TECHNICAL REPORT

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Cosmetics — Good Manufacturing Practices — General training document

Cosmétiques — Bonnes pratiques de fabrication — Document général de formation

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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.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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/TR 24475 was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

Introduction

ISO 22716 was published in 2007. It is aimed at:

— guiding companies with regard to their manner of organizing and conducting the activities of a plant, so as to control the factors which may affect the quality of cosmetic products;

— reaching a common and harmonized perception between companies and authorities throughout the world;

— placing at their disposal a reference document which is recognised by everyone and consistent with the needs of globilzation of the markets.

This Technical Report has an educational purpose; it is aimed at encouraging a clearer understanding of the training needs of ISO 22716 within the context of the practical introduction of Good Manufacturing Practices. This Technical Report can be complemented by tools such as CD-ROMs illustrating Good Manufacturing Practices in the cosmetic field, which can be developed in each country/region and each company showing examples of practical scenarios, but under no circumstances can these be taken as recommendations or requirements.

Cosmetics — Good Manufacturing Practices — General training document

1 Scope

This Technical Report is aimed at contributing to the training of personnel in cosmetic production plants within the context of the introduction of Good Manufacturing Practices and therefore does not introduce additional requirements to ISO 22716.

It is intended to complement personal involvement and reasoning in the implementation of ISO 22716.

This Technical Report covers the quality aspects of the cosmetic product, but does not take into account safety aspects for the personnel, nor does it cover aspects of protection of the environment or those concerning the safety and efficacy of the finished products.

WARNING — This Technical Report cannot be used alone and needs as a prerequisite a good knowledge of ISO 22716 which is the reference document.

2 Personnel concerned

This Technical Report is intended for any managerial and non-managerial personnel, directly involved in the production, control, storage and shipment of cosmetic products in the plant [manufacturing, packaging, engineering, technical department, maintenance, receipt of the raw materials and packaging materials, storage, shipments, quality (Quality assurance, quality control laboratories, …) but also purchasing, logistics, administration, finance, management, human resources, cleaning personnel (contract acceptors of cleaning personnel included)].

Temporary staff should also be taken into account in this general training.

3 Content

3.1 Preliminary recommendations

ISO 22716 subdivides the Good Manufacturing Practices into 15 key activities which cannot be considered separately. Therefore, in order to facilitate the integration and the educational approach of these Good Manufacturing Practices, it is recommended to tackle them according to the following three major topics.

— Quality, comprised of:

  — quality principles;

  — quality control;

  — quality assurance and GMP.

— Justification for the existence of Good Manufacturing Practices (common data):

  — risks inherent to the production of cosmetic products;

  — elements common to the activities (personnel, premises, equipment, raw materials and packaging materials, documentation).

— Justification for the existence of Good Manufacturing Practices (specific data);

  — receipt and storage of the raw materials and packaging materials, sampling, release, manufacturing operations, packaging operations, quality control laboratory, storage and shipment of the finished products, out of specification products, wastes, subcontracting, change control, deviations, returns, complaints and recalls, document management, internal audit.

IMPORTANT — The content of the following paragraphs can be used for the training of personnel for example in presentations, courses, etc.

3.2 General considerations

The cosmetic industry is becoming increasingly complex due to the fact that the products face worldwide consumer demands and global competitiveness, which generate an obligation to meet international quality requirements.

As a consequence:

— the products are more and more complex and diverse;

— the technology implemented is becoming more sophisticated;

— the procedures tend to become more complicated;

— the economic burdens become greater.

Thus, the quality in producing the products becomes a key point of their success in the market.

It is also important to consider that the production process of cosmetic products corresponds to a complex chain where several people are involved and several processes are implemented.

In this context, the cosmetic companies look out for any potential problem and risk that can occur during the production process of their products:

— the risk of confusion that can result from the simultaneous handling of many raw materials, packaging materials, bulk products and finished products;

— the risk of errors that can result from the number of ingredients and components introduced during the formulation of the products;

— the risk of contamination, that can result from numerous movements involving the flow of persons, materials and products;

— the risk of deterioration that can result from the improper handling and transfers of materials and products;

— the risks resulting from all other types of handling errors, for example a poorly tightened seal after a maintenance operation or poor sealing of a container of raw materials after weighing;

— the risk in the management of returned products.

The risks mentioned above might also have a long-term impact on the cosmetic production site and on the brand, in terms of image and finances, not to mention the health and legal perspectives. All these considerations underline the need to implement a prevention policy shared by all and taking into account the management of all foreseeable potential risks.

The implementation of the activities described in the Good Manufacturing Practices can significantly reduce such potential risks.

3.3 Quality considerations

3.3.1 Quality principles

In the area of cosmetic products, the quality is defined as a set of characteristics, visible and non-visible, established by the researchers and the development laboratories and able to be reproduced consistently. This clearly defines in advance the characteristics which should correspond to the general requirements and specific needs according to the market sector.

3.3.2 Quality control

See 2.13 and 9.1.2 of ISO 22716:2007.

In ISO 22716, the quality control laboratory is responsible for verifying that the quality fulfills the required accepted defined criteria. But such controls alone cannot guarantee the quality of the production process.

This is why it remains necessary to rely on the processes implemented by the manufacturer, according to the procedures performed by trained personnel, based on Good Manufacturing Practices for cosmetic products, in order to guarantee that what is done is done well and that what will be done tomorrow will be identical to what is done today.

3.3.3 Quality assurance and GMP

See Introduction and 2.27 of ISO 22716:2007.

Quality assurance is defined as the set of necessary pre-established and systematic activities put in place to provide confidence that the products satisfy the accepted defined criteria.

GMPs constitute the practical development of the quality assurance concept, to reduce the risks, their occurrence and to manage problems that can occur while making sure that they do not re-occur.

3.3.4 The risks inherent to the production of cosmetic products

Even when all possible precautions are taken, every activity can still generate quality defects.

Some examples can be considered to illustrate deficiencies that may occur during the production process:

— referring to confusion: untidiness, non-observance of a product nomenclature, failure to follow labelling rules, incorrect separation of flows, improper assignment of tasks to workers, all leading to the risk of confusion, etc.;

— referring to omissions: forgetting a raw material, forgetting a stage in a procedure, forgetting to note something down, etc.;

— referring to contamination: presence in the product of undesirable chemical elements, hair left uncovered near a vessel, sneezing over an open container of raw material, handling with dirty hands, leaving outside doors and windows open, eating near open/uncovered containers, etc.;

— referring to deterioration: poor storage or transport conditions, lack of maintenance of a piece of equipment, etc.;

— referring to improper implementation of procedures, etc.;

— many other kinds of error may occur: poorly performed crimping control, erroneous choice of equipment or of raw material, etc.

All of these risks impact on the quality of the products with a strong negative repercussion for the brand's image.

3.4 The activities of Good Manufacturing Practices

3.4.1 Personnel

See Clause 3 of ISO 22716:2007.

The personnel represent a permanent source of potential errors and contaminations and therefore need to have undergone appropriate training in accordance with their level of responsibility. Such training has to be adapted to the level of experience acquired and therefore should be regularly updated, evaluated and documented. The training programme should be complemented by the hygiene programme. Personnel health should form part of the training programme thereby ensuring that personnel that are ill or have open lesions do not knowingly come into contact with the product. Visitors and untrained personnel should be given information in advance before they are allowed to enter production, control and storage areas.

Together with experience, training is the key to the skills: however, one cannot learn solely through experience, as the knowledge acquired through training helps to understand the reason for rules, to perfect the "how to do" and, lastly, to take initiatives more successfully to improve quality.

The implementation of GMPs remains the responsibility of the management, but their application requires the permanent participation and involvement of the personnel from all departments and at all levels.

3.4.2 Premises

See Clause 4 of ISO 22716:2007.

The premises should be designed or adapted to protect the product from contamination, whether of microbial, physical or chemical origin. The premises should be designed to prevent the intrusion of pests, such as insects, birds, rodents and others.

A programme to protect the premises against such pests should be implemented. For example it could consist of laying rodent traps or substances to attract and trap insects inside the premises. Outside the premises, measures should be taken to ensure that pests are not attracted or offered shelter.

The premises should also be well ventilated in a manner that does not allow outside contaminants to enter through any open windows or doors. Other solutions can be implemented as long as they arrive at the same result.

Clean and suitable washing and toilet facilities should be provided for personnel, in a differentiated location from, but accessible to production areas.

A cleaning programme and, if necessary, a sanitization programme should be available for all areas within the premises.

On an industrial site where hundreds of different products used for multiple activities are constantly circulating, the risk of errors of destination and accidental mixing is not to be underestimated. For this reason sufficient space is necessary to facilitate operations in the areas where these risks are significant, in particular at receipt, in storage, in manufacturing and in packaging. These areas should be clearly separated from each other or identified.

3.4.3 Equipment

See Clause 5 of ISO 22716:2007.

It should be possible to determine, at any time, what the equipment is, what is inside, what is the batch number. Therefore all equipment has to be correctly labelled and identifiable.

In order to ensure that a piece of equipment is used under optimum conditions, its conditions of use should be clearly defined and controlled by trained and authorized personnel. For example, and referring to the manufacturing or packaging parameters, the temperature, pressure, speed, duration, etc.

In the same way, the mixing vessel should be sealable in order to protect the product from dust and the surrounding humidity, the materials it is made of should not be able to interact with the product, or with the cleaning agents.

If there are ridges or unreachable corners, there is a risk of contamination of the previous manufacturing run mixing with the current batch.

Inaccurate directions for use of the equipment can directly affect the quality. For example, an excessive or an insufficient quantity of a given raw material, too slow a mixing speed or too high a temperature can result in the entire finished product losing the characteristics that give it its quality. Therefore, the equipment should be used as instructed and regularly maintained.

Such maintenance operations, both preventive and curative, should be documented. They are not to affect the quality of the products.

Similarly, defective equipment should be clearly identified and where possible isolated from the production circuit.

All equipment should have a specific cleaning programme and, if necessary, a sanitization programme, the methods and frequency of which should be specified along with the cleaning agents and means of sanitization.

The measuring instruments in the quality control laboratory as well as in the manufacturing and packaging areas should be calibrated regularly: the results are then recorded and any result out of the accepted defined criteria should be investigated.

In the event of the results being out of the accepted defined criteria, the measuring instrument concerned has to be identified, if possible corrected and if not possible then replaced.

3.4.4 Raw materials and packaging materials

See Clause 6 of ISO 22716:2007.

3.4.4.1 Principle

See Clause 6 and 6.5.3 of ISO 22716:2007.

All incoming raw materials and packaging materials should come from suppliers who have demonstrated that they are capable of guaranteeing the quality and regularity of the orders in accordance with the criteria defined by the manufacturer. The verification of such guarantees are to be controlled periodically.

However a control restricted to external supplies is not sufficient to ensure the quality of the finished product; it concerns also the raw materials produced, transformed or treated inside the production site.

For example, the characteristics of the water can easily change under the action of internal factors but also as a result of the installation itself. A poorly designed installation can encourage stagnation and thereby increase the risk of degradation and microbial contamination of the water. It is therefore necessary to implement a programme for the installation maintenance and the control of the quality of the water by means of tests or through a specific water production process.