GMP GUIDE

FOR

COSMETIC INGREDIENTS

Including the Certification Standard and Scheme for GMP for Cosmetic Ingredients

Revision 2012

FOREWORD

The quality of cosmetic ingredients is critical to assure the safety, quality and efficacy of cosmetic products and related personal care products. Cosmetic ingredients have a wide range of applications and are essential components of the cosmetic product formulation. Therefore, applying appropriate good manufacturing practice (GMP) principles to cosmetic ingredients is essential.

EFfCI is a European trade association representing the chemical and natural ingredient industries, the suppliers and service providers for the cosmetic industries. EFfCI was set up in 2000 to represent the collective interests of more than 100 cosmetic ingredient companies in Europe.

The idea underlying this EFfCI GMP Guide for Cosmetic Ingredients is to provide manufacturers with a tool for implementing an appropriate and workable GMP system.

The authors would very much appreciate comments as input in the further development of this EFfCI GMP Guide.

This is the third printing of this guide following the successful introduction in 2005 and updated with details of the certification scheme and standard in 2008. At this point the three new appendices were added. These appendices set out the requirements for obtaining certification according to the guide by an independent assessment body when organizations already hold ISO 9001 certification.

- Appendix D details the further requirements in addition to those in ISO 9001.
- Appendix E provides details of how the GMP certifiable scheme shall be administered.
- Appendix F provides guidance on the criteria for auditor training so that they are competent to assess organizations against the requirements of the certifiable annex to ISO 9001.

These additions will allow cosmetic ingredient suppliers to provide independent certification in order to show that their products have been prepared in accordance with the EFfCI GMP Guide.

With the publication of ISO 9001:2008 this guide and the Certification Standard were updated and fully aligned with the updated ISO standard in 2010. Texts have been adapted and highlighted to aid review and implementation.

This ensures that the EFfCI GMP Guide reflects the most recent version of the standard ISO 9001.

The 2012 version has been created in collaboration with the French cosmetic manufacturing association, FEBEA and opportunity has been taken to introduce quality risk management approaches to aid the implementation of suitable GMP principles to chemical synthesis and related manufacturing processes.

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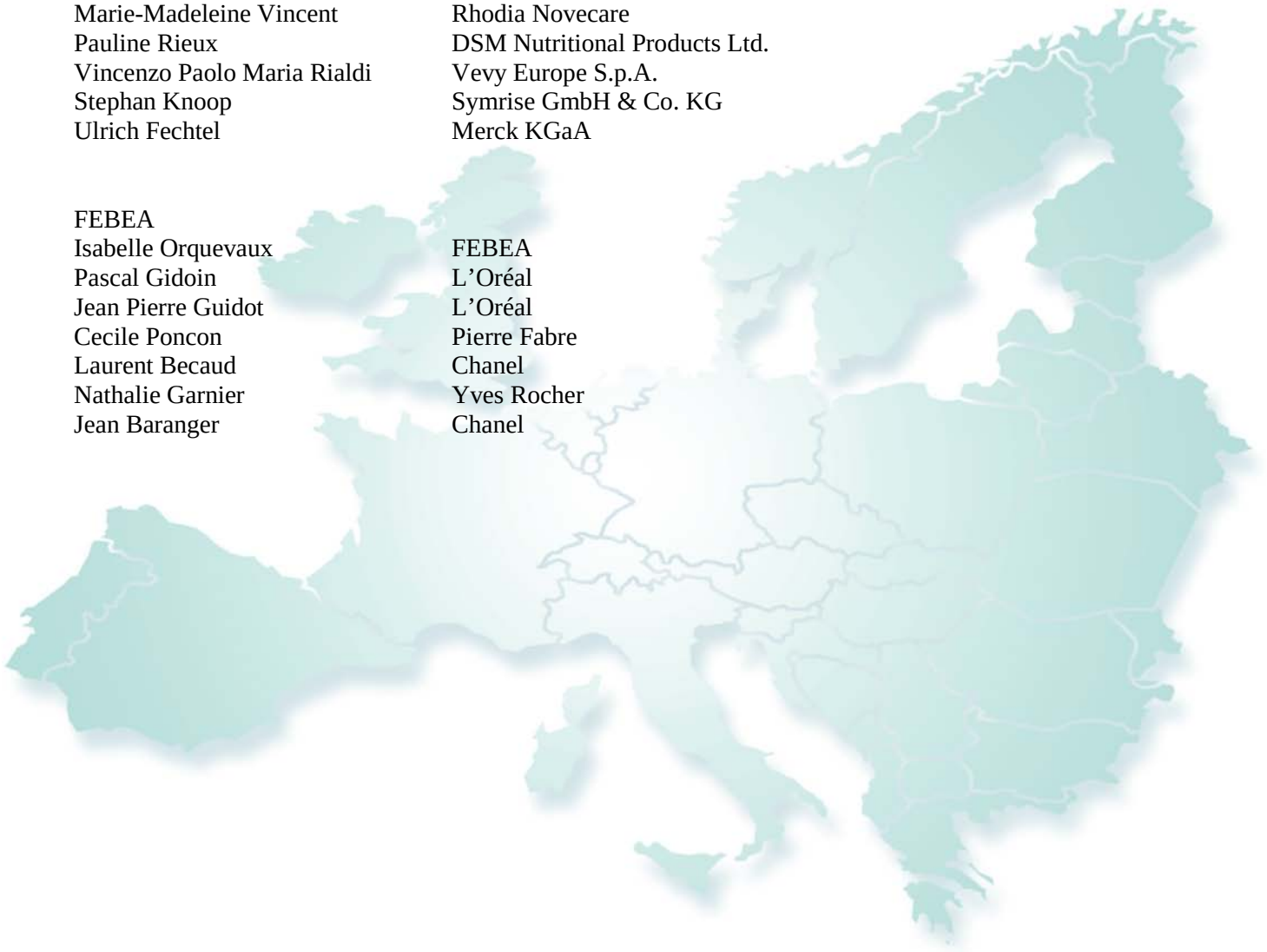

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ACKNOWLEDGEMENTS

This guide was prepared by the EFfCI GMP Working group, who used the draft version 11 of the IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients as a reference and a basis for further development of a GMP Guide. The IPEC-PQG Guide has been adapted in such a way that it is better suited for use by cosmetic ingredient manufacturers.

EFfCI has requested and received permission from IPEC Europe and PQG to use their joint IPEC-PQG GMP Guide as basis for further development of a tailor made EFfCI cosmetic ingredients GMP Guide. This permission resulted in an acceleration of the development of this guide.

We would like to thank IPEC-PQG for allowing us to use their guide in this way.

IPEC

The International Pharmaceutical Excipients Council (IPEC) is an international industry association, formed in 1991 by manufacturers and end users of pharmaceutical excipients. It is an umbrella organisation comprising three regional pharmaceutical excipient industry associations in the United States, Europe, and Japan (which are known respectively as IPEC Americas, IPEC Europe and JPEC). IPEC's objective is to contribute to the development and harmonization of international pharmaceutical excipient standards and the development of good manufacturing practices for pharmaceutical excipients.

PQG

The Pharmaceutical Quality Group (PQG) was formed in 1977 to promote development of a consistent approach to pharmaceutical quality and good manufacturing practices. The group has expanded since that time and in 1990 the PQG produced three codes of practice to cover pharmaceutical raw materials, and printed and contact packaging materials. In 1995 the codes were revised and integrated with ISO 9002:1994. The code for raw materials was revised and reissued as PS 9100:2002 Pharmaceutical excipients, an application standard and GMP guide for pharmaceutical excipients.

FEBEA

The Fédération des Entreprises de la Beauté - French Federation of Fragrance, Cosmetics and Toiletries (FEBEA) is a trade association for beauty and wellness companies (perfume, cosmetics, hygiene and personal care products, hair care), is made up of more than 300 companies. FEBEA has two central missions.

- **convince** public authorities to implement the most favourable framework for the cosmetics industry (lobbying),
- **assist** (on a national and international scale) its members in developing their business to its full potential (consulting).

1 INTRODUCTION

1.1 Purpose and Scope

This guide is intended to be a baseline guide that defines the extent and point of application of fundamental good manufacturing practice (GMP) principles for cosmetic ingredient manufacture. The guide is applicable to the manufacture of cosmetic ingredients intended for use in cosmetic products. It covers the quality management systems and the extent of GMP necessary throughout the manufacturing process. It is intended to be used as international guidance to assist in determining whether the facilities and manufacturing controls used for the production of cosmetic ingredients adequately ensure that they possess the quality and purity which they purport to possess, and that they are suitable for their intended use.

1.2 Principles Adopted

1.2.1 The Guide and its Use

The guide is organized to have international application, bearing in mind that there is an enormous range of cosmetic ingredients and they often have uses other than in the cosmetic industry. When considering how to use this guide, each manufacturer should find out how it might apply to their products and processes. Since cosmetic ingredients are diverse, some principles of the guide may not be applicable to certain products and processes.

The term "should" indicates recommendations that are expected to apply unless shown to be inapplicable or replaced by an alternative demonstrated to provide at least an equivalent level of quality assurance. Note that “should” does not mean “must”.

1.2.2 Application

The text provides the guidance necessary for manufacturing cosmetic ingredients but not all of the details. As an international guidance document, it cannot specify all national legal requirements or cover all particular characteristics of every cosmetic ingredient.

1.2.3 Quality System Standard

The quality management system standard chosen as a framework for this guide is ISO 9001:2008, which is appropriate for manufacturing facilities. The headings in this document have been aligned with the ISO 9001:2008 numbering because many cosmetic ingredient manufacturers already use that standard as a basis for their quality management system, including those companies that already have third party certification. Additional headings are included as required to introduce the additional guidance on GMP, where not covered by existing ISO 9001:2008 clauses.

A manufacturer may apply the ISO standard with or without certification. However, ISO certification has the benefit of providing assurance to customers confirming that this quality management system has been independently verified. EFfCI believes that merging GMP principles for cosmetic ingredient manufacturing into the ISO 9001:2008 quality management system enhances not only the quality management, but an organization’s operational procedures as well. Cosmetic product formulators worldwide have shown increasing regard for compliance with ISO 9001:2008 as almost a necessary qualification for their suppliers. Obtaining certification is however, a business decision and not a recommendation of this guide.

1.3 Document Structure

The guide incorporates existing GMP principles, WHO (World Health Organization) GMP Guidelines for Excipients, IPEC Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients 2006, and international quality management system requirements as developed by The International Organization for Standardization (ISO).

Section 3, General Guidance, provides an overview of the appropriate GMP criteria applicable to cosmetic ingredient manufacture.

Sections 4-8, provide guidance for compliance with relevant GMP principles and implementation of a quality management system. These sections also recommend measures to limit cosmetic ingredient contamination. No attempt has been made to include details specific to particular cosmetic ingredients. Individual manufacturers should address these as they apply to their products and processes.

The Appendices cover supporting guidance for the cosmetic ingredient GMP including Definitions and Glossary, the Certification Standard and References.

2 DEFINITIONS

(See Appendix A)

3 GENERAL GUIDANCE

3.1 Cosmetic ingredients

Cosmetic ingredients are substances or preparations that are intentionally included in a cosmetic product.

3.2 Applying cosmetic ingredient GMP

Cosmetic ingredient manufacture should be carried out in accordance with GMP concepts consistent with this guide. The objective of cosmetic ingredient GMP is to ensure that the manufacture of cosmetic ingredients results in a consistent material with the desired appropriate quality characteristics. The emphasis of the GMP for cosmetic ingredients is to assure product integrity, consistency, avoid product contamination, and ensure that appropriate records are maintained.

Judgement based on a thorough knowledge of the process and an understanding as to the intended use of the product is required to determine at which processing step GMP should be implemented. Methods such as HACCP (Hazard Analysis and Critical Control Point), or a detailed process flow diagram may be used to identify the unit operations, required equipment, stages at which various substances are added, key steps in the process, critical parameters (time, temperature, pressure, etc.), and necessary monitoring points.

4 QUALITY MANAGEMENT SYSTEM - COSMETIC INGREDIENT QUALITY SYSTEM

4.1 General Requirements

The principles outlined in this guide provide a reasonable basis for the quality management system used in the manufacture of cosmetic ingredients. Cosmetic ingredient manufacturers should identify the quality management processes required to assure cosmetic ingredient quality.

Where manufacturing, testing or other operations that could affect cosmetic ingredient quality are outsourced, these activities should be controlled and identified in the cosmetic ingredient manufacturer's quality management system (see also 7.4.2).

4.2 Documentation Requirements

4.2.1 General

The cosmetic ingredient manufacturer should have a system to control documents and data that relate to the requirements of the quality management system.

4.2.2 Quality Manual

The cosmetic ingredient manufacturer should prepare a quality manual describing the quality management system, the quality policy and the commitment of the cosmetic ingredient manufacturer to the appropriate GMP and quality standards contained in this guidance. This manual should include the scope of the quality management system, reference to supporting procedures, and a description of the interaction between quality management processes.

4.2.3 Control of Documents

The cosmetic ingredient manufacturer should establish and maintain procedures for the identification, collection, indexing, filing, storage, maintenance, and disposition of controlled documents, including documents of external origin that are part of the quality management system.

Procedures used in the manufacture and control of cosmetic ingredients should be written, implemented, and maintained. In addition, there should be adequate formal controls related to procedure approval, revision, and distribution. These controls should provide assurance that the relevant version of a procedure is being used throughout the operation and that previous revisions of documents are removed.

Documents and subsequent changes to documents should be reviewed and approved by designated personnel before issuance to the appropriate areas as identified in the documents. Documents that impact product quality should be reviewed and approved by the Quality Unit.

The Quality Unit should securely retain at least one copy of obsolete documents to aid traceability and investigations. The retention period of obsolete documents should be defined, after which period they could be discarded.

Controlled documents should include a unique identifier, date of issue, and a revision number to facilitate identification of the most recent document. Where practical, all changes and the reasons for the change should be documented.

Electronic documentation should meet the requirements for the document control system stated above. If electronic signatures are used on documents, they should be authenticated and secure.

4.2.4 Control of Quality Records

The cosmetic ingredient manufacturer should establish and maintain procedures for the identification, collection, indexing, filing, storage, maintenance, and disposition of quality records.

Quality records should be maintained to demonstrate achievement of the required quality and the effective operation of the quality management system. Quality records should be legible and identifiable to the product involved. Pertinent subcontractor quality data should be an element of these records.

Entries in quality records should be clear, indelible and made directly after performing the activity (in the order performed). Quality records and any corrections made to them should be traceable.

Quality records should be kept for a defined period. This interval should be justified based on the nature of the cosmetic ingredient, and the knowledge of its stability. The retention period for batch records should be at least one year more than the cosmetic ingredient's expiry date or retest interval. Quality records should be stored and maintained in such a manner that they are readily retrievable and in facilities that provide a suitable environment to minimize deterioration or damage.

4.3 Change Control

There should be a documented procedure defining the responsibilities and requirements for the evaluation and approval of changes that may impact the quality of the cosmetic ingredient. The evaluation of changes should determine those that are deemed significant in terms of altering the quality of the cosmetic ingredient, performance, or its regulatory status.

Examples of significant changes could be:

- raw materials and their origins,
- packaging of the cosmetic ingredient,
- product specifications,
- test methods,
- production processes,
- manufacturing or packaging sites,
- alterations to regulatory status etc.

Evaluation and approval of changes should occur prior to their implementation. Records of the change control process should be retained.

Where the evaluation of the change has determined that it is significant, then the quality unit should evaluate these changes. Significant changes should be communicated to customers (see 7.2.3).

5 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Top management should demonstrate the importance they place on meeting customer satisfaction complying with appropriate regulations and these GMP principles. This should be accomplished through the development of a quality policy and establishment of quality objectives. Where quality objectives are set, the progress towards these should be reviewed at planned intervals.

5.2 Customer Focus

It is the responsibility of top management to ensure a corporate emphasis on satisfying customer requirements.

5.3 Quality Policy

Top management should demonstrate its commitment to the corporate quality policy and ensure that it is implemented within the operational unit. The quality policy should support continual improvement of the quality management system. Management should participate in the development of the company's quality policy and provide the resources necessary for its development, maintenance, and deployment.

5.4 Planning

5.4.1 Quality Objectives

Top management should set objectives for adherence to GMP to ensure that the cosmetic ingredient manufacturer maintains and improves its performance. Objectives should be deployed throughout the organization and should be measurable and consistent with the quality policy.

5.4.2 Quality Management System Planning

Top management should provide adequate resources to ensure conformance to the principles of this guide. There should be a process for the identification of resources needed for GMP compliance. A gap analysis based on this guide as well as audits by internal personnel, customers, or outside contractors could be used for the purpose of identifying resource requirements.

Top management should ensure that the integrity of the quality management system is maintained when changes are planned and implemented.

5.5 Responsibility, Authority, and Communication

5.5.1 Responsibility and Authority

Responsibility and authority should be clearly defined by the management and communicated within the organization.

The following responsibilities should be defined:

- approving suppliers of quality critical materials and services,
- approving or rejecting raw materials, packaging components, intermediates and finished cosmetic ingredients,
- reviewing records to ensure that no critical errors have occurred or, if these occur, that they are fully investigated,
- participating in authorizing changes to processes, specifications, procedures, test methods and in investigating failures and complaints (see also 4.3),

- approving or rejecting of the cosmetic ingredient if it is manufactured, processed, packaged, or held under contract by another company,
- releasing the cosmetic ingredient for sale.

Internal audits should verify that these responsibilities have been taken care of (see 8.2.2).

An organization chart by function should show interdepartmental relationships as well as relationships to top management of the company. Personnel whose role has an impact on cosmetic ingredient quality should have written job descriptions.

5.5.2 Management Representative

The cosmetic ingredient manufacturer should appoint a management representative with sufficient authority to ensure that the provisions of this guide are properly implemented. The representative should periodically report to top management on conformance to the quality management system, including changing cosmetic ingredient customers and regulatory requirements.

5.5.3 Internal Communication

The cosmetic ingredient manufacturer should ensure that appropriate processes are established to communicate GMP and regulatory requirements, quality policies, quality objectives and procedures throughout the organization. The communication should also provide information about the effectiveness of the quality management system.

Top management should be notified in a timely manner of quality critical situations, such as recall or withdrawal of cosmetic ingredients, in accordance with a documented procedure.

5.6 Management Review

5.6.1 General

The top management of the company should hold periodic reviews of the quality management system and GMP application to confirm the organization's continued conformance to this guide.

The review should be recorded and include assessing opportunities for improvement and the need for changes to the quality management system.

5.6.2 Review Input

Management review inputs should include for example:

- results of internal and external audits,
- customer ratings of the company performance,
- product conformity and process performance,
- action items from the previous management review,
- customer complaints,
- status of preventive or corrective actions,
- changes that could affect the quality management system.

5.6.3 Review Output

The management review should identify the resources needed and opportunities presented for improvement of the quality management system and improvement of product conformance to customer and regulatory requirements. A record should be made of all actions ordered and taken.

6 RESOURCE MANAGEMENT

6.1 Provision of Resources

There should be an adequate number of trained personnel and sufficient resources (e.g., equipment, materials, buildings and facilities) to implement, maintain and improve the quality management system and to manufacture, package, test, store and release each cosmetic ingredient in a manner consistent with this guide.

6.2 Human Resources

6.2.1 General

Personnel performing work affecting the quality of cosmetic ingredients should have the appropriate education, training and/or experience for their assigned tasks.

6.2.2 Competence, Training and Awareness

The cosmetic ingredient manufacturer should establish and maintain procedures for identifying training needs and providing the necessary training to all personnel performing activities affecting cosmetic ingredient quality. Appropriate records of training should be maintained. Training should be in the particular operations that the employee performs and in GMP as they relate to the employee's functions.

GMP training on this guideline should be refreshed with sufficient frequency to ensure that employees remain familiar with applicable GMP principles. Management should establish adequate and continued personal hygiene training for all personnel handling materials so that they understand the precautions necessary to prevent contamination of cosmetic ingredients.

6.2.3 Personnel Hygiene

Where cosmetic ingredients are exposed to the environment, personnel should wear protective apparel such as head, face, hand, arm coverings as necessary, and jewellery and other loose items should be removed or covered to protect the cosmetic ingredient.

Personnel should practice good sanitation and health habits.

The storage and use of food, drink, tobacco products or similar items should be restricted to certain designated locations separate from manufacturing areas.

6.3 Infrastructure

The organization should provide and maintain the infrastructure required to avoid raw material, intermediate and cosmetic ingredient contamination (including control of particulate matter, microbiological control and control of water quality where applicable).

The organization should conduct and record a risk assessment based on the organization’s intended use of the infrastructure to identify areas in which the cosmetic ingredient is at risk for contamination from deficiencies in buildings and/or facilities. The risk assessment should consider the following at a minimum:

a) location of the operations (e.g. internal, external),
b) state of repair of the building and facility,
c) suitable size, construction and location,
d) ability to maintain a suitably clean building and facility environment,

e) operations that can affect the cosmetic ingredient quality,
f) presence of airborne contaminants, especially highly sensitizing or toxic substances.

Where existing controls to minimize the risks of cosmetic ingredient contamination are not considered effective then additional measures should implemented and these measures documented in the quality management system.

A suitable risk assessment could be in the form of a listing of identified threats to cosmetic ingredient quality with an assessment of the probability of realising those threats and the consequences those threats may have on cosmetic ingredient quality. In determining the residual risks consideration should be given to existing mitigation measures as well as any new ones identified by the risk analysis. Acceptance criteria for residual risks should be defined.

6.3.1 Buildings and Facilities

Buildings and facilities used in the manufacture, processing, packaging, testing**,** or storage of a cosmetic ingredient should be maintained in a good state of repair and should be of suitable size, construction, and location to facilitate cleaning, maintenance, and correct operation. The prevention of cross contamination should be considered in the design and operation of the manufacturing processes and facilities.

There should be adequate facilities for the testing of raw materials, packaging components, intermediates, and finished cosmetic ingredients.

6.3.2 Equipment

Equipment used in the manufacture, processing, packaging, testing**,** or storage of a cosmetic ingredient should be maintained in a good state of repair and should be of suitable size, construction, and location to facilitate cleaning, maintenance, and correct operation.

Where equipment is located outdoors there should be suitable controls to minimise the risk to the cosmetic ingredient from the environment (e.g. processing within a closed system).

6.3.2.1 Equipment Construction

Process equipment should be constructed so that contact surfaces will not be reactive, additive, or absorptive and thus not alter the quality of the cosmetic ingredient. Substances required for operation, such as lubricants or coolants, should preferably not come into contact with raw materials, packaging materials, intermediates, or finished cosmetic ingredients. Where exposure to the cosmetic ingredient is possible, the substances should be compatible with use in cosmetics.

Equipment should be designed to minimize the possibility of contamination caused by direct operator contact.

6.3.2.2 Equipment Maintenance

Written procedures should be established and followed for maintenance of critical equipment used in the manufacture, processing, packaging, testing or, holding of the cosmetic ingredient. There should be records of the use and maintenance of quality critical equipment. These records can be in the form of a log, computer database, or other appropriate documentation.

6.3.2.3 Computer Systems

Computer systems that may impact upon cosmetic ingredient quality should have sufficient controls for operation, maintenance and to prevent unauthorized access or changes to data software and computer hardware.

The following controls should be established:

- retention of suitable back-up systems such as copies of the programs and files,
- assurance that changes are verified and documented, and only made by designated personnel.

6.3.3 Utilities used in manufacture of cosmetic ingredients

Utilities (e.g. nitrogen, compressed air, steam etc.) used in the manufacture of cosmetic ingredients that could impact upon product quality should be assessed and appropriate action taken to control the risk.

6.3.4 Water used in manufacture of cosmetic ingredients

Water that comes into direct contact with the cosmetic ingredient during manufacture or remains in the final product should be suitable for its intended use.

Unless otherwise justified, water that comes into direct contact with the cosmetic ingredient should, at a minimum, meet World Health Organization (WHO) guidelines for drinking (potable) water quality. If drinking (potable) water is insufficient to assure quality, and tighter chemical and/or microbiological water quality specifications are required, appropriate specifications should be set, e.g. physical and chemical attributes, total microbial counts and objectionable organisms.

Where water used in the process is treated by the manufacturer to achieve a defined quality, the treatment process should be specified and monitored with appropriate action limits.

6.4 Work Environment

The work environment should be managed and controlled to minimize risks of cosmetic ingredient contamination. A documented risk assessment should be carried out (see 6.3) and recorded to determine the necessary controls.

The documented risk assessment should cover the following controls, as applicable:

a) air handling systems,
b) special environments,
c) cleanliness and sanitary conditions,
d) waste segregation and disposal,
e) pest control,
f) other risk assessments required by this Annex.

Where maintenance of the work environment is critical to ensure cosmetic ingredient quality, the controls should be documented in the quality management system and suitable records retained.

The following subsections of 6.4 provide more detailed guidance on the specific areas evaluated in the risk assessment and should be adopted where the risk assessment has identified the need for these controls.

6.4.1 Cleaning

Adequate cleanliness is an important consideration in the design of cosmetic ingredient manufacturing facilities. Buildings used in the manufacture, processing, packaging, or holding of a cosmetic ingredient should be maintained in an appropriately clean condition.

Where maintenance of clean and sanitary conditions is critical to cosmetic ingredient quality, written procedures should assign responsibility for cleaning and describe in sufficient detail the schedules, methods, equipment, and materials to be used in cleaning the buildings and facilities. These procedures should be followed and cleaning should be documented.

Waste should be segregated, held and disposed of in a timely and appropriate manner.

6.4.2 Pest Control

Buildings should be free of infestation by rodents, birds, insects, and other vermin.

Some starting materials, particularly botanicals, may contain some unavoidable contamination, such as rodent or other animal filth or infestation. Control methods should be identified to prevent the increase of such contamination or infestation in holding areas, or its spread to other areas of the plant.

6.4.3 Lighting

Adequate light should be provided in all areas to facilitate cleaning, maintenance and operations.

6.4.4 Drainage

In areas where the cosmetic ingredient is open to the environment, drains should be of adequate size and, where connected directly to a sewer, should be provided with an air break or other mechanical device to prevent back siphoning.

6.4.5 Washing and Toilet Facilities

Adequate washing facilities, including hot and cold water, soap or detergent, air dryers or single service towels, and clean toilet facilities should be provided. These should be easily accessible from working areas. Adequate facilities for showering and/or changing clothes should be provided, where appropriate.

7 PRODUCT REALIZATION

7.1 Planning of Product Realization

The cosmetic ingredient manufacturer should plan and develop the processes and controls needed for product manufacture.

These plans and controls should be appropriate to the process, cosmetic ingredient specification, equipment and facilities used in the manufacture of the product.

Key aspects of the planning of suitable process and controls should include as appropriate:

- written testing programs for quality critical materials and the cosmetic ingredients that include appropriate specifications, sampling plans, test and release procedures,
- the generation and maintenance of records (see 4.2.4) that provide evidence that these plans have been realised as intended and enable traceability to be demonstrated (see 7.5.3),

- provision of resources to realise these plans,
- environmental, contamination and hygiene control programs,
- that in-process samples should not be returned to production for incorporation into the final batch unless appropriate authorisation from the quality unit has been received.

7.2 Customer-related Processes

7.2.1 Determination of Requirements Related to the Product

The delivery requirements of the customer should be identified, including labelling. Requirements not stated by the customer but necessary for specified or intended use, where known, should be considered.

7.2.2 Review of Requirements Related to the Product

The cosmetic ingredient manufacturer and customer should mutually agree upon the requirements identified in 7.2.1 before supply commences. The manufacturer should have the facility and process capability to consistently meet the mutually agreed upon cosmetic ingredient specifications. Where the requirements determined in 7.2.1 are changed, this review should be repeated before supply recommences.

7.2.3 Customer Communication

There should be provision for providing accurate and pertinent communication to the customer. Provision should be made for replying to customer inquiries, contracts, and order handling. Customer feedback and complaints should be documented. Customers should be notified of significant changes (see 4.3).

7.3 Design and Development

ISO 9001:2008 includes requirements for ensuring control over design and development activities. Companies involved in such activities are recommended to follow the requirements of ISO 9001:2008. GMP is not always applicable during the design and development of new cosmetic ingredients and/or manufacturing processes.

7.4 Purchasing

7.4.1 Purchasing Process

Manufacturers of cosmetic ingredients should have a system for selecting suppliers of quality critical materials and services (e.g. subcontract manufacturers and laboratories). This should require an evaluation including adequate evidence that the supplier can consistently meet agreed requirements. Records of these activities should be maintained.

Materials should be purchased against an agreed specification from approved suppliers.

7.4.2 Purchasing Information

Purchasing agreements should contain data clearly describing the material or service ordered, including, where applicable, the following:

- the need to comply with the appropriate sections of this guide for any relevant contract manufacturers or laboratories;
- a requirement to notify the cosmetic ingredient manufacturer of changes in quality critical raw materials.

7.4.3 Verification of Purchased Product

There should be procedures for the approval and release of each raw material used in the production of cosmetic ingredients. Upon receipt, raw materials should not be

used prior to acceptance. Verification should include a supplier certificate of analysis and wherever feasible, at least an identification test. Testing schedules should be organised to separate those tests that are routine from those that are performed infrequently or only for new suppliers.

Sampling activities should be conducted under defined conditions, in accordance with a sampling method, using procedures designed to prevent contamination of the raw material.

Deliveries made by bulk tankers should have appropriate controls to assure material purity and freedom from contamination (for example dedicated tankers, a certificate of cleaning, analytical testing or audit of the supplier).

These processes, activities and results should be documented.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

Production activities should be carried out under controlled conditions (see 7.1).

Specific examples of controls that are important are illustrated in the following sections. Not all of these may be applicable to all cosmetic ingredient manufacturers.

7.5.1.1 Production Instructions and Records

Production instructions and records are required but may differ for the type of operation, for example batch versus continuous.

Production instructions should be prepared for each cosmetic ingredient to be manufactured. An accurate reproduction of the master production instructions should be issued to the production area.

Records should be available for each batch of cosmetic ingredient produced and should include information relating to the production and control of each batch, including continuous processes. Records may be in different locations but should be readily retrievable.

Records should include, where critical to cosmetic ingredient quality, documentation that each significant step in the manufacture, processing, packing, or holding of the batch has been accomplished, for example:

- date/time each step was completed,
- identification of individual major equipment and lines used,
- specific identification of each batch of component or in-process material used,
- weights and measures of components used in the course of processing,
- in-process and laboratory control results,
- a record of the inspection of the packaging and labelling area before and after use,
- a recorded statement of the actual yield or quantity produced and a statement of the percentage of theoretical yield,
- labelling control records,
- description of cosmetic ingredient product containers and closures,
- description of sampling performed,
- identification of persons performing and directly supervising or checking each significant step in the operation,
- a record of investigations made for failures and discrepancies,
- results of final product inspection.

7.5.1.2 Equipment Cleaning

A risk assessment should be used to identify the need for equipment cleaning and/or sanitisation procedures. Where required, then they should be documented and contain sufficient details to allow operators to clean each type of equipment in a reproducible and effective manner. Evidence of the effectiveness of such cleaning and/or sanitisation procedures should be available.

Equipment and utensils should be cleaned, where critical to cosmetic ingredient quality, at appropriate intervals to prevent contamination of the cosmetic ingredient. The cleaning status of equipment should be recorded appropriately.

Where multipurpose equipment is in use, it is important to be able to determine previous usage when investigating cross-contamination or the possibility of such contamination (see 7.5.1.7).

During a production campaign, incidental carryover frequently occurs and usually is acceptable since clean-up between successive batches of the same cosmetic ingredient is not normally required to maintain quality levels.

For continuous processing the frequency of equipment cleaning should be determined by the manufacturer and justified.

7.5.1.3 Recovery of Solvents, Mother Liquors and Second Crop Crystallizations

Where solvents are recovered and reused in the same process or different processes they should meet appropriate standards prior to reuse or mixing with other approved material.

Mother liquors or filtrates containing recoverable amounts of cosmetic ingredient, reactants, or intermediates are frequently reused. Such processes should be documented in the batch production records to enable traceability.

7.5.1.4 In-process Blending/Mixing

In-process blending or mixing to assure batch uniformity or to facilitate processing should be adequately controlled and documented. If the intent of the operation is to ensure batch uniformity, it should be performed so as to assure homogenous mixing of all materials to the extent feasible and should be reproducible from batch to batch (see also 8.3.1).

7.5.1.5 In-process Control

In-process inspection and testing should be performed based upon monitoring the process or actual sample analysis at defined locations and times. Sampling methods should be documented to ensure that the sample is representative and clearly labelled.

The results of in-process tests should be recorded and conform to established process parameters or acceptable tolerances. Work instructions should define the procedure to follow and how to utilise the inspection and test data to control the process. There should be defined actions to be taken when the results are outside specified limits.

Where approval to continue with the process is issued within the production department, the specified tests should be performed by trained personnel and the results should be recorded.

7.5.1.6 Packaging and Labelling

Procedures should be employed to protect the quality and purity of the cosmetic ingredient when it is packaged, and to assure that the correct label is applied to all containers. Packaging and labelling operations should be designed to prevent mix-ups.

Procedures should be implemented to ensure that the correct labels are printed, issued and contain the correct information. The procedure should also define that any excess labels are immediately destroyed or returned to controlled storage. All excess labels bearing batch numbers should be destroyed. Packaging and labelling facilities should be inspected immediately before use to ensure, that all materials that are not required for the next packaging operation, have been removed.

In instances where cosmetic ingredients are labelled on the packaging line, packaged in pre-printed bags, or bulk shipped in tank cars, there should be documentation of the system used to satisfy the intent of the above principles.

7.5.1.7 Records of Equipment Use

Records of quality critical equipment use should be retained. These records should allow the sequence of cleaning, maintenance and production activities to be determined.

7.5.2 Validation of Processes for Production and Service Provision

Validation of the manufacturing processes used for cosmetic ingredients is not normally necessary as the product quality can be adequately determined at the end of processing. Where this is not possible, the manufacturing process should be validated.

Where cosmetic ingredient manufacturers have evaluated their processes using process capability studies, they provide additional assurance about process control and cosmetic ingredient quality.

7.5.3 Identification and Traceability

7.5.3.1 Traceability

Quality critical items, for example raw materials, packaging materials, intermediates, and finished cosmetic ingredients should be clearly identified and traceable through a documented system. The quality management system should allow traceability of the cosmetic ingredient to raw materials and upstream to customers. Identification of raw materials used in batch production processes should be traceable through the batch numbering system or any other appropriate system. Identification of raw materials used in cosmetic ingredients manufactured by continuous processing should indicate batches that were present in the equipment at a designated point in time.

Raw materials, including solvents, are sometimes stored in bulk tanks or other large containers, making precise separation of batches difficult. Nevertheless, the use of such materials should be documented in production records.

7.5.3.2 Inspection and Test Status

There should be a system to identify the inspection status of quality critical items including raw materials, packaging materials, intermediates, and finished cosmetic ingredients. Continuously-fed materials may need special consideration in order to satisfy these requirements.

7.5.3.3 Labelling

Labelling requirements for cosmetic ingredient packages are subject to national and international regulatory requirements, which may include transportation and safety measures. At a minimum, labels should include:

- the name of the cosmetic ingredient, and grade if applicable,
- the cosmetic ingredient manufacturer's, and/or distributor's name,
- the batch number from which the complete batch history can be determined,
- if special storage conditions are required, such restrictions should be placed on the label or otherwise communicated to the customer with the consignment.

7.5.4 Customer Property

Where applicable, the manufacturer should establish and maintain procedures for verification, storage, and maintenance of customer supplied materials, intended for incorporation into the customer's cosmetic ingredient. Verification by the manufacturer does not relieve the customer of the responsibility to provide an acceptable material. Any material that is lost, damaged, or is otherwise unsuitable for use, should be recorded and reported to the customer. In this case, procedures should be in place for acceptable disposition and replacement of the material. The manufacturer should also make provisions to protect other real and intellectual property that is provided by the customer (e.g., test equipment, test methods, and specifications).

7.5.5 Preservation of Product

7.5.5.1 Handling, Storage, and Preservation

Cosmetic ingredients, intermediates, and raw materials should be handled and stored under appropriate temperature, humidity, and light conditions, so that their identity, quality, and purity is not affected. Outdoor storage of raw materials (e.g., acids, other corrosive substances, or explosive materials) is acceptable provided the containers give suitable protection to their contents, identifying labels remain legible, and containers are adequately cleaned prior to opening and use.

Special storage conditions should be maintained if they have been identified as necessary for the maintenance of material quality characteristics. Records of these conditions should be retained.

7.5.5.2 Packaging Systems

A cosmetic ingredient packaging system should include the following features:

- written specifications, examination or testing methods,
- cleaning procedures where containers are re-used,
- containers that provide adequate protection against deterioration or contamination of the cosmetic ingredient that may occur during transportation and recommended storage,

- storage and handling procedures which protect containers and closures and minimise the risk of contamination, damage or deterioration, and which will avoid mix-ups (e.g., between containers that have different specifications but are similar in appearance),
- a written justification that the packaging does not introduce impurities to the cosmetic ingredient.

If returnable cosmetic ingredient containers are re-used, all previous labelling should be removed or defaced. If the containers are repetitively used solely for the same cosmetic ingredient, all previous batch numbers, or the entire label should be removed or completely obliterated.

7.5.5.3 Delivery and Distribution

Identification and traceability of quality critical items are required of cosmetic ingredient manufacturers. Distribution records should be kept that document all cosmetic ingredient shipments. These records should identify by cosmetic ingredient batch, where and to whom the product was shipped, the amount shipped, and the date of shipment.

The manufacturer should arrange for the protection of the quality of the product after final inspection and test. Where contractually specified, this protection should be extended to include delivery to the final destination. Cosmetic ingredients should only be supplied within their expiry and/or retest period.

7.6 Control of Monitoring and Measuring Equipment

Measuring and test equipment, including computer software, identified as being critical parts of the quality management system, should be properly calibrated and maintained. This includes all in-process instruments identified as quality management system instruments, as well as test equipment used in the laboratory. The control program should include the standardisation or calibration of quality critical instruments and equipment at suitable intervals in accordance with an established written program. This program should contain specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event that accuracy and/or precision limits are not met. Calibration standards should be traceable to recognised national or compendial standards as appropriate.

Instruments and equipment not meeting established specifications should not be used and an investigation should be conducted to determine the validity of the previous results since the last successful calibration. The current calibration status of quality critical equipment should be known and verifiable to users.

8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

The organization should plan and implement the monitoring, measurement and improvement activities required to demonstrate conformity of the product and to ensure conformity of the quality management system.

The organization should evaluate opportunities for improvements through the measurement and analysis of product and process trends.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

The cosmetic ingredient manufacturer should establish measurement activities to assess customer satisfaction. Such measurements can include customer complaints, return of cosmetic ingredients, and customer ratings of the cosmetic ingredient manufacturer. This information should drive activities that strive to continuously improve customer satisfaction.

8.2.2 Internal Audit

The cosmetic ingredient manufacturer should carry out a comprehensive system of planned and documented internal quality audits to determine whether quality activities comply with planned arrangements and to determine the effectiveness of the quality management system. Audits should be scheduled on the basis of the status and importance of the activity. Audits and follow-up actions should be carried out in accordance with documented procedures.

Audit results should be documented and discussed with management personnel having responsibility in the area audited. Management personnel responsible for the area audited should take corrective action on the non-conformities found.

8.2.3 Monitoring and Measurement of Processes

The cosmetic ingredient manufacturer should identify the tests and measurements necessary to adequately control manufacturing and quality management system processes. Where appropriate, techniques that may be used to verify that the processes are under control should be established.

When deviations from planned results occur, corrective action should be taken to ensure the product meets requirements.

Periodic reviews of key indicators such as process quality attributes and process failures should be conducted to assess the need for improvements.

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8.2.4 Monitoring and Measurement of Product

The cosmetic ingredient manufacturer should establish the test methods and procedures to ensure the product consistently meets specifications.

Analytical methods should be fit for purpose and should provide a high degree of assurance about their suitability.

8.2.4.1 Laboratory Controls

Laboratory controls should include data derived from all tests necessary to ensure conformance with established specifications and standards, for example:

- a description of the sample received for testing including the material name, batch number or other distinctive code, and date the sample was taken,
- a statement referencing each test method used,
- a record of raw data secured during each test including graphs, chromatograms, charts, and spectra from laboratory instrumentation, identified to show the specific material and batch tested,
- a record of calculations performed in connection with the test,

- test results and how they compare with established specifications,
- traceability to the person who performs each test and the date(s) the tests were performed.

There should be a written procedure for the preparation of laboratory reagents and solutions. Purchased reagents and solutions should be labelled with the name, concentration, and expiry date. Volumetric solutions should be standardized according to an internal method or using a recognised standard.

8.2.4.2 Cosmetic Ingredient Testing and Release

Cosmetic ingredient testing should be performed on each batch or lot to ensure that the cosmetic ingredient conforms to written specifications. For cosmetic ingredients produced by continuous processes assurance that the cosmetic ingredient conforms to documented specification may be achieved through the results of in-process testing or other process control records.
Cosmetic ingredient batch release should be based on conformance to final test specifications and an evaluation of the manufacturing process records.

8.2.4.3 Out-of-Specification Test Results

Out-of-specification (OOS) test results should be investigated and documented according to a documented procedure.

Retest sample results may only be used to replace the original test result if it is demonstrated that the original result is erroneous, based on a documented investigation.

When statistical analysis is used, both the original and retest data must be included. The OOS procedure should explain which statistical techniques are to be used and under what circumstances.

These same principles apply when the sample is suspected of not being representative of the material from which it was taken.

8.2.4.4 Retained Samples

Where it is practical, retained samples of the cosmetic ingredient should be kept. The retention period should be defined. The retained samples should be stored and maintained in such a manner that they are readily retrievable in facilities that provide a suitable environment. The sample size should be at least twice the amount required to perform complete specification testing.

8.2.4.5 Certificates of Analysis

Where the customer requires it, certificates of analysis should be provided to the required specification for each batch of cosmetic ingredient supplied.

8.2.4.6 Impurities

Manufacturers should be aware of the impurities and their typical levels present in cosmetic ingredients.

Any impurity critical to product quality should be identified and have appropriate limits established. Manufacturing processes should be adequately controlled so that the impurities, including solvent residues, do not exceed such established specifications.

8.2.4.7 Stability

Many cosmetic ingredients are stable and may not require testing to demonstrate their stability. For cosmetic ingredients that have been in the market for a long time, historic and/or retrospective data of the material and its uses may be used to demonstrate stability.

Where there is no information about stability, a documented testing and/or evaluation program designed to assess the stability characteristics of the cosmetic ingredient should be undertaken.

8.2.4.8 Expiry/Retest Periods

An expiry or retest period for each cosmetic ingredient should be assigned and justified. Where stability data is available, it can be used to assign the expiry or retest period. Common practice is to use a retest period, rather than an expiry period. The expiry or retest period should be communicated to the customer.

8.3 Control of Nonconforming Product

Raw material, intermediate, or finished cosmetic ingredient found not to meet its specification should be clearly identified and controlled to prevent inadvertent use or release for sale. A record of non-conforming product should be maintained. Incidences of non-conformance should be investigated to identify the root cause. The investigation should be documented and corrective action taken to prevent recurrence of the problem.

There should be a procedure defining how the recall (withdrawal) of a cosmetic ingredient should be conducted.

Procedures should exist for the evaluation and subsequent fate of non-conforming products. Nonconforming product should be reviewed in accordance with documented procedures to determine its final outcome. The non-conforming product may be:

- reprocessed/reworked to meet the specified requirements,
- accepted with the agreement of the customer,
- re-graded for other applications,
- destroyed.

8.3.1 Reprocessing/Reworking

Blending, reprocessing or reworking that is not a normal part of the manufacturing process and should be documented in the batch record to ensure traceability.

When considering reprocessing or reworking, a review of risk to cosmetic ingredient quality can be undertaken, and consideration can be given to:

- new impurities that may have been introduced as a result of the reprocessing/reworking,
- additional testing to control the reprocessing/rework,
- establishment of suitable acceptance criteria for the reprocessed/reworked cosmetic ingredient,
- performance.

The equivalence of the quality of reprocessed material to original material should also be evaluated and documented to ensure that the reprocessed batch will conform to established standards, specifications, and characteristics.

8.3.2 Returned cosmetic ingredients

Returned cosmetic ingredients should be identified and held until there has been an evaluation of their quality. There should be procedures for the holding, testing, and reprocessing of the returned cosmetic ingredient. Records of returned products should be maintained.

8.4 Analysis of Data

The cosmetic ingredient manufacturer should develop methods for evaluating the effectiveness of its quality management system to identify opportunities for improvement. Such data can be derived from customer complaints, product reviews, process capability studies, internal audits, and audits by the customer. The analysis of such data may be used as part of the management review (see 5.6).

It is suggested that a periodic review of key indicators such as product quality attributes, customer complaints and product non-conformities, should be conducted to assess the need for improvements.

8.5 Improvement

8.5.1 Continual Improvement

The cosmetic ingredient manufacturer should take proactive measures to continuously improve manufacturing and Quality Management System processes. The cosmetic ingredient manufacturer should establish, document, and maintain procedures for:

- investigating the cause of non-conforming product, internal audits, customer returns, and complaints along with the corrective action needed to prevent recurrence,
- analyzing processes, work operations, concessions/special release, quality records, and to detect and eliminate potential causes of non-conforming product.

8.5.2 Corrective Action

The cosmetic ingredient manufacturer should establish, document, and maintain procedures for:

- applying controls to ensure that corrective actions are taken and that they are effective,
- implementing and recording changes in procedures resulting from corrective action,
- determining the causes of non-conformities.

8.5.3 Preventive Action

The cosmetic ingredient manufacturer should establish, document, and maintain procedures for:

- initiating preventive actions to deal with problems at a level corresponding to the risks encountered,
- implementing and recording changes in procedures resulting from preventive action.

APPENDIX A DEFINITIONS AND GLOSSARY

As used throughout this guide, the terms below have the following meaning.

Batch (Lot)
A specific quantity of material produced in a process or series of processes so that it can be expected to be homogeneous. In the case of continuous processes, a batch may correspond to a defined fraction of the production. The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval.

Batch Number (Lot Number)
A distinctive identification (e.g. combination of numbers, letters and/or symbols) that identifies a batch and from which the production and distribution history can be determined.

Batch Process
A manufacturing process that produces the cosmetic ingredient from a discrete supply of raw materials that are present before the completion of the reaction.

Batch Record
Documentation that provides the history of a batch from the raw materials used, manufacturing steps performed and in-process and final testing.

Blending (Mixing)
Blending is the process of combining materials with the same specifications to produce a homogeneous substance. Combining different conforming batches into one homogeneous batch.

Calibration
The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference or traceable standard over an appropriate range of measurements.

Certificate of Analysis (CofA or CoA)
A document listing the results of testing a representative sample drawn from the batch to be delivered.

Concession
An agreement reached with a customer whereby they accept a non-conforming material.

Contaminant
An impurity not intended to be present in a material that may be introduced through such things as poor cleaning, processing, or the lack of appropriate environmental and personnel controls during the manufacturing process.

Continuous Process
A manufacturing process that continually produces material from a continuing supply of raw material.

Cosmetic Ingredient
Substances or preparations that are intentionally included in a cosmetic product.

Cosmetic Product
"Cosmetic product" means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours. (Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, Article 2, 1(a).)

Critical Deficiency
A deficiency which has produced, or leads to a significant risk of producing a product which is harmful to the customer or which does not comply with regulatory requirements or commercial claims.

Critical Process
A manufacturing process step that directly influences quality attributes.

Cross-Contamination
Contamination of a raw material, intermediate, or a finished cosmetic ingredient with another raw material, intermediate, or cosmetic ingredient during production.

Customer
The next organization to receive the cosmetic ingredient once it has left the control of the cosmetic ingredient manufacturer, brokers, agents and distributors.

Expiry (Expiration) Date
The date beyond which a product may no longer conform to relevant specifications.

Good Manufacturing Practices (GMP)
That part of quality assurance which ensures that products are consistently produced and controlled with a quality standard appropriate to their intended use.

Homogeneous (Material)
Material of uniform consistency and composition throughout a batch.

Impurity
Any component of a cosmetic ingredient that is not the desired entity.

In-process Testing
Monitoring checks performed during production to ensure that the process is in control and the material, substance, or product conforms to established specifications.

Intermediate (Product)
Material that must undergo further manufacturing steps before it becomes a finished cosmetic ingredient.

Lot
See "Batch".

Manufacturer
A company holding the trademark for the cosmetic ingredient or that performs the final release of the cosmetic ingredient.

Manufacturing Process
All the steps necessary to produce a finished cosmetic ingredient.

Master Production Instruction
Documentation that describes the manufacture of the cosmetic ingredient from raw material to completion of the batch.

Mother Liquor
A concentrated solution from which the product is obtained by evaporation, freezing, and/or crystallization.

Nonconforming Material
Any material that does not meet the manufacturer's specifications or that has not been manufactured according to applicable GMP.

Packaging
The act of filling a cosmetic ingredient into a container.

Packaging Material
The containers, closures, and labels employed in the packaging of a product.

Production
See “Manufacturing process”.

Quality
The totality of features and characteristics of a product that bear on its ability to satisfy stated or implied needs.

Quality Assurance
All the planned and systematic actions necessary to provide confidence that a product or a service will satisfy given requirements for quality.

Quality Control
Includes all activities such as measuring, examining, testing, or gauging one or more characteristics of a material (including finished cosmetic ingredients, intermediates, packaging materials and starting materials) and comparing the findings with specified requirements to determine conformity.

Quality Unit (ref: ICH Q7)
An organizational unit independent of production which fulfils both Quality Assurance and Quality Control responsibilities. This may be in the form of separate QA and QC Units, a single individual (or group), depending on the size and structure of the organization.

Raw Material
See “Starting Material”.

Recall
A process for withdrawing or removing a cosmetic ingredient from the distribution chain because of defects in the material or complaints of a serious nature. Does not necessarily involve notification of any regulatory authority.

Representative Sample
A sample drawn according to an appropriate sampling plan, which may involve regular or random selection.

Reprocessing
Introduction of previously processed material which did not conform to standards or specifications back into the process and repeating one or more necessary steps that are part of the normal manufacturing process.

Retained Sample
A representative sample from the finished cosmetic ingredient batch that is of sufficient quantity to perform at least two full quality control analyses.

Retest Date
The date beyond which the cosmetic ingredient should not be used without further appropriate re-examination.

Returned Products
Finished cosmetic ingredients returned to the manufacturer for a specified reason.

Reworking
Introducing previously processed material that did not conform to standards or specifications to processing steps that differ from the normal process.

Sanitization (ref ISO 22716)
An operation, used to reduce undesirable micro-organisms on inert contaminated surfaces depending on the objectives set.

Specification
A list of tests, references to analytical procedures, and appropriate acceptance criteria for a material.

Stability
Continued conformance of the cosmetic ingredient to its specifications.

Starting Material
Any substance used in the production of a cosmetic ingredient excluding packaging materials.

Top Management
Person or group of people who direct and control an organization at the highest level. The highest level can either be at the site or on corporate level and will depend on the way that the quality management system is organized.

Traceability
Ability to track the history, application or location of that which is under consideration.

Validation
A program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting predetermined acceptance criteria.

Withdrawal
See “Recall”.

APPENDIX B REFERENCES

International Organization for Standardization, Quality Management Systems-Requirements, ISO 9001:2008.

IPEC PQG Draft Good Manufacturing Practices Guide for Pharmaceutical Excipients (Version 11).

76/768/EEC Council Directive of 27 July 1976 on the approximation of the laws of the member states relating to cosmetic products, as amended.

Institute of Quality Assurance, Pharmaceutical Quality Group PS 9100:2002 Pharmaceutical excipients, an application standard and GMP guide for pharmaceutical excipients, 2002.

WHO Technical Report Series No. 917, 2003 Annex 2, Good trade and distribution practices for pharmaceutical starting materials.

APPENDIX C ADDITIONAL SOURCES OF INFORMATION

The following references provide further information about the various GMP guides and standards that are used in other industries. The concepts and controls may provide useful sources of additional information.

Bulk Pharmaceutical Chemicals (BPCs), Drug Quality Assurance, Chapter 56, Program 7356.002F, FDA Compliance Program Guidance Manual, October 2000.

Code of Federal Regulations Title 21 Food and Drugs Parts 210 and 211, US Food and Drug Administration (FDA), Washington DC, USA.

Codex Alimentarius – Food Hygiene – Basic Texts – Second Edition, Food Hygiene, Food and Agriculture Organization of the United Nations and World Health Organization, Rome, 2001.

Council of Europe; 93SPT28E.CO, Guidelines for Good Manufacturing Practice in the Cosmetics Industry.

European Commission, Committee for Proprietary Medicinal Products, *The Rules Governing Medicinal Products in the European Union*, Volume 4, Good Manufacturing Practices.

European Union, Commission Directive, 2004/27/EC, amending Directive 2001/83/EC on the community code relating to medical products for human use.

European Union, The Rules Governing Medicinal Products in the European Union, Notice to Applicants, Volume 2B CTD (June 2004).

European Union, Council Directive, 93/43/EEC, On the Hygiene of Foodstuffs.

Guide to Inspection of Bulk Pharmaceutical Chemicals, (Reference Materials and Training Aids for Investigators), Food and Drug Administration, Div. of Field Investigations (IBC-130), Division of Manufacturing and Product Quality (HFD-320), Rev. Sept. 1991.

Hazard Analysis and Critical Control Point Principles and Application Guidelines, FDA - August 1997.

International Conference on Harmonization (ICH), Note for Guidance on Good Manufacturing Practices for Active Pharmaceutical Ingredients Q7A, 2001.

International Standard ISO 10011-1 to 10011-3, Auditing, Including Qualification Criteria and Management of Audit Programs.

International Standard ISO 9000:2005, "Quality Management Systems - Fundamentals and Vocabulary".

IPEC Good Manufacturing Practices Guide for Bulk Pharmaceutical Excipients, 2001.

IPEC Good Manufacturing Practices Audit Guideline for Bulk Pharmaceutical Excipients, 2004.

IPEC-Americas Certificate of Analysis Guide for Bulk Pharmaceutical Excipients, 2000.

IPEC-Americas Significant Change Guide for Bulk Pharmaceutical Excipients, 2005.

Pharmaceutical Inspection Convention, PH 2/87 of June 1987, Guidelines for the Manufacture of Active Pharmaceutical Ingredients (Bulk Drug Substances).

APPENDIX D ANNEX TO ISO 9001:2008: ADDITIONAL REQUIREMENTS FOR COSMETIC INGREDIENTS TO BE CERTIFIED AS COMPLYING TO THE EFFCI GMP GUIDE 2012

Foreword

With the widespread adoption by industry of ISO 9001 EFfCI has developed the following additional requirements to that international standard to allow organizations to seek certification to the EFfCI GMP Guide 2005. This Appendix details the additional requirements to ISO 9001:2008. The clauses are laid out according to the ISO 9001 headings, however the full text of ISO 9001 is not reproduced due to copyright reasons, and thus these requirements should be read in conjunction with a copy of the full ISO 9001 text.

Certification to these requirements can be obtained from accredited certification bodies who have agreed to abide by the EFfCI GMP Certification Scheme Rules (see Appendix E).

0 INTRODUCTION

0.1 General

Cosmetic ingredient manufacture shall be carried out in accordance with GMP concepts consistent with this annex. The objective of cosmetic ingredient GMP is to ensure that the manufacture of cosmetic ingredients results in a consistent material with the desired appropriate quality characteristics. The emphasis of the GMP for cosmetic ingredients is to assure product integrity, avoid product contamination, and ensure that appropriate records are maintained.

This document is an annex to ISO 9001:2008.
It includes additional requirements that support the application of GMP to the manufacture and distribution of Cosmetic Ingredients.

This annex should be read in conjunction with the EFfCI GMP Guide for Cosmetic Ingredients 2005.

0.2 Process approach

No additional requirements to ISO 9001.

0.3 Relationship with ISO 9004

No additional requirements to ISO 9001.

0.4 Compatibility with other management systems

No additional requirements to ISO 9001.

1 SCOPE

1.1 General

Purpose and Scope

The scope of this annex is an addition of GMP for Cosmetic Ingredients to ISO 9001:2008 requirements.
Throughout this annex, references to “GMP for Cosmetic Ingredients” will be referred to as “GMP”.

The Annex and its Use
For guidance on the additional requirements in this annex consult the EFfCI GMP Guide for Cosmetic Ingredients 2012.

1.2 Application
This annex includes additional requirements to ISO 9001:2008 for certification purposes which allows organizations to demonstrate compliance with GMP.

2 NORMATIVE REFERENCE
No additional requirements to ISO 9001.

3 TERMS AND DEFINITIONS
See end of document, section "Definitions and Glossary".

GENERAL GUIDANCE
Cosmetic ingredients
Cosmetic ingredients are substances or preparations that are intentionally included in a cosmetic product.

4 QUALITY MANAGEMENT SYSTEM
4.1 General requirements
No additional requirements to ISO 9001.

4.2 Documentation requirements
4.2.1 General
The quality management system documentation shall include:
e) the organization's overall intentions and approach to GMP, and
f) documented procedures required for GMP.

4.2.2 Quality manual
d) a definition of the extent to which this annex applies to its quality management system and its business processes.

4.2.3 Control of documents
Documents that impact product quality shall be reviewed and approved by the Quality Unit.

The Quality Unit shall securely retain at least one copy of obsolete documents. The retention period of obsolete documents shall be defined.

If electronic signatures are used on documents they shall be controlled to provide equivalent security to that given by a hand written signature.

4.2.4 Control of records
Entries in quality records shall be clear, indelible and made directly after performing the activity (in the order performed). Quality records and any corrections made to them shall be traceable.

Quality records shall be kept for a defined period. The period shall be justified. For batch records, this period shall not be less than one year past the cosmetic ingredient expiry or retest interval.

4.3 Change Control
There shall be a documented procedure defining the responsibilities and requirements for the evaluation and approval of changes that may impact the quality of the cosmetic ingredient.

Evaluation and approval of changes shall occur prior to the implementation. The quality unit shall evaluate changes that may impact on the quality of the cosmetic ingredient. Where the impact of the change on the quality of the cosmetic ingredient is determined to be significant, such changes shall be communicated to customers (see 7.2.3). Records of the change control process shall be retained.

5. Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to GMP by:

f) communicating to the organization the importance of GMP; and

g) ensuring that GMP objectives are established.

5.2 Customer focus

No additional requirements to ISO 9001.

5.3 Quality policy

f) includes a statement on the extent to which GMP as defined in this annex will be used in the organization.

5.4 Planning

5.4.1 Quality objectives

Top management shall set objectives for adherence to GMP.

5.4.2 Quality Management system planning

No additional requirements to ISO 9001.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

The following responsibilities shall be defined:

- approving suppliers of quality critical materials and services,
- approving or rejecting raw materials, packaging components, intermediates and finished cosmetic ingredients,
- reviewing records to ensure that no critical errors have occurred or, if these occur, that they are fully investigated,
- participating in authorizing changes to processes, specifications, procedures, test methods and investigating failures and complaints,
- approving or rejecting of the cosmetic ingredient if it is manufactured, processed, packaged, or held under contract by another company, and
- releasing the cosmetic ingredient for sale (see 8.2.4).

Internal audits shall verify that these responsibilities have been undertaken as defined (see section 8.2.2 of the EFfCI Guide for Cosmetic Ingredients 2005).
Personnel whose role is critical to ensuring cosmetic ingredient quality shall have written job descriptions.

5.5.2 Management representative

No additional requirements to ISO 9001.

5.5.3 Internal communication

GMP and regulatory requirements shall be communicated as appropriate throughout the organization.

Top management shall be notified in a timely manner of quality critical situations, such as recall or withdrawal of cosmetic ingredients, in accordance with a documented procedure.

5.6 Management review

5.6.1 General

No additional requirements to ISO 9001.

5.6.2 Review input

No additional requirements to ISO 9001.

5.6.3 Review output

No additional requirements to ISO 9001.

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

c) to meet the GMP requirements of this annex.

6.2 Human resources

6.2.1 General

No additional requirements to ISO 9001.

6.2.2 Competence, training and awareness

The organization shall

g) ensure appropriate refresher training on GMP and personal hygiene is carried out at defined intervals.

Personnel Hygiene

Where cosmetic ingredients are exposed to the environment ("open product areas"), the organization shall control personal hygiene to ensure the product is not contaminated.

Note: For guidance see the sub-chapters of section 6.2.3 in the EFfCI GMP Guide for Cosmetic Ingredients 2005.

6.3 Infrastructure

The infrastructure shall be managed, operated, cleaned and maintained to avoid raw material, intermediate and cosmetic ingredient contamination (including control of particulate matter, microbiological control and control of water quality where applicable).

The organization shall conduct and record a risk assessment based on the organization's intended use of the infrastructure to identify areas in which the cosmetic ingredient is at risk for contamination from deficiencies in buildings and/or facilities. The risk assessment shall consider the following at a minimum to identify where the cosmetic ingredient is at risk from contamination:

d) location of the operations (e.g. internal, external),
e) state of repair of the building and facility,
f) suitable size, construction and location,
g) ability to maintain a suitably clean building and facility environment,
h) operations that can affect the cosmetic ingredient quality,
i) presence of airborne contaminants, especially highly sensitizing or toxic substances.

Where existing controls to minimize the risks of cosmetic ingredient contamination are not considered effective then additional measures shall be documented and implemented.

Note: For guidance see the sub-chapter of section 6.3 in the EFfCI GMP Guide for Cosmetic Ingredients 2005.

6.4 Work environment

The work environment shall be managed to minimize risks of cosmetic ingredient contamination.

The work environment shall be managed and controlled to minimize risks of cosmetic ingredient contamination. A documented risk assessment shall be carried out to determine the necessary controls.

The documented risk assessment shall cover the following controls, as applicable:

a) air handling systems,
b) special environments,
c) cleanliness and sanitary conditions,
d) waste segregation and disposal,
e) pest control,
f) other risk assessments required by this annex.

Where maintenance of the work environment is critical to cosmetic ingredient quality, the controls shall be documented.

Note: For guidance see the sub-chapter of section 6.4 in the EFfCI GMP Guide for Cosmetic Ingredients 2005.

7 Product realization

7.1 Planning of product realization

In planning product realization, the organization shall determine the following, as appropriate

e) written testing programs for quality critical materials and the cosmetic ingredients that include specifications, sampling plans, test and release procedures, and
f) environmental, contamination and hygiene control programs.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

No additional requirements to ISO 9001.

7.2.2 Review of requirements related to the product

No additional requirements to ISO 9001.

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

d) significant operational changes.

7.3 Design and development

7.3.1 Design and development planning

No additional requirements to ISO 9001.

7.3.2 Design and development inputs

No additional requirements to ISO 9001.

7.3.3 Design and development outputs

No additional requirements to ISO 9001.

7.3.4 Design and development review

No additional requirements to ISO 9001.

7.3.5 Design and development verification

No additional requirements to ISO 9001.

7.3.6 Design and development validation
No additional requirements to ISO 9001.

7.3.7 Control of design and development changes
No additional requirements to ISO 9001.

7.4 Purchasing
7.4.1 Purchasing process
No additional requirements to ISO 9001.

7.4.2 Purchasing information
No additional requirements to ISO 9001.

7.4.3 Verification of purchased product
Activities to verify the purchased product shall use procedures designed to prevent contamination of the material.

Note: For guidance see the sub-chapters of section 7.5.1. in the EFfCI GMP Guide for Cosmetic Ingredients 2005.

7.5 Production and service provision
7.5.1 Control of production and service provision
Controlled conditions shall include, as applicable:
g) Production instructions and records,
h) Equipment cleaning,
i) Recovery of solvents and similar activities,
j) In-process mixing and blending,
k) In-process control,
l) Packaging and labelling, and
m) Records of equipment use.

The organization shall identify the need for and justify equipment cleaning and sanitization procedures and provide evidence of their effectiveness.

7.5.2 Validation of processes for production and service provision
No additional requirements to ISO 9001.

7.5.3 Identification and traceability
Identification and traceability are specified requirements; the quality management system shall include records that allow traceability of the cosmetic ingredient to raw materials and upstream to customers.

If defined storage conditions are required to ensure cosmetic ingredient quality these shall be stated on the label.

7.5.4 Customer property
No additional requirements to ISO 9001.

7.5.5 Preservation of product
The organisation shall determine if specific storage conditions are required to maintain cosmetic ingredient quality, where identified records of storage conditions shall be retained.

A cosmetic ingredient packaging system shall include:
a) written packaging specifications,
b) a rationale that the packaging does not introduce impurities to the cosmetic ingredient, and
c) cleaning procedures where containers are re-used.

Distribution records shall be kept that document all cosmetic ingredient shipments.

Note: For guidance see the sub-chapters of section 7.5.5 in the EFfCI GMP Guide for Cosmetic Ingredients 2005.

7.6 Control of monitoring and measuring equipment

No additional requirements to ISO 9001.

8 Measurement, analysis and improvement

8.1 General

No additional requirements to ISO 9001.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

No additional requirements to ISO 9001.

8.2.2 Internal audit

No additional requirements to ISO 9001.

8.2.3 Monitoring and measurement of processes

No additional requirements to ISO 9001.

8.2.4 Monitoring and measurement of product

Written procedures shall be established to monitor and control the quality characteristics of cosmetic ingredients.

These shall include, as applicable:

a) Laboratory controls,
b) Cosmetic ingredient testing and release,
c) Out-of-specification test results,
d) Retained samples,
e) Certificate of Analysis,
f) Impurities,
g) Stability, and
h) Expiry/Retest periods.

Records of in-process and final cosmetic ingredient testing shall be retained and shall identify the person performing the tests and the dates the tests were performed.

The organization shall evaluate cosmetic ingredient stability based on historic data or specific studies. The organization shall define and justify an expiry or retest interval and ensure this is communicated to the customer.

Note: For guidance see the sub-chapters of section 8.2.4 in the EFfCI GMP Guide for Cosmetic Ingredients 2005.

8.3 Control of nonconforming products

The organization shall deal with nonconforming products by one or more of the following ways:

d) By blending, reprocessing or reworking. Where this is not a normal part of the manufacturing process it shall be documented in the batch record to ensure traceability, and

e) By defining procedures for the holding, testing, and reprocessing of the returned cosmetic ingredient. Records of returned products shall be maintained.

There shall be a procedure defining how to manage the recall (withdrawal) of a cosmetic ingredient.

Note: For guidance see the sub-chapters of section 8.3 in the EFfCI GMP Guide for Cosmetic Ingredients 2005.

8.4 Analysis of data

No additional requirements to ISO 9001.

8.5 Improvement

8.5.1 Continual improvement

No additional requirements to ISO 9001.

8.5.2 Corrective action

No additional requirements to ISO 9001.

8.5.3 Preventive action

No additional requirements to ISO 9001.

DEFINITIONS AND GLOSSARY

For more details see Appendix A as well as chapter 3 of ISO 9001:2008.

APPENDIX E EFfCI GMP CERTIFICATION SCHEME RULES

Requirements for delivering EFfCI GMP Guide certified supplier status

1 European Federation for Cosmetic Ingredients (EFfCI)

EFfCI shall:

a) administer the EFfCI GMP Certifiable Standard and set up agreements with interested parties,

b) develop and publish the EFfCI GMP Guide and Certifiable Standard,

c) issue EFfCI rules of use to certification bodies and certified companies,

d) publish a list of approved certification bodies,

e) upon recommendation from an accreditation body, allocate a certificate number, sign and issue an EFfCI GMP Scheme certificate,

f) publish a list of certified companies, including the scope of their registration and the validity dates of the certificates,

g) establish an expert working group to oversee the scheme and which will address any issues arising from the implementation of the scheme,

h) update and amend the Scheme and the GMP Guide in light of experience in the operation of this scheme, and

i) where an accreditation body or organization has an issue with the Scheme, convene an expert panel that is comprised of members of the EFfCI GMP Committee to review the situation and make appropriate recommendations to resolve the issue. No member of the expert panel shall have any interest in the issue.

2 The accredited certification body

The accredited certification body shall:

a) be accredited to EN 45000 / ISO 17021 series of standards by the independent organization in the country where the certification body is registered,

b) sign an agreement with EFfCI to meet the EFfCI GMP Certifiable Standard requirements including,

   i) all certification audits (including surveillance/periodic and re-certification audits) shall be carried out by qualified auditors/lead auditors meeting the requirements in section 3,

   ii) the EFfCI GMP Certifiable Standard requirements shall be sampled at every audit, even if they represent only a small part of the business of the supplier, and

   iii) surveillance/periodic audits shall be carried out at least annually,

c) ensure that the cosmetic ingredient supplier holds and continues to hold an ISO 9001 certificate or has implemented an equivalent independently assessed quality management system that meets or exceeds the requirements in ISO 9001: Verification of this requirement can be met by reviewing the last ISO 9001 audit report, validation of the current ISO 9001 certificate, etc.,

d) ensure EFfCI GMP Certifiable Standard supplier auditors are experienced and familiar with the technology of the cosmetic ingredient supplier company/client concerned,

e) provide feedback on the EFfCI GMP Certifiable Standard's effectiveness,

i) following successful assessment recommend to EFfCI that the organization is certified to the EFfCI GMP Scheme rules,

ii) following unsuccessful assessment recommend to EFfCI that the organization certification be suspended or withdrawn,

f) following the outcome of the audit, promptly make a recommendation to EFfCI to issue, suspend, withdraw or reissue an EFfCI GMP Certificate,

g) immediately advise EFfCI if certification is suspended or withdrawn,

h) permit their logo to be included on the EFfCI GMP Scheme certificate,

i) countersign issued certificates with EFfCI,

j) seek clarification/advice from EFfCI as necessary.

3 The auditor

The auditor shall:

a) meet the EFfCI GMP Certifiable Standard Auditor requirements. They should meet the accredited certification body's requirements to be a lead auditor / auditor. Auditor registration with IRCA, ICQ-CEPAS or equivalent schemes is desirable, and

b) have experience/familiarity with the manufacturing technology used by the chemical industry or the pharmaceutical industry.

4 The organization

The organization (cosmetic ingredient supplier company) shall:

a) hold a current ISO 9001 certificate or have implemented an equivalent independently assessed quality management system that meets or exceeds the requirements in ISO 9001 (e.g. IPEC-PQG GMP, Active Pharmaceutical Ingredient GMP, Food GMP, ISO 22001, ISO 22716 etc.). Self-certification is not acceptable,

b) include the EFfCI GMP Certifiable Standard requirements in its quality system,

c) seek certification to the EFfCI GMP Certifiable Standard from an EFfCI approved certification body (see 1.1 d),

d) if appropriate, make suggestions for improving the EFfCI GMP Guide and Certifiable Standard,

e) seek clarification/advice from EFfCI as necessary.

APPENDIX F EFfCI GMP CERTIFICATION STANDARD – AUDITOR TRAINING REQUIREMENTS

These training requirements are aimed at ensuring auditors can reliably and consistently assess cosmetic ingredient suppliers for compliance with the EFfCI GMP Certification standard.

These training requirements have been designed to illustrate the key principles of GMP, in particular to auditors who are familiar with the chemical industry. Similarly these requirements will help auditors who are familiar with more demanding GMP industries (e.g. pharmaceuticals) relate to the less documented systems that will be in place for the manufacture of cosmetic ingredients.

Prerequisites

- What is a cosmetic?
  - Any substance or preparations to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and mucus membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and or protecting them or keeping them in good condition (76/768/EC updated 93/35/EC Article 1).

- What is a cosmetic ingredient?
  - Any substance or preparation that is intentionally included in a cosmetic product. Note that some substances are prohibited in law (Annex II of the cosmetic directive 76/768/EC and amendments) but there is no corresponding positive list of substances. The key requirement for a substance is that it has been assessed for safety in the cosmetic, but this duty lies with the cosmetic manufacturer.
  - Substances and materials that:
    - Impart a specific cosmetic effect. Usually these materials can be the basis of a label claim by the cosmetic manufacturer,
    - Functional aid to a formulation, e.g.
      - Surfactants,
      - Rheology modifiers,
      - Appearance modifiers,
      - Preservatives and antioxidants,
      - Colourants,
      - Perfumes,
      - Etc.
  - These substances can be manufactured by chemical, biological, synthetic and other suitable methods.

- What is GMP?
  - That part of quality assurance which ensures that products are consistently produced and controlled with a quality standard appropriate to their intended use. The GMP principles are elaborated in a later section.

- What is Cosmetic Ingredient GMP?
  - The application of the principles of GMP to the manufacture of cosmetic ingredients, such that the safety of the cosmetic ingredient is assured in a reproducible manner.
  - A set of rules designed to minimise or eliminate the risks posed to end users (consumers) from poor quality and/or contaminated cosmetic ingredients.

- An emphasis on the application and implementation of the GMP principles (see next section) which are sufficiently documented.
- Note: Validation of the manufacturing processes (including cleaning methods, equipment, computer and analytical methods) is not normally where the product quality can be adequately determined at the end of processing.

GMP Principles

These principles should be applied in relation to the risks posed to the user of the cosmetic itself, i.e. the consumer.

- The product shall not intentionally or unintentionally harm the end user.

- The product specification is not a complete definition of product quality.

- Product purity
  - Contamination control
    - Microbiology,
    - Dust and dirt,
    - Foreign objects,
    - Water quality,
    - Sampling activities,
    - etc.
  - Cross contamination control from other substances in the manufacturing environment, including other products, raw materials and process aids (e.g. lubricants etc),
  - Personal Hygiene,
  - Equipment and workplace cleanliness,
  - Equipment maintenance.

- Consistency of product quality from batch to batch, through use of the same
    - Product plant/manufacturing process,
    - Raw materials,
    - Analysis of batches,
    - Recipe,
    - Controls over reprocessing and reworking,
    - Controls over reused ingredients (e.g. solvents, recrystalisations),

- Change Management System
  - Consideration of impact of change on product quality before implementation of the change,
  - Verification that changes result in a product that is unaltered and has the same performance.

- Traceability of actions to planned arrangements
  - Records of these activities (equipment use, personnel performing functions, labelling etc)

- Traceability of raw materials to finished products
  - Not optional

- Traceability of sold products to customers
  - Not optional,
  - Ability to recall a batch from the market.

- Scientific basis for making product quality decisions – Good science - a result is worth a thousand words
  - Use of risk assessments (to product quality and end user safety)

- Suitable evidence of cosmetic ingredient stability in the supply chain up until the point of use by the cosmetic manufacturer.

- Out of Specification Procedure
  - Scientific evaluation of unexpected results

- Quality unit separate from production and commercial pressures
  - Product release

- Calibration of critical manufacturing and analytical equipment
  - Note this is to the same standards as required in ISO 9001.

Main differences between Annex and ISO 9001

- Emphasis to controlling the quality of the cosmetic ingredient

- Commitment to GMP policy, QA Manual, communication to customers etc.

- Enhanced role of quality unit in regard to
  - Reviewing and approving quality documents,
  - Batch release

- Requirement to define specific responsibilities, e.g.
  - Supplier approval,
  - Raw material, packaging release for use,
  - Batch release,
  - etc.

- Additional requirements for documented procedures (as applicable)
  - Laboratory controls,
  - Cosmetic ingredient testing and release,
  - Out-of-specification test results,
  - Retained samples,
  - Certificate of Analysis,
  - Impurities,
  - Stability,
  - Expiry/Retest periods,
  - Reworking,
  - Product Recall.

- Additional requirements for records of activities
  - Clarity of records,
  - Traceability to person performing activity,
  - Record retention periods,
  - Returned goods.

- Change control system
- Emphasis on control of the work environment to prevent contamination, for example and as applicable through controls over personnel hygiene practices, equipment construction and maintenance, cleaning etc.

- Traceability is not optional

- Raw material and packing specifications

Key Risks for Auditors to Identify

- Threats to product quality and purity
  - Management commitment to GMP,
  - Implementation of GMP principles throughout the Quality Management System,
  - Competency of personnel performing critical functions (e.g. handling exposed product, authorising changes, batch release etc) with respect to the principles of GMP,
  - Visual appearance of the Work Environment especially where the product is exposed to that environment,
  - Calibration of critical process equipment,
  - Implementation of suitable cleaning of manufacturing equipment,
  - Suitable and sufficiently documented procedures to support these critical activities, including who authorises changes,
  - Records of material and equipment use so that traceability can be effected,
  - Rework processes that have not been evaluated for impact on product quality
  - Product release process.

Photographs of Cosmetic Ingredient Manufacturing Activities
The Photographs show actual cosmetic ingredient manufacturing activities and should be used to aid Auditor training. There are no specific comments about each photograph. We recommend that the following questions be asked when examining each photograph:

- Are there areas of concern with regard to the EFfCI GMP Guide and Standard?
- What other questions would you ask to determine the risks to product quality?
- Could the photograph show a compliant situation?

Photographs and some comments are available from EFfCI in a PowerPoint presentation as an aid to auditor training and assessment.