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South African Bureau of Standards

Technical report

Cosmetics — Good Manufacturing Practices — General training document

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Change No.	Date	Scope

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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.

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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.

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— 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.

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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.;

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— 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.

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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.

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All raw materials and packaging materials should be controlled before their use. They may however be accepted on the basis of the supplier certificate of analysis but only under the specific conditions defined in ISO 22716.

3.4.4.2 Receipt and storage

See 6.3 and 6.6 of ISO 22716:2007.

Once ordered, raw materials and packaging materials are transported to the production site. A preliminary control should be made, for example by the reception on delivery, in order to ensure that their quality has not been compromised, for example by damage, cold, humidity, proximity to other products, etc., not to mention the possibility of confusion at the time of the order's preparation on the supplier premises.

It is therefore essential to verify concordance between the order, the delivery document and the product delivered.

The integrity of the packaging should also be the subject of a special check: a damaged container can possibly be the sign of contaminated goods.

In order to correctly identify the goods and to avoid all risk of confusion, labelling of the containers has to be carried out. The label should contain essential information such as the product name, as written on the delivery document and the packaging, an identification code, the receipt date, the supplier's name, the batch reference, etc.

The storage conditions should be defined in an appropriate manner according to the specific requirements of each raw material and packaging material, for example in a cold room.

If the raw materials or packaging materials are repackaged, the new containers should bear the same labelling as the original. For raw materials it is also important to use a container preferably made of the same substance as the original container or another compatible substance.

3.4.4.3 Release

See 6.5 of ISO 22716:2007.

A batch is released when the samples taken for this batch correspond to all of the accepted defined criteria.

A specific procedure has to be implemented for the raw materials and packaging materials in quarantine prohibiting their use until they have been released, whether they are stored in an area physically separated from the areas used for the storage of released products, or stored with the other products

Raw materials and packaging materials that have failed controls should be stored separately or in their respective physical locations or by using any other system providing the same level of assurance, awaiting the results of the investigation being carried out to determine their acceptability or rejection.

Lastly, where stock rotation is concerned, the first-in-first-out (FiFo) procedure should be used. Except in special circumstances, stock rotation should ensure that the oldest released stock is used first.

An appropriate system should be implemented to determine on a case-by-case basis the use by date of the raw materials.

3.4.5 Manufacturing operations

See 7.2 of ISO 22716:2007.

When a manufacturing run starts, three requirements are of concern: a manufacturing order, functional equipment and the availability of raw materials corresponding to the quality required to manufacture an adequate bulk product.

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In addition, it is necessary to have available all procedures to ensure that the quality is maintained during the whole process: the preparation and weighing of the raw materials, the return to stock of unused raw materials, the preparation of the manufacturing area, the actual manufacturing, the in-process controls, the transfer and storage of the bulk products and of course, the collection of the waste and the cleaning, and if necessary the sanitization of the area.

For example, the weighing process:

— weighing of the raw materials should take place in a clean environment, away from any draughts, using clean equipment and materials; everything relating to previous weighings should have been removed;

— in order to prevent weighing errors, the measuring equipment should be appropriate to the quantity to be measured and controlled regularly using specific standards;

— after weighing, the personnel should reseal the raw material containers correctly, whether these are containers of weighed materials or remaining materials;

— the containers of weighed raw materials should be labelled and clearly identified in order to avoid any confusion.

3.4.6 Packaging operations

See 7.3 of ISO 22716:2007.

For packaging, the principle is the same as for manufacturing: measures are to be taken to ensure that the finished product corresponds to the previously defined characteristics.

Before starting packaging, it is therefore necessary to ensure that a packaging order is available and the clearance of the area has been carried out. Such clearance of a packaging line is a delicate operation. The risk of omissions is significant. For example, it is easy to miss a bottle, a tube, a cap or printed material in a corner of a machine.

Consequently, the area clearance is to be carried out methodically, using appropriate techniques to avoid confusion and contamination.

The personnel should then refer to a checklist and note the actions carried out.

A batch number has to be allocated to each finished product. This batch number, depending on the procedures specific to the company, can be identical or different from that of the bulk product.

In-process controls should be carried out regularly, during packaging: control of mass, air tightness, stamping, etc.

If any results are out of the accepted-defined criteria they should be reported immediately for investigation and, possibly, to stop the operations in order, for example, to avoid the risk of loss of bulk product and packaging materials until implementation of corrective action(s).

At the end of packaging, the area clearance is to be carried out methodically using appropriate techniques to avoid confusion and contamination.

3.4.7 Finished products

See Clause 8 of ISO 22716:2007.

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3.4.7.1 Release

See 8.2 ISO 22716:2007.

The release of a batch of the finished product is carried out when the samples taken for this batch correspond to all of the accepted defined criteria.

A specific procedure has to be implemented for the products in quarantine prohibiting their use until they have been released, whether they are stored in an area physically separated from the areas used for the storage of released products, or stored with the other products.

Lastly, where stock rotation is concerned, except in special circumstances, the FiFo procedure should be used.

3.4.7.2 Storage and shipment of the finished products

See 8.3 of ISO 22716:2007.

All the necessary precautions should be taken to ensure that the storage of the finished products, whether released or not, is suitable to preserve their quality.

The same approaches as for the storage of raw materials and packaging materials apply: well-organized storage in defined and clean areas, released, rejected or quarantined products in specific areas, appropriate storage conditions, adequate storage duration, etc.

The containers should be correctly labelled, mentioning the product name, identification code and batch number in order to avoid any confusion or error. Shipping conditions, where appropriate, should be defined and monitored.

To summarise, the management of the store should guarantee that only the released products are shipped, allowing, except in special circumstances, a rotation that assures that the oldest released products are used first.

In addition, a periodic physical inventory should be performed to ensure the accuracy and acceptability of the stock.

3.4.7.3 Returns

See 8.5 of ISO 22716:2007.

The return of products to the plant does not necessarily result from the observation of a quality defect.

In all cases, however, they have to be identified and stored separately in a controlled area, their re-integration into the stock being under control of an authorized person.

3.4.8 Quality control laboratory

See Clause 9 of ISO 22716:2007.

3.4.8.1 Principles

See 9.1 to 9.6 of ISO 22716:2007.

The quality control laboratory has a central role in the GMP process. Therefore quality control personnel have to be trained, the premises and equipment are to be appropriate, the methods and tests are to be defined and records are to be kept.

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The quality control laboratory works on samples from each batch according to predetermined specifications and test methods. It should be borne in mind that the quality control laboratory can only find that for which it is looking.

Materials such as reagents, titration solutions, culture media, references or standards should meet predetermined criteria; whether purchased or prepared, they are to be recorded and labelled, from the time of their receipt, their opening or their preparation, considering for example, their name, dosage and expiry date if applicable.

The analyses performed by the quality control laboratory have to be precise and accurate, thus the personnel of the quality control laboratory should refer to established methods of analysis.

In other words, as it has already been mentioned, the quality control laboratory should be a link in constructing the quality assurance chain to which each activity and each individual contributes.

3.4.8.2 Sampling

See 9.7 and 9.8 of ISO 22716:2007.

Sampling is a key parameter in the quality control process since it checks and approves the raw materials and the packaging materials. Sampling should therefore be carried out by qualified and authorized personnel according to approved methods using specific equipment and ensuring that all precautions are taken to avoid risks of confusion, error and, of course, contamination.

The sampling equipment and the sample containers have to be suitable for the nature and quantity of the product being sampled and be correctly labelled.

When sampling, care should be taken to avoid subsequent contamination.

After use, the samples are stored with a view to possible further analysis and investigations.

Lastly, as in all operations linked to production, the information relating to the sampling is to be recorded.

3.4.9 Out of specification products

See Clause 10 of ISO 22716:2007.

The raw materials and packaging materials, bulk products and finished products are accepted when they meet all the accepted defined criteria. If this is not the case, they are referred to as “out of specification”.

The decision to destroy any raw material and packaging material or to return it to the supplier should be approved by the personnel responsible for quality.

If all or part of a batch of finished products does not correspond to the accepted defined criteria, a reprocessing may be done which is aimed at obtaining the defined quality. Such a reprocessing method should also be well defined, approved and controlled by the personnel responsible for quality.

3.4.10 Waste

See Clause 11 of ISO 22716:2007.

Waste should have specific procedures for collection, transfer, storage and destruction, including the labelling of the containers specifying the nature of the contents.

Even when the waste is correctly collected it remains necessary to check that it has been removed in its entirety, for example: no documents, no raw materials, no bulk product, no special equipment.

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3.4.11 Subcontracting

See Clause 12 of ISO 22716:2007.

Almost all the activities of a production plant can be subcontracted, from manufacturing and packaging to analysis or shipment.

Whatever the importance of the activity which is subcontracted, it is vital that the contract acceptor's process conforms to the GMPs.

This is why the obligations and responsibilities between the contract giver and the contract acceptor have to be clearly established and fixed within a document duly signed by both parties guaranteeing that the contract acceptors possess all the appropriate resources to fulfill the contract.

In addition periodic audits should be made in order to control that the guarantees initially given by the contract acceptor are still current.

3.4.12 Deviations

See Clause 13 of ISO 22716:2007.

A deviation consists of temporarily setting aside specified requirements due to an unforeseen circumstance. By definition, it should be temporary and such a decision should only be authorized in circumstances where sufficient data are available.

As a consequence it is essential to do whatever is necessary to ensure that the deviation will not re-occur and therefore to implement the necessary corrective actions.

Such a deviation should only be accepted on the basis of sufficient data to justify the decision.

3.4.13 Complaints and recalls

See Clause 14 of ISO 22716:2007.

A complaint generates a suspicion of non-conformity to the accepted defined criteria. However such a complaint has to be considered with care as it could be justified but not necessarily related to a quality defect.

Complaints should therefore be centralized by authorized personnel, documented and investigated to first assess their relevance. Then a decision regarding the future of the returned products and the implementation of possible corrective actions should be taken. The level of the decision has to be related to the seriousness of the defect observed.

The recall of a batch is fortunately exceptional but if needed, such an operation is to be initiated and treated rapidly and coordinated by authorized personnel.

The relevant authorities, as applicable, are to be informed of the recall when the defect can have an impact on consumer safety.

Even if not commonly used, the recall procedure should be evaluated periodically.

3.4.14 Change control

See Clause 15 of ISO 22716:2007.

A change consists of modifying, in an organized and foreseeable manner, one or other of the activities within the production process. This is the case, for example, when changing the supplier of a raw material, when modifying the formula of a product, when changing its packaging or when replacing major equipment.

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Whatever the change concerned, it needs to be planned, organized and controlled at all levels and should be authorized on the basis of sufficient data to justify the decision.

3.4.15 Internal audit

See Clause 16 of ISO 22716:2007.

Internal audits are of utmost importance to ensure that the GMPs conform to the expectations of the company regarding the quality of the products.

The audits have an integrating aspect, as they allow analysis of details. Not only the interaction between the components of the activities: personnel in relation to equipment, premises, documents, but also the interaction between the activities themselves: manufacturing in relation to packaging and to the quality control laboratory.

Such audits have to be organized in accordance with the capacity of the company. They can take place regularly or occasionally.

3.4.16 Documentation

See Clause 17 of ISO 22716:2007.

Documents are necessary in order to define what to do and how to do it, and later to record what has been done. Anything that is not written down has no value in the cosmetic industry as the basis of the control of activities according to GMPs, documents such as procedures, instructions, specifications, protocols and records are to be accessible to the personnel requiring them.

However, the management of the documents, namely their design, distribution, revision and archiving, is also a fully-fledged activity of the cosmetic production plant, and it is an activity that comes under GMPs.

To be usable, they are to be correctly produced and written. Therefore rules for the writing of documents should be specified, whatever they are: procedures, instructions, specifications, protocols or records. They should be drafted in a comprehensible manner, approved, signed and dated by authorized persons before being used. They should also be referenced in order to prevent obsolete documents being used and to facilitate their withdrawal.

When handwritten data are required, these documents should indicate what is to be entered, be written legibly with permanent ink, be signed and dated, be corrected if necessary while still permitting the original text to be read and, where applicable, the reason for the correction is to be recorded.

It is likely that the documents, except filled-in records, can and have to be revised. A document update, whatever the change made, is accompanied by a revision number. The reasons for successive updates should be kept and documented.

Lastly, as the documents retrace a history of the activities and of the application of GMPs in the production plant, it is necessary to archive them, or at least their originals, in either paper or electronic form in a safe place.

The archiving duration should meet the applicable current legislation and regulations.

Documents are referenced in order to guarantee that obsolete ones are not used. Obsolete documents are to be withdrawn from the work areas and original documents should be archived in a secure manner.

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4 Conclusion

ISO 22716 constitutes a guideline for the activities that it is appropriate to implement.

Observance of GMPs enables one to guarantee and to prove that the day-to-day reality meets the expectations in terms of quality.

The observance of GMPs commits not only the cosmetic company as a whole but also and directly each member of the staff.

Each one has to arm themself to achieve these objectives; one of the resources available is permanent training, of which this training document forms part.

Each one should understand practical training supported by a permanent reference to the ISO 22716 guidance is essential to respect the finality of the cosmetic GMPs.

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