEN) standard to incorporate the ISO 22716 standard. The Japan Chemical

Industry Association (JCIA) has adopted ISO 22716 and advised the regulators in the government to act accordingly. Finally, in a meeting in late 2006 the ASEAN Consultative Committee for Standards and Quality (ACCSQ) agreed to recognise the forthcoming ISO 22716 as equivalent to the ASEAN Cosmetic GMP guideline, which was published in 2003.

Each of these regions has its own regulations that have to be adhered to for any cosmetic products being brought to the market. It is from these regulations that their guidelines are generated. GMP is referred to within each country's regulations but it is also an essential element to meeting the requirements throughout.

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**THE INTERNATIONAL COOPERATION ON COSMETIC REGULATION (ICCR) AGREED TO IMPLEMENT ISO 22716, WHEREVER POSSIBLE.**

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# IV. THE EC COSMETICS REGULATION 1223/2009

The EU has recently reviewed its cosmetics regulation and published the revised edition on 22nd December 2009 in the Official Journal of the European Union. The complete regulation came into force on 11 July, 2013, with some elements at earlier dates. As a result the European Community has now introduced a harmonised regulatory framework. With the framework coming into force, the laws of each of the respective countries must be in accordance with the regulation, along with any relevant standards or guidance affecting the cosmetics industry. This requirement also applies to any cosmetics manufacturers outside the EU that wish to import products into countries within the region.

The regulation has been put in place so that across the EU the cosmetics industry is using standardised terminology along with simple common procedures. The framework outlines stronger in-market controls than were required before and with this, aims to ensure a higher level of protection of human health. It focuses on 'simplification' with reduced red tape and better administration, alongside a 'new-approach' covering uniform standards across the EU, one of which being that of Good Manufacturing Practice. It also talks about general standards for sampling and analytical methods. Fundamental to each of these is the requirement that cosmetic products must be safe when applied in normal or reasonably foreseeable conditions of use. All common standards discussed in the regulations, including the ISO 22716, aim to put procedures in place that enable manufacturers to reach this safety goal. The importance of ISO 22716 for those organisations that need to comply with GMP has been stressed by EU publication 2011/C 123/04 from April 2011.

The regulations clearly outline the differences between the manufacturer, distributor and importer and emphasise that the 'responsible person' must guarantee compliance with all safety and labelling requirements as well as notification obligations and corrective measures. The 'responsible person' can be the manufacturer, importer or distributor as long as that party has a registered office within the EU, which is detailed on the cosmetic's packaging.

With safety key to the new regulations, each responsible person needs to have a full Product Information File readily available to public authorities, therefore placing greater responsibility on the manufacturer in regards to the ingredients and make-up of each cosmetics product. The regulations also clearly state that sampling and analysis of cosmetics products during the manufacturing process must be

done in a standardised and reproducible manner to ensure the control of all restricted substances as detailed within the Product Information File. This applies both within companies and within the market. A Europe-wide notification method for all cosmetics products on the market, which is a requirement before market entry is also in the process of being introduced. This replaces any notification schemes currently in operation within the individual countries of the region.

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**A 'RESPONSIBLE PERSON' GUARANTEES COMPLIANCE WITH ALL SAFETY AND LABELLING REQUIREMENTS.**

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## V. US COSMETICS REGULATIONS

The United States requires that any cosmetics comply with the 'Cosmetics Safety Amendments Act of 2012'. This legislation was introduced to strengthen and modernise the previous Federal Food, Drug and Cosmetic Act (FD&C Act, March 2005) and the Fair Packaging and Labelling Act (FPLA, August 1992) giving the Food & Drug Administration a greater role in assessing the safety of personal care products.

With the 2012 regulation, all manufacturers marketing products in the US have to register their facilities, file and report on their cosmetics ingredients and prepare adverse event reporting. Compliance with each of these key areas provides greater transparency and gives the FDA a formal process through which to review ingredients for safety, demand safety

levels for impurities and to achieve national uniformity for cosmetics regulations. Part of this comes from setting industry-wide GMP, along with ensuring the best processes are in place to engage the Cosmetic Ingredient Review (CIR) Expert Panel of scientific and medical experts in assessing cosmetic ingredient safety.

The 2012 regulation also required a new set of Good Manufacturing Practice requirements to be drafted. These formed the basis for the June 2013 GMP requirements for US manufacturers.

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**AS OF 2012, THE FDA HAS A GREATER ROLE IN ASSESSING THE SAFETY OF COSMETICS AND PERSONAL CARE PRODUCTS.**

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## VI. CANADIAN COSMETICS REGULATIONS

The Canadian regulations relating to Cosmetics (C.R.C, c.869) form part of Canada's Food & Drugs Act and while they are stated as being current to 20 October, 2010, as yet there are no further updates in circulation. They cover cosmetics that are both manufactured and sold within Canada as well as those that are imported, both of which must adhere in full to the Act and regulations.

Inspectors carry out responsibilities in accordance with the regulations to ensure that cosmetics on the market are not illegal in any way. Strict requirements are detailed relating to the sampling the Inspector can carry out and what is required should a cosmetic product be made available for sale. As with the EU and US regulations, evidence of safety and exacting labelling

is central to the requirements. A manufacturer needs to be able to submit in writing at any time it is requested by the Department of Justice, evidence establishing the safety of a cosmetic under the recommended or normal conditions of use. If the manufacturer cannot supply this evidence when requested to do so they are no longer permitted to sell the product. There is also a notification required within the first 10 days that a product is brought to market. This has to be signed by the manufacturer, importer or an alternative specified person and has to provide the Department of Justice with the full information required, as detailed in the regulations. Under ICCR it was decided to adopt ISO 22716 as guidance documentation for the industry sector.

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**FIRM EVIDENCE OF SAFETY AND EXACTING LABELLING IS CENTRAL TO THE REQUIREMENTS.**

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## VII. JAPANESE COSMETICS REGULATIONS

The Japanese Pharmaceutical Affairs Act of 1948 and all its subsequent revisions include articles that regulate cosmetics products.

Japan separates cosmetics from 'quasi drugs', which the EU, US and Canada would still consider under the heading of cosmetics. Quasi drugs are products that have a mild effect on the body which fall between pharmaceuticals and cosmetics. Due to this Japanese Law requires them to be treated differently.

The Law in Japan was relaxed in April 2001, since this date pre-approval of cosmetics being brought to the market has not been needed if they meet the requirements of the negative list system and the full ingredients labelling system. In these instances, notification is sufficient. Both products manufactured

in Japan and imported need to be fully notified before they are on the market. This does not apply to products that are quasi drugs or to those that do not meet the full labelling specifications. For any cosmetic that requires authorisation the assessment and granting of this is done by the Prefectural government. Companies manufacturing cosmetics have to meet certain quality and safety criteria, and support this with an appropriately skilled workforce as detailed in the regulations for any cosmetics product on the market. Under the International Cooperation on Cosmetics Regulation (ICCR), it was decided that the ISO 22716 document would be adopted as GMP guidance for the cosmetics industry sector and as such Japan follows this standard.

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**PRE-APPROVAL OF COSMETICS IS NOT NEEDED IN JAPAN IF THE NEGATIVE LIST SYSTEM AND THE FULL INGREDIENTS LABELLING SYSTEM REQUIREMENTS ARE MET.**

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## VIII. KOREAN COSMETICS REGULATIONS

The Ministry of Food and Drug Safety (MFDS) is also responsible for the Cosmetics and Personal care sector under a number of Directives. In this regard they take control of the risk profile of the products, hazardous substance criteria, label information, test methods, and GMP qualification of manufacturing sites. Product launches need to be registered and manufacturers need to take notice of the Cosmetic Ingredient Database for forbidden substances. For substances that are not listed in this database additional testing

is required, for example toxicology testing, mutagenicity testing, etc. All products are registered and product performance has to be reported to the MFDS annually.

The Korean MFDS Cosmetics GMP is benchmarked against ISO 22716 and while adherence to it is not currently mandatory across all products, it is expected to be in the near future to support the recognition of the standard of Korean manufactured products within other markets.

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**MANUFACTURERS MUST CHECK THE COSMETIC INGREDIENTS DATABASE FOR FORBIDDEN SUBSTANCES.**

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# IX. TAIWANESE COSMETICS REGULATIONS

The Taiwan Food and Drug Administration (TFDA) is the government body responsible for cosmetics regulation. Certification against the Cosmetic GMP Standard, which is based on the ISO 22716, is voluntary. To date, 34 factories have been assessed by the TFDA and awarded the certificate.

Over the coming years, the TFDA is planning to build a Product Information File (PIF) and registration platform; develop coverage for the CNS 22716 standard; and build a cosmetics GMP programme to as a compulsory scheme for manufacturers.

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**IN TAIWAN,  
CERTIFICATION  
AGAINST THE  
COSMETIC GMP  
STANDARD IS  
VOLUNTARY.**

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# X. THE COMPONENTS OF ISO 22716

ISO 22716 deals with all aspects of the supply chain of cosmetic products, from the early delivery of raw materials and components until the shipment of the final product to the consumer. The guidelines support those organisations that wish to follow the practical advices to manage their human, technical, and administrative sections that are affecting product quality. Good Manufacturing Practices follow the principles of sound scientific judgement and risk assessment to produce products that meet defined characteristics.

## Broad Scope for ISO 22716

ISO 22716 gives guidelines for the production, control, storage and shipment of cosmetic products. These guidelines cover the quality and safety aspects of the product. In this way manufacturers of cosmetic final products are affected, as are the suppliers of cosmetic ingredients. In addition, the standard is relevant for retailers, brand holders and wholesalers of cosmetic products striving to enhance the overall quality performance of their third party suppliers, but excludes distributors. Furthermore, it specifies general requirements for quality management systems by incorporating a risk assessment based approach to define critical and non-critical elements ensuring high quality supply chain operations.

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**ISO 22716 PROVIDES PRODUCTION, CONTROL, STORAGE AND SHIPMENT QUALITY GUIDELINES.**

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## Consistent Terminology

In an effort to reach and maintain consistency and encourage the use of common terminology, the ISO 22716 terms and definitions section contains a set 36 definitions that are specific to their application. The rationale behind the definition section is to provide clarity of terminology and promote the use of a common language.

## CORE ELEMENTS

ISO 22716 can be thought of as being composed of five core elements:

- The cosmetics quality management system and organisation
- Premises and equipment
- Product realisation and materials management
- Deviations, complaints and recalls
- Continuous improvement

## The Cosmetics Quality Management System and Organisation

In a cosmetics GMP quality management organisation, the emphasis is on establishing and maintaining a qualified personnel base that is well trained and capable of consistently producing safe products. A sound knowledge base of the personnel in a cosmetics manufacturing organisation is of the utmost importance and this area is receiving serious attention in quality guidance. Another crucial element is a clear description of tasks and lines of responsibilities of all personnel in the organisation. Furthermore, setting up effective internal and external communication channels has to be the top priority of management to ensure the participation and commitment of personnel at all levels of the organisation. All these and other aspects of the quality organisation need to be established in formal writing – a controlled documentation system is therefore an intrinsic part of organisations working under ISO 22716.

## IN PRACTICE

### THE INDEPENDENCE OF THE QUALITY UNIT FROM THE MANUFACTURING UNIT NEEDS TO BE ESTABLISHED AND DOCUMENTED

The Quality unit of an organisation needs to be independent in its decision making process from the Manufacturing/Operations unit. This can be established through organisational charts: both the Quality unit and the Manufacturing/Operations units need to report to the senior management of the site. The organisational chart needs to be a unique (version controlled) document and be signed and dated by senior management. Individual job descriptions of the Head of Quality and the Head of Manufacturing/Operations need to be published and also signed by their respective managers. The job description of the Head of Quality needs to contain clear references to the responsibilities and authority of quality issues: to release product; move product to a different quality status (e.g., quarantine, release, rejected); deviation control and investigation; change control; and internal audit among other responsibilities.

## Premises and Equipment

Proper design of areas for manufacturing, storage, quality control, and others is a key element and well described in the standard. Areas should fit to their purpose to allow for proper access and flow of materials. Clear segregation of manufacturing and storage activities, and proper cleaning and sanitisation are important to avoid the occurrence of mix-ups and (cross-) contamination. Scheduled maintenance of premises and equipment and frequent calibration of monitoring devices have to be organised in the facilities in order to perform tasks according to defined and pre-set parameters of manufacturing, packaging, and storage. Within all of these aspects the quality unit of the organisation needs to be heavily involved to approve and evaluate all changes that occur and allow for an objective overview of results obtained.

## Product Realisation and Materials Management

The organisation working under ISO 22716 has to set criteria for quality during the different stages of manufacturing, like specifications for purchased raw materials, components and packaging materials. Furthermore, it should establish the criteria for in process checks and release parameters of starting materials, intermediates (also called cosmetic ingredients) and finished products. It is important that these characteristics are strictly followed with a clear designation of the quality status of these materials during the entire supply chain of operations. In this regard it is important to note that contractors, like third party transporters and packaging units, have to be included in the quality efforts of the organisation. Applying changes in the quality status of starting materials and (intermediate) products are the responsibilities of the Quality Unit solely, and for this reason this unit needs to be fully integrated in the operational activities of the organisation.

## IN PRACTICE

### **RESPONSIBILITIES OF ALL PERSONNEL FOR MANUFACTURING AND QUALITY SHOULD BE DEFINED**

The management of the organisation should support and encourage the qualification for GMP in the organisation. This is usually accomplished by setting quality KPIs that are regularly reviewed and updated. Management review is a frequently occurring activity in GMP compliant facilities demonstrating the commitment from management that their intent to improve the quality behaviour of the organisation is a serious matter. Responsibilities for all personnel should be clearly defined, i.e. within written job descriptions. This is particularly relevant to those that are active in manufacturing and quality control laboratories. Personnel in those facilities are encouraged to report any irregularity from normal processing to allow for swift action in case of deviations.

## IN PRACTICE

### **CRITERIA FOR THE SELECTION OF SUPPLIERS OF RAW MATERIALS, COMPONENTS AND PACKAGING MATERIALS MUST NOT BE SOLELY BASED ON COMMERCIAL TERMS**

Under a Good Manufacturing Practices regime, the selection of suppliers of raw materials and all other components and supplies used for the manufacturing of cosmetic products needs to be done following written and approved procedures as defined by the organisation, following clear pre-defined quality guidance. Based upon this procedure a once approved supplier cannot change on financial terms but needs to go through a similar qualification programme as set earlier for the original supplier (following a formal quality change control programme). The organisation needs to have a written, controlled and quality-approved list of approved suppliers and vendors.

## IN PRACTICE

### **METHOD OF RE-PROCESSING OF PRODUCT NEEDS TO BE DEFINED AND WRITTEN DOWN.**

Re-processing is done by organisations when the regular and defined method does not yield the expected result. Re-processing can involve all the different steps included in the supply chain of operations, including manufacturing, packaging, storage and transportation. Re-processing needs to follow pre-defined and pre-established steps. For example an ISO 22716 organisation must determine the appropriate steps to take before applying for re-processing. In other words, the organisation has to develop criteria for when it permits re-processing and when it does not. These pre-defined and pre-established steps need to be laid down in controlled and documented procedures, and the actual re-processing steps need to be tracked and traced in Batch Manufacturing Records.

## IN PRACTICE

### **PROPER EVALUATION AND AUDITS OF SUB-CONTRACTORS AND SUPPLIERS HAVE TO BE ORGANISED.**

The organisation working under GMP following ISO 22716 needs to have a vendor or sub-contractor qualification programme in place. This qualification process involves the initial qualification of a vendor or sub-contractor in order to compile a list of approved vendors and sub-contractors. In addition, this programme requires that organisations from time to time need to re-assess their vendors and sub-contractors. Based upon risk assessment this can result in performing regular audits (high risk classification) or remote controls (low risk classification) of these third parties, for example via a questionnaire. The ISO 22716 organisation needs to be able to present an appropriate risk based approach for their third party qualification programme.

### Deviations, Complaints and Recalls

Each organisation needs to have a system in place to deal with deviations occurring anywhere in the supply chain of operations. These deviations can have multiple origins and occur internally but also arise externally, for example during transportation to a customer organisation. These customer organisations need to have the ability to raise complaints if necessary and the organisation working under an ISO 22716 quality regime should investigate these complaints until a satisfactory solution has been found and communicated to the customer. In case of serious quality deviations posing a serious threat to consumer health and safety the organisation needs to be able to coordinate an effective recall of the product or products.

### Continuous Improvement

GMP is a quality system making use of state-of-the-art organisational aspects relevant for the cosmetics industry. For that reason organisations need to be aware of the current practices in their field and have to aim for continuous quality improvement in their operations and throughout their supply chain. The auditing process is the ultimate tool to accomplish this. The internal audit is an intrinsic part of Cosmetics GMP in which non-conformities are documented, evaluated, resolved and prevented from future recurrence. An optimal auditing system is the basis for an effective Corrective Action / Preventive Action (CAPA) planning.



# XI. GLOBAL SOLUTIONS FOR ENSURING THE SAFETY OF COSMETIC PRODUCTS

## WHY ISO 22716?

ISO 22716 is a comprehensive cosmetic safety management systems standard, because it:

- Integrates the typical requirements for product and process quality Good Manufacturing Practices requirements with other quality guidance, for example as laid down in the pre-requisites for ISO 9001

- Allows for easy implementation in organisations of all sizes and levels of complexity
- Forms an internationally accepted basis for quality and safety compliance in the cosmetic products supply chain
- Fosters legal compliance as adopted by regulators around the world
- Controls and reduces cosmetic products hazards and promotes continuous improvement throughout the supply chain

**ISO 22716 INTEGRATES GOOD MANUFACTURING PRACTICES REQUIREMENTS WITH OTHER QUALITY GUIDANCE.**

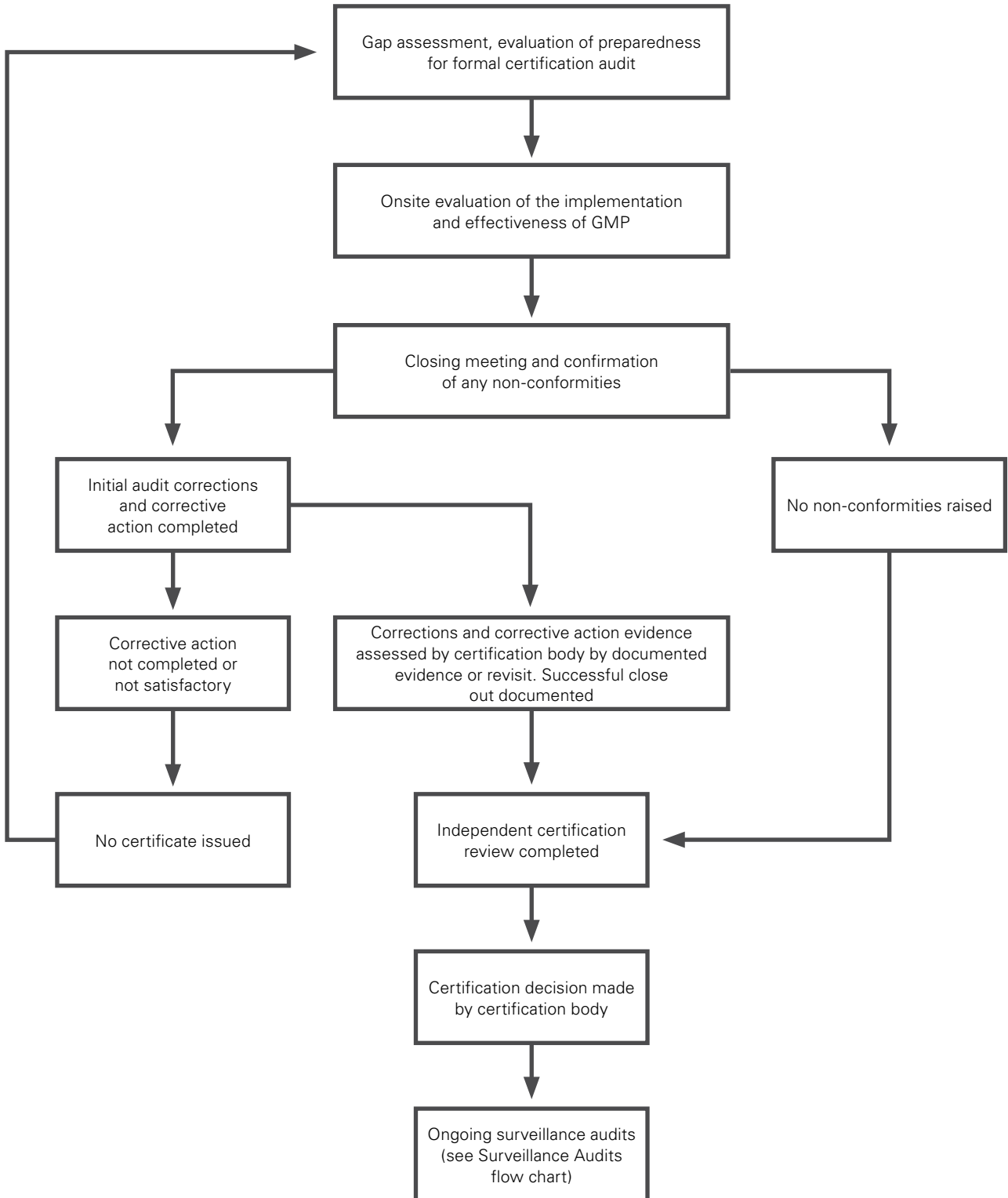
## COSMETIC QUALITY AND SAFETY REQUIREMENTS BY INTERNATIONAL PRODUCT SAFETY STANDARDS

QUALITY AND SAFETY REQUIREMENT	ISO 22716:2007	US FDA (2013)	ASEAN (2003)	BRC CONSUMER PRODUCTS (2010)*
The Cosmetics Quality Management System and Organisation	Clauses 3, 9, 15, 17	Included	Clauses 1, 2, 7, 8	Clauses 1, 2, 4, 5, 6
Premises and Equipment	Clauses 4, 5	Included	Clause 3, 4	Clause 3
Product Realisation and Materials Management	Clauses 6, 7, 8, 11, 12	Included	Clauses 5, 6, 10, 11	Clauses 3, 4
Deviations, Complaints and Recalls	Clauses 10, 13, 14	Included	Clause 12, 13	Clause 2
Continuous Improvement	Clause 16	Not included	Clause 9	Clause 2

\* The BRC Global Standard for Consumer Products from 2010 is not a true standard for cosmetic products, but was utilised in cases where a reliable alternative was missing.

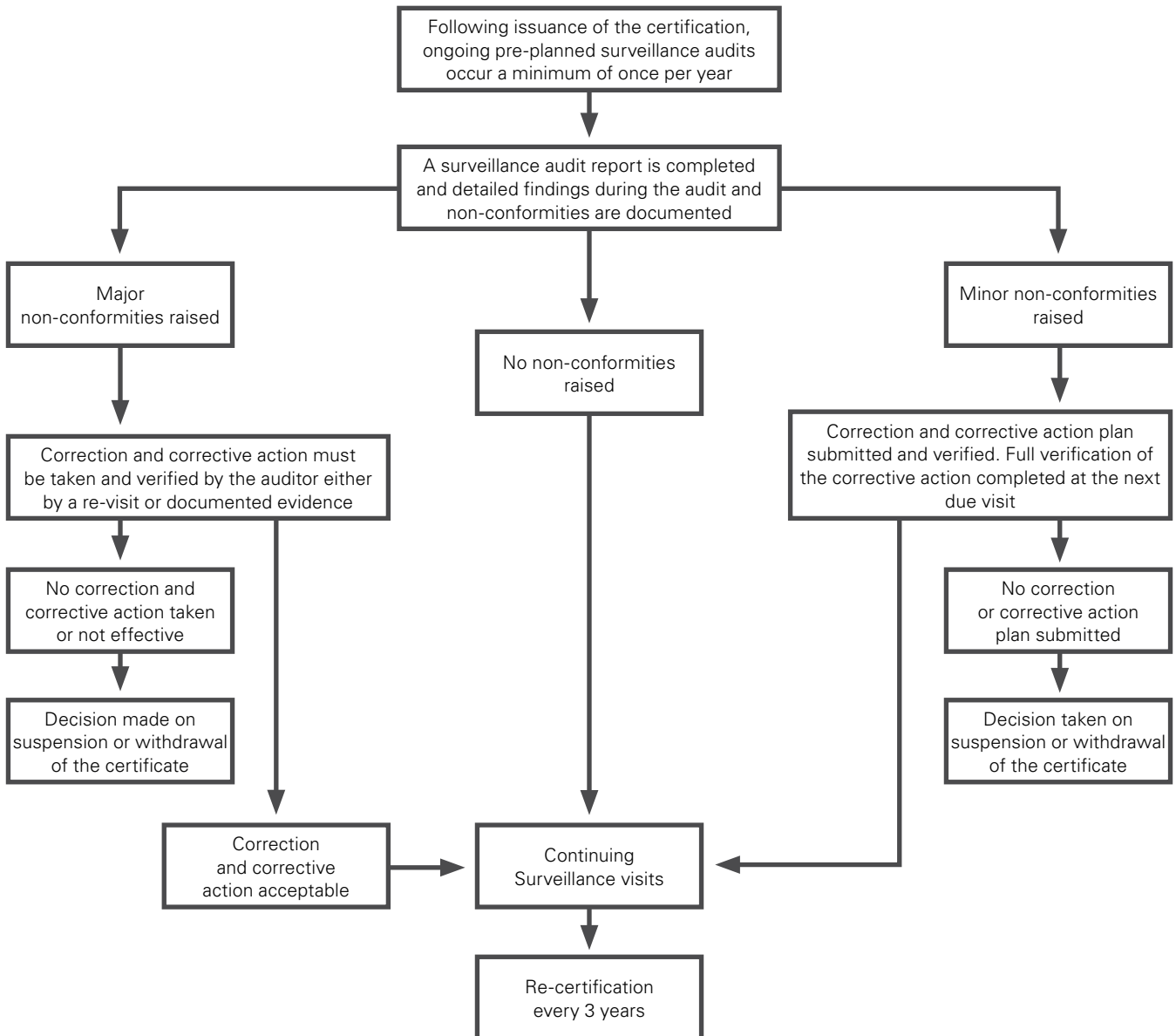
### AUDITING AGAINST ISO 22716

The audit process for ISO 22716 is based upon the ISO 9001 framework and runs on a three-year cycle.



## SURVEILLANCE AUDITS FOR ISO 22716

To ensure continuous improvement, a series of surveillance audits are scheduled, with a minimum of one per year.



### MOVING TOWARDS ISO 22716 CERTIFICATION

Organisations with an existing quality management programme can incorporate the elements of ISO 22716 into their existing quality management system by using a step-by-step approach to achieving compliance with global cosmetic GMP principles.

An organisation with any of the existing cosmetic quality programmes discussed here can build on its existing platform and seamlessly transition to ISO 22716. The ISO 22716 Standard combines general principles of quality management in organisations with the typical elements of cosmetic product GMP with a risk management based approach.

**ORGANISATIONS WITH EXISTING QUALITY MANAGEMENT PROGRAMMES CAN INCORPORATE ISO 22716.**



# XII. AUDITS AGAINST CUSTOMER-SPECIFIC CRITERIA

Audits can be performed against specific, customised criteria for all industries within the global supply chain to verify an organisation’s ability to meet quality, consumer safety, environmental, occupational health and safety standards, social responsibility and/or legal requirements. These include:

- Supplier/Vendor/Co-packer/Licensee Assessments: by monitoring the adherence of suppliers to an organisation’s requirements and/or contractual agreements, products can be verified as meeting quality, consumer safety, environmental, occupational and/or social responsibility requirements, preserving brand equity and company values throughout the supply chain

- Auditing against an organisations Code of Practice: by monitoring the compliance of an organisation’s network with the values and procedures defined in its Code of Practice, an organisation can ensure its brand is protected and practices remain consistent throughout its network

How does the process work?

Second Party Audit Programmes are tailored to suit the particular requirements of an organisation. A programme typically consists of a series of steps:

- Step A - Defining an audit programme, which transforms an organisation’s needs into a checklist of criteria based on the level of control it wishes to

have internally and over partners. This includes analysing opportunities to foster continuous improvement of systems and the performance criteria to better meet customer requirements

- Step B - Conducting the audit. This can be done both off site and/ or on site based on agreed audit requirements as in Step A. Auditors follow the audit protocol as per the agreement
- Step C - On completion of the audit, an audit report is provided and submitted for technical review and approval prior to sending to all relevant parties as per contractual requirements
- Step D - Ongoing monitoring audits are performed as per the agreement

## PROCESS FOR AUDITS WITH CUSTOMER-SPECIFIC CRITERIA



# XIII. CONCLUSION

ISO 22716 combines the benefits of a business management tool linking cosmetics quality and business processes with the ability to meet growing global legal and customer requirements for safe cosmetic products. Specifically, this globally recognised Standard addresses and responds to international laws for cosmetic Good Manufacturing Practice. It has gained worldwide support through the International Cooperation on Cosmetic Regulation (ICCR) regions of the European Union, US, Canada and Japan and as such has led to adaptations of their own home-grown standards and guidance as it ties in so effectively with their legislation. ISO 22716 demands that organisations define their processes and demonstrate consistent control over identified hazards, updating and improving systems to adapt to changes in processes. It provides real value to an organisation irrespective of its size and complexity. It levels the playing field for customers and suppliers throughout the supply chain and around the world.

## ABOUT THE AUTHOR

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Eize de Boer is responsible for the worldwide project management of our second and third party auditing programmes. The purpose of these programmes is to support SGS' service offering to organisations within and associated with the cosmetics industry. These programmes emphasise quality management systems following the principles of Good Manufacturing Practices.

He has over 20 years of experience in Good Manufacturing Practices quality assurance systems obtained from working in product development, manufacturing and quality assurance. He holds a PhD degree in biochemistry from the University of Amsterdam.

## ABOUT SGS

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognised as the global benchmark for quality and integrity. With more than 80 000 employees, SGS operates a network of over 1 650 offices and laboratories around the world.

We help customers all over the world operate in a more sustainable manner by improving quality and productivity, reducing risk, verifying compliance and increasing speed to market. We provide manufacturers, distributors and suppliers of cosmetics products with solutions in all aspects of product quality assurance and quality control. Our auditors know the characteristics of your products and are able to apply this knowledge during the assessment of the quality management systems to all of the critical steps, from the

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## ISO 22716 ADDRESSES INTERNATIONAL LAWS FOR COSMETICS GOOD MANUFACTURING PRACTICE.

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acceptation of the raw material until the release, shipment and distribution of the products. Our laboratories offer integrated customer-specific solutions for safety compliance and can assist you in controlling the quality of your products, including its raw materials and packaging, and in complying with regulations applicable to your industry.

**FOR MORE INFORMATION, VISIT  
[WWW.SGS.COM/COSMETICSGMP](http://WWW.SGS.COM/COSMETICSGMP)  
OR EMAIL [COSMETICS@SGS.COM](mailto:COSMETICS@SGS.COM)**

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