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PERSONAL CARE PRODUCTS COUNCIL
TECHNICAL GUIDELINES

Quality Assurance Guidelines

Personal Care  Products Council
Committed to Safety,
Quality & Innovation

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**PERSONAL CARE PRODUCTS COUNCIL
TECHNICAL GUIDELINES**

Quality Assurance Guidelines

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The Personal Care Products Council

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Foreword

The *Technical Guidelines* has been an important industry resource for more than 35 years. Product quality assurance is essential to the cosmetics industry in their continual efforts to manufacture and market high quality products worldwide. Through the initiatives of the Council'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).

The *Quality Assurance Guidelines* are based on the principles described in the international standard, ISO 22716 Cosmetics – Good Manufacturing Practices (GMP) Guidelines which is included as a companion reference document in this publication. While the *Quality Assurance 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. The *Quality Assurance Guidelines* is non-binding and strictly intended to be one of the illustrative approaches which could be followed when implementing the GMP activities as described in ISO 22716 in the framework of voluntary guidance to cosmetic and personal care products manufacturers.

The *Quality Assurance Guidelines* provide a thorough approach to GMP, but are not intended to be prescriptive in nature, or to be implemented as standards. Quality professionals considering setting up QA and GMP systems must carefully assess their specific circumstances and adapt these Guidelines as appropriate. Companies 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 *Quality Assurance Guidelines* have been written specifically for cosmetics, and therefore may not meet regulatory requirements for other product classifications. Readers are referred to the applicable FDA regulations and guidance documents for these requirements.

The *Quality Assurance Guidelines* undergo thorough review by industry experts prior to publication. Suggestions for inclusion in future editions are welcome at any time. The Council takes pride in the reputation the industry has earned for providing consumers with safe, high quality products. We hope this publication will assist you in your quality programs as cosmetic production in the 21st century increasingly requires a global perspective with heightened awareness of product quality best practices.

Lezlee Westine
President & CEO

Beth Lange, Ph.D.
Executive Vice President - Science

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The *Guidelines* presented in this volume were developed by the Council's Quality Assurance Committee, with assistance from many members of the Council's Scientific and Regulatory Forum. The Council expresses its sincere appreciation to these experts, and their management who supported their participation in this important work. A special thank you is extended to Cathleen Owen (Knowlton Development Corporation), Steve Greer (Procter & Gamble), and Tim Parrent (Mary Kay) who served as chairpersons on the Quality Assurance Committee during the preparation of this edition. Their contributions and leadership are gratefully acknowledged.

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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 cosmetic and personal care product manufacturing. GMPs encompass all aspects of production, from the premises and equipment to the training of staff. The Council's *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 approach 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 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, trends, and pursuit of corrective action.
- Maintenance of quality records.

Two elements essential to an effective GMP program include:

- 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 the provision of safe and effective cosmetic products, and to highlight areas that may require improvement.

The *Quality Assurance Guidelines* is based on the principles described in the international standard, *ISO 22716 Cosmetics – GMP – Guidelines on Good Manufacturing Practices*, which is included for reference as a General Chapter. While the *Quality Assurance Guidelines* is modeled after ISO 22716, it is non-binding and strictly intended to be one of the illustrative approaches which could be followed when implementing the GMP activities as described in ISO 22716 in the framework of voluntary guidance to cosmetic and personal care products manufacturers.

The *Quality Assurance Guidelines* contains 24 chapters developed to illustrate approaches to the implementation of the principles described in ISO 22716. They are presented in the same order as the quality elements described in ISO 22716, and referred to as “annexes” since they complement and build on the ISO 22716 concepts. As an example, new to this edition the chapter on Consumer Complaints/Comments has been expanded to address criteria important to developing a system for handling adverse events.

Since publication of ISO 22716 in 2007, the global harmonization of GMPs for cosmetics has been an ongoing topic of discussion among various regulatory authorities. In 2007, the International Cooperation on Cosmetics Regulation (ICCR) was formed as a voluntary partnership among the health authorities of Canada, Europe, Japan and the U.S., with alignment of GMPs as a key priority. An outcome of ICCR was the adoption of ISO 22716 as a regulatory reference in the EU under Regulation (EC) No 1223/2009; and agreement to implement ISO 22716 as a voluntary guideline by Japan, Canada and the U.S. On June 24, 2013, the FDA updated their *2008 GMP Guidelines/Inspections Checklist with Guidance for Industry: Cosmetic Good Manufacturing Practices* which makes reference to ISO 22716.

With the worldwide acknowledgement of ISO 22716, coupled with the recent legislative activity in the U.S. calling for mandatory cosmetic GMPs; Regulation (EC) No 1223/2009 mandating GMPs for cosmetic products in the EU; and increased scrutiny of supply chain management from the public and private sectors, a trend has emerged for the independent evaluation of quality systems. To meet this need, the Council initiated a voluntary program called the Personal Care Products Manufacturing Assessment Program (PCMAP). PCMAP is based on a third-party independent assessment which companies may use to verify their internal manufacturing processes, the capabilities of their business partners such as ingredient and component suppliers, or the qualifications of contract manufacturers. The PCMAP checklist tool was developed as a collaborative effort by the Council’s Quality Assurance Committee, and is included for reference as an appendix in the *Quality Assurance Guidelines*.

The *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.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/default.htm>). 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.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm?cfrpart=210>, and <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm?cfrpart=211>.

INTERNATIONAL STANDARD

ISO 22716

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ISO 22716 INTERNATIONAL
STANDARD

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

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



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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