



ISO 22716

**COSMETICS – GOOD MANUFACTURING PRACTICES (GMP)
– GUIDELINES**

SGS



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Why ISO 22716?

The safety of cosmetic products is often on the minds of manufacturers, suppliers, regulators and consumers.

What is ISO 22716?

ISO 22716 provides guidance on Good Manufacturing Practices (GMP) for cosmetic products.

It also constitutes the practical development of the quality assurance concept. It does this by offering advice on managing factors that could impact product quality to organizations of all sizes and complexity, from receipt to shipment, including production and storage.

Key benefits

Certification follows successful completion of an audit and allows:

- Your organization to identify and control the human, technical and administrative factors that can affect product quality, thus reducing risk
- Essential quality assurance elements to be implemented and maintained, in a continuous improvement process
- GMP elements to be integrated with other standards, such as ISO 9001
- You to demonstrate the adoption of essential GMP relating to cosmetic activities

Align with the UN Sustainable Development Goals
Implementing ISO 22716 can contribute to:



Terminology, elements & adoption status

ISO 22716 is the global reference for regulatory and supply chain compliance in the cosmetics industry. It has been incorporated into, referenced or endorsed by many cosmetics regulations across the world.

Consistent terminology

To reach and maintain consistency and encourage common terminology, ISO 22716 has 36 definitions specific to its application.

Five core elements

The guidelines essentially have five core elements:

- The cosmetics Quality Management System (QMS) and organization
- Premises and equipment
- Product realization and materials management
- Deviations, complaints and recalls
- Continuous improvement

COUNTRY/REGION	ISO 22716 ADOPTION STATUS
US	Incorporated in revised FDA guidance
EU	Referenced as GMP compliance standard (1223/2009)
Japan	Adopted by Japan Cosmetic Industry Association
ASEAN (Indonesia, Malaysia, Philippines, Singapore, Thailand, Brunei, Cambodia, Laos, Myanmar & Vietnam)	Acknowledged as equivalent to ASEAN cosmetics GMP
Canada	Endorsed as a voluntary standard
Brazil	Regulation RDC 48/2013 is based on ISO 22716, with additional requirements



Pinpointing the pain points

Over the years, numerous regional and international standards have aimed to enhance cosmetic product quality and safety, many specifically addressing manufacturer, supplier, wholesaler and retailer requirements.

Main pain points

Each standard or set of guidelines have their own problems that must be overcome if you want to achieve the greatest benefits. Here are some key pain points to consider early on:

- Understanding the requirements
- The independence of the quality unit from the manufacturing units
- Clarification of responsibilities of all personnel for manufacturing and quality
- Supplier selection, evaluation and re-evaluation of raw materials, components and packaging materials
- Evaluation and audits of subcontractors and suppliers
- Reprocessing of products

Using our extensive experience of the pain points organizations face on the road to certification, we deliver a range of tailor-made services to support you every step of the way.



Moving toward ISO 22716 certification

Organizations with an existing cosmetic quality program(s) can incorporate ISO 22716 elements into it through a step-by-step approach, thus achieving compliance with global cosmetic GMP principles.

Key ISO 22716 elements

An organization with an existing cosmetic quality program(s) can build upon its existing platform to seamlessly transition to ISO 22716.

The guidelines combine general quality management principles and typical elements of cosmetic product GMP with a risk management-based approach, including:

- Personnel
- Premises
- Equipment
- Raw and packaging materials
- Production, including packaging and labeling
- Finished products
- Quality-control laboratory
- Treatment of a product that is out of specification
- Waste
- Subcontracting
- Deviations
- Complaints and recalls
- Change control
- Internal audit
- Documentation



Implementing ISO 22716

It is essential that ISO 22716 is implemented correctly to reap all of the rewards.

The guidelines cover all aspects of the cosmetic product supply chain, from raw materials to final product shipment.

Key implementation considerations

ISO 22716 supports organizations that wish to follow advice to manage the human, technical and administrative factors that affect product quality.

GMP follows the principles of sound scientific judgment and risk assessment to produce cosmetic products that meet defined characteristics.

You must consider:

- The quality unit to create an independent decision-making process from manufacturing/operations
- Management support and encouragement concerning GMP compliance
- Enabling manufacturing and quality-control laboratory staff to report irregularities to allow for swift action in case of deviations
- The selection of raw material suppliers and supplies used for manufacturing cosmetic products, following approved quality procedures
- Reprocessing that follows defined/established steps when regular and distinct methods do not yield the expected results
- Following ISO 22716 needs, so a supplier or subcontractor qualification program is in place
- Presenting an appropriate risk-based approach for a third-party qualification program

Audits against customer-specific criteria

Our audits can be customized for all industries within the global supply chain to verify an organization's ability to meet criteria, including quality, consumer safety and occupational health and safety.

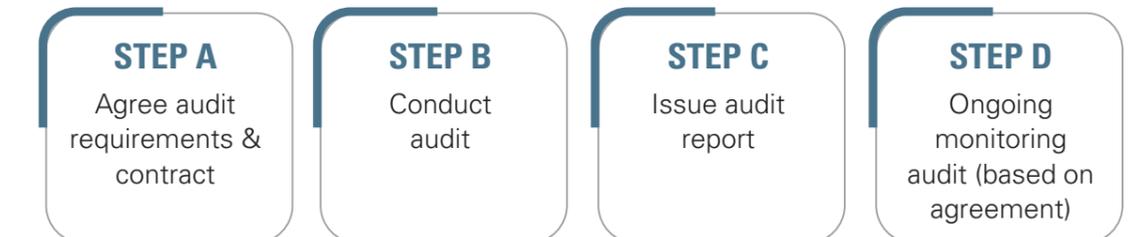
Covering suppliers & codes of practice

Supplier/vendor/co-packer/licensee assessments can monitor suppliers' adherence to your requirements and/or contractual agreements.

Products can also be verified as meeting quality, consumer safety, environmental, occupational and/or social responsibility requirements, protecting your brand and values.

Auditing against your code of practice can monitor your network's compliance with what is defined within it, ensuring brand protection and that practices remain consistent throughout the network.

The customer-specific audit process



A close-up photograph of a black cosmetic palette with numerous circular wells containing various shades of eyeshadow, including purples, pinks, oranges, and greys. Several makeup brushes with wooden handles and black bristles are scattered across the palette. The image is partially obscured by a dark blue diagonal shape on the right side.

Why our ISO 22716 services?

With expertise in all major industries, we help customers across the world to operate more sustainably by improving quality and productivity, reducing risk, verifying compliance and increasing speed to market.

What we offer

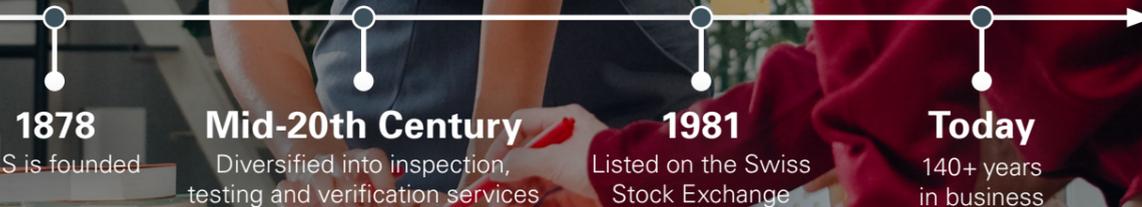
An audit against ISO 22716 from SGS will help your organization to stand out from the crowd by supporting your product quality assurance and control.

Our auditors know the characteristics of cosmetic products and can apply this to all critical steps during QMS assessment, from acceptance of raw materials to product distribution.

Our laboratories offer integrated customer-specific solutions for safety compliance and can assist you in controlling product quality, including its raw materials, packaging and compliance with cosmetics industry regulations.

About SGS

OUR HISTORY



About SGS

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognized as the global benchmark for quality and integrity. With more than 96,000 employees, SGS operates a network of over 2,600 offices and laboratories around the world. Enhancing products, processes, systems and skills is fundamental to your ongoing success and sustained growth. We enable you to continuously improve, transforming your products, services and value chain by increasing performance, managing risks, better meeting stakeholder requirements, and managing sustainability. With a global presence, we have a history of successfully executing large-scale, complex international projects. Our people speak the language, understand the culture of the local market and operate globally in a consistent, reliable and effective manner.

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WHEN YOU NEED TO BE SURE

