CTFA TECHNICAL GUIDELINES

# CTFA Quality Assurance Guidelines

CTFA
Cosmetic, Toiletry, and Fragrance Association

# CTFA Quality Assurance Guidelines

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# Foreword

The publication of *Technical Guidelines* as a resource for manufacturers in the development of quality control programs has been an important association activity for more than 35 years. The assurance of product quality is essential in the continual efforts of the cosmetics industry to manufacture and market products in a global setting. Through the initiatives of the CTFA's Quality Assurance Committee, we bring you this updated volume of work which provides voluntary guidelines for the development of a Quality Assurance (QA) system based on Good Manufacturing Practices (GMPs).

These guidelines are intended to illustrate the different approaches that manufacturers of cosmetics and personal care products might follow to implement the principles of Good Manufacturing Practices as described in the ISO Technical Committee 217 International Standard 22716:2007 — Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices. ISO Standard 22716 is included as a companion reference document with these guidelines. While these guidelines are intended to supplement ISO International Standard 22716, they are prepared from the perspective of product manufacturing and marketing in the United States and systems may be different in other jurisdictions.

These *CTFA Quality Assurance Guidelines* provide approaches that cosmetic manufacturers can use for establishing their good manufacturing practices and quality assurance programs. These Guidelines are not intended to be prescriptive in nature and are not intended to be implemented as standards. Individuals considering setting up QA and GMP systems must carefully assess their specific circumstances and adapt them as needed. Individuals using these Guidelines must also take into account any federal, state or local laws and regulations that may be applicable and ensure that they are complying with these requirements. Finally, these guidelines apply only to products that are defined as cosmetics according to applicable laws and regulations. In the United States, products that meet the legal definition for Over-The-Counter (OTC) drugs must follow the FDA GMP regulations that are described in 21 CFR Parts 210 and 211. The *CTFA Quality Assurance Guidelines* have been written for cosmetics, and therefore may not meet these regulatory requirements. Readers are referred to the applicable FDA regulations and guidance documents for these requirements.

CTFA's technical committees, staff, and public review by member and non-member companies, federal government agencies, and scientific professional societies. We are always open to suggestions, and to assist you in this regard, a comment form is provided at the end of the Introduction. The CTFA takes pride in the reputation the industry has earned for providing consumers with high quality products. We hope this publication will assist you in your mission to continue this achievement, as production in the 21st century increasingly requires a global perspective.

Pamela G. Bailey
President

John E. Bailey, Ph.D.
Executive Vice President – Science

# Acknowledgements

The *Guidelines* presented in this volume were developed by the CTFA's Quality Assurance Committee, with assistance from many members of the Scientific Advisory Committee. As the development and updating effort has been a continuing one, listing all of the experts involved from member companies would be beyond the capabilities of the current editors. Therefore, to the Quality Assurance Committee, and to all who had a part, a very warm and sincere thank you.

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# Introduction

Good Manufacturing Practices (GMPs) refer to a system designed to ensure that products are consistently produced according to quality standards with the goal of consumer safety and product acceptability. It is a term recognized worldwide for the management of quality and manufacturing.

The establishment, implementation, and enforcement of GMPs are essential elements in cosmetics manufacturing. GMPs encompass all aspects of production, from the premises and equipment to the training of staff. *The CTFA Quality Assurance Guidelines* provide a framework for establishing systems and procedures that are necessary to achieve a high level of product quality and avoid problems that could adversely affect the product.

Effective GMPs are predicated on a management that establishes the necessary systems to ensure attainment and maintenance of quality requirements, and drives plant-wide understanding of the principle that "quality is everyone's responsibility."

Responsibility for managing the quality assurance systems must be assigned to a quality person or organizational element that is appropriately independent and staffed with trained personnel. The responsibilities of the Quality Group should embrace all activities concerned with attainment and verification of required quality, particularly:

- Maintenance and control of documented good manufacturing practice systems, and performance of appropriate monitoring in order to ensure system compliance.
- Review and approval of specifications, manufacturing and control procedures, test methods, and all other documents that impact upon quality and GMP.
- Assurance of suitable inspection and testing to verify quality conformance.
- Quality disposition of raw materials, packaging materials, in-process materials, and finished products.
- Review of quality results, identification of problems, and pursuit of corrective action.
- Maintenance of quality records.

- Provision of documented systems and procedures that govern the appropriate elements set forth in these guidelines and any other requirements that may be needed due to local circumstances, laws, or regulations. Such documentation will help to ensure clear understanding, consistent performance, and long-term continuity.
- Periodic internal audits to verify consistent compliance with GMP systems, to confirm that the systems remain adequate for provision of safe and effective cosmetic products, and to highlight areas that may require improvement.

Comprehensive guidance for developing GMP programs is provided in *The CTFA Quality Assurance Guidelines*. This publication is intended to be a companion to the, Cosmetics – GMP – Guidelines on Good Manufacturing Practices (ISO 22716), developed by ISO/TC 217 of the International Organization for Standardization (ISO). The Guidelines contain 24 chapters developed to illustrate approaches to implementation of the principles described in ISO 22716. The Guideline chapters are referred to as "annexes" since they complement and embellish the concepts outlined in ISO 22716. *The CTFA Quality Assurance Guidelines* are strictly intended to be illustrative and constitute voluntary guidance for companies manufacturing cosmetics and personal care products. Furthermore, these Guidelines are not intended for products that have been designated as drugs or pharmaceuticals by regulatory agencies (for the U.S., see the definition of a cosmetic and drug in the Federal Food, Drug and Cosmetic Act: http://www.cfsan.fda.gov/~dms/cos-218.html). FDA's Current Good Manufacturing Practices (cGMP's) for Finished Pharmaceuticals may be found in Title 21, Code of Federal Regulations, Parts 210 and 211 available at the FDA website: http://www.fda.gov/cder/dmpq/.

# Comment Form

The CTFA values your suggestions and ideas for future publications of the *Quality Assurance Guidelines*. This form has been provided for your convenience. Please include any comments directly on this page and fax or mail it to:

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# Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices

*Cosmétiques — Bonnes Pratiques de Fabrication (BPF) — Lignes directrices relatives aux Bonnes Pratiques de Fabrication*

Reference number
ISO 22716:2007(E)

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 22716 was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

## Introduction

These guidelines are intended to provide guidance regarding Good Manufacturing Practices for cosmetic products. These guidelines have been prepared for consideration by the cosmetic industry and take into account the specific needs of this sector. These guidelines offer organizational and practical advice on the management of the human, technical and administrative factors affecting product quality.

These guidelines have been written to allow them to be used following the flow of products from receipt to shipment. Additionally, in order to clarify the way this document reaches its objectives, a 'principle' is added to each major section.

Good Manufacturing Practices constitute the practical development of the quality assurance concept through the description of the plant activities that are based on sound scientific judgement and risk assessments. The objective of these GMP guidelines is to define the activities that enable you to obtain a product that meets defined characteristics.

Documentation is an integral part of Good Manufacturing Practices.

# Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices

## 1 Scope

This International Standard gives guidelines for the production, control, storage and shipment of cosmetic products.

These guidelines cover the quality aspects of the product, but as a whole do not cover safety aspects for the personnel engaged in the plant, nor do they cover aspects of protection of the environment. Safety and environmental aspects are inherent responsibilities of the company and could be governed by local legislation and regulation.

These guidelines are not applicable to research and development activities and distribution of finished products.

## 2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

**2.1**
**acceptance criteria**
numerical limits, ranges, or other suitable measures for acceptance of test results

**2.2**
**audit**
systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable for achieving objectives

**2.3**
**batch**
defined quantity of raw material, packaging material or product issued from one process or series of processes so that it could be expected to be homogeneous

**2.4**
**batch number**
distinctive combination of numbers, letters and/or symbols, which specifically identifies a batch

**2.5**
**bulk product**
any product which has completed manufacturing stages up to, but not including, final packaging

**2.6**
**calibration**
set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard