# D 23v07

# ISO 22716 readiness

Goal


1 Good Manufacturing Practices
- 1.1 History
- 1.2 Benefits
- 1.3 Application
- 1.4 Standards, definitions, books
- 1.5 Principles and steps

2 Process approach
- 2.1 Processes
- 2.2 Mapping
- 2.3 Approach

3 Personnel
- 3.1 Principle
- 3.2 Organization
- 3.3 Responsibilities
- 3.4 Training
- 3.5 Hygiene
- 3.6 Visitors

4 Premises
- 4.1 Principle
- 4.2 Areas
- 4.3 Space
- 4.4 Flow
- 4.5 Floors
- 4.6 Toilet facilities
- 4.7 Lighting
- 4.8 Ventilation
- 4.9 Pipework
- 4.10 Cleaning
- 4.11 Maintenance
- 4.12 Consumables
- 4.13 Pest control

5 Equipment
- 5.1 Principle
- 5.2 Design
- 5.3 Installation
- 5.4 Calibration
- 5.5 Cleaning
- 5.6 Maintenance
- 5.7 Consumables
- 5.8 Authorizations
- 5.9 Back-up

6 Raw materials
- 6.1 Principle
- 6.2 Purchasing
- 6.3 Receipt
- 6.4 Identification
- 6.5 Release
- 6.6 Storage
- 6.7 Re-evaluation
- 6.8 Water

7 Production
- 7.1 Principle
- 7.2 Manufacturing
- 7.3 Packaging

8 Finished products
- 8.1 Principle
- 8.2 Release
- 8.3 Storage
- 8.4 Shipment
- 8.5 Returns

9 Laboratory
- 9.1 Principle
- 9.2 Test
- 9.3 Criteria
- 9.4 Results
- 9.5 Out-of-specification
- 9.6 Reagents
- 9.7 Sampling
- 9.8 Retain sample

10 Nonconforming products
- 10.1 Rejected products
- 10.2 Reprocessed products

11 Wastes
- 11.1 Principle
- 11.2 Types of waste
- 11.3 Flow
- 11.4 Containers
- 11.5 Disposal

12 Subcontracting
- 12.1 Principle
- 12.2 Types
- 12.3 Contract giver
- 12.4 Contract acceptor
- 12.5 Contract

13 Deviations

14 Complaints and recalls
- 14.1 Principle
- 14.2 Complaints
- 14.3 Recalls

15 Change controls

16 Internal audit
- 16.1 Principle
- 16.2 Approach
- 16.3 Follow-up

17 Documentation
- 17.1 Principle
- 17.2 Types
- 17.3 Writing
- 17.4 Revision
- 17.5 Archiving

18 Placing on the market
- 18.1 Cosmetic Regulation
- 18.2 Before placing on the market
- 18.3 After placing on the market

Annexes


**Goal of the module:** Readiness for implementation, certification, maintenance and improvement of your ISO 22716 cosmetic good manufacturing practices to be able to:

- guarantee the quality of the product with regard to consumer protection
- control the risks of cosmetics-related activities
- improve your overall performance

# 1 Good Manufacturing Practices

## 1.1 History

A "Partial Agreement" in the social and public health field was concluded in 1959 by seven Council of Europe member states (Belgium, France, Germany, Italy, Luxembourg, the Netherlands and the United Kingdom). This "Partial Agreement" was binding only on the signatory states. Subsequently many other states joined the Partial Agreement.

In 1976 the Council Directive 76/768/EEC on the “rapprochement” of the laws of the Member States relating to cosmetic products was published.

In 1994 COLIPA, (now Cosmetics Europe) the European Cosmetics and Perfume Association published the Good Manufacturing Practices for Cosmetics.

In 1995 the Council of Europe published the "Guidelines on Good Production Practice for Cosmetic Products (GPPC), Consumer Health Protection", the result of a study commissioned by the Committee of Experts on Cosmetic Products. These recommendations, intended to guide cosmetics production companies, concern the different stages of the production process allowing the control of factors affecting product quality.

In 2003 ASEAN (Association of Southeast Asian Nations) published an agreement on the Cosmetic Regulatory Scheme.

In 2006 the European Commission amended Decision 96/335/EC on the establishment of an inventory and a common nomenclature of ingredients employed in cosmetic products, Decision 2006/257/EC.

In 2007 the ISO (International Organization for Standardization) publishes the international standard ISO 22716 "Guidelines on Good Manufacturing Practices, Cosmetics". These are guidelines intended to ensure the manufacturing quality of cosmetic products concerning the different processes of production, control, storage and shipment. In form, the document is a standard, but in substance, the text is a guideline (use of the verb "should" 238 times). Only the aspects related to the quality and safety of the product are taken into account. These guidelines do not cover aspects related to product design, personnel safety or environmental protection.

Regulation (EC) No 1272/2008, known as CLP (Classification, Labeling and Packaging) of the European Parliament and of the Council of 2008, concerns the classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006. In France it has been in force since 11 July 2013.

The "Cosmetics Regulation" (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009, which entered into force on 11 July 2013, relating to cosmetic products is an essential text for any cosmetics producer (replaces Directive 76/768/EC). The Cosmetic Regulation requires that each cosmetic product placed on the European market has been manufactured in accordance with the Good Manufacturing Practices described in the ISO 22716 standard.

Commission Regulation (EU) No. 655/2013 of 10 July 2013 (the so-called "Claims Regulation") establishes common criteria that cosmetic product claims must meet in order to be used.

The implementing Commission decision of 25 November 2013 2013/674/EU concerns the Guidelines for the application of Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products.

In 2013 the FDA (Food and Drug Administration) publishes recommendations under the title Cosmetic Good Manufacturing Practices - Draft Guidance based on the ISO 22716 standard.

Law No. 2014-201 of 24 February 2014 includes the various provisions for adaptation to European Union law in the field of health. One part concerns cosmetic products and the amendments in the articles of the Public Health Code.

Commission Regulation (EU) 2015/830 of 28 May 2015 amends Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and contains in its Annex II the requirements for drawing up the Safety Data Sheet (SDS).

In 2015, the Institute for Reference Materials and Measurements will publish the Guidelines for Analytical Methods in Cosmetics (for use by laboratories) - JRC guidelines for selecting and/or validating analytical methods for cosmetics, and recommending standardization steps for analytical methods for cosmetics.

Decree No. 2015-1417 of 2015, in French, relates to cosmetic products and tattoo products.

The decree of 30 November 2016 sets the list of information contained in the declaration of establishment of manufacture or packaging of cosmetic products provided for in Article L. 5131-2 of the Public Health Code, in French.

In the French Public Health Code (CSP), Articles L.5131-1 to L.5131-8 and L.5431-1 to L.5431-9 of Law No. 2014-201 of 24 February 2014 relate to the various provisions for adaptation to European Union law in the field of health (Article 3, I and II) and Articles R.5131-1 to R.5131-15 from decree n° 2015-1417 of 4 November 2015 relating to cosmetic products and tattoo products and articles R.5431-1 to R.5431-3.

The ICCR (International Cooperation on Cosmetics Regulation) is a voluntary international group of cosmetics regulators aiming to provide the best possible protection for consumers worldwide while minimizing barriers to international trade.

The ANSM (French National Agency for the Safety of Medicines and Public Health) website contains a lot of useful information dedicated, among others, to the market surveillance of cosmetic products (Activities tab) with dedicated pages:

- market surveillance of cosmetic products: the ANSM's professions
- the post-opening period (POP)
- contacts
- the regulation of cosmetic products
- the authorities in charge of cosmetic products

In the ANSM Publications tab, a dedicated page gives access to recommendations of good practice (RBP) concerning optimal strategies for the use of cosmetic products. The pointers are short documents, answering a specific question.

The Cosmetics Observatory is a very rich site with a wide range of information.

Perfumes are regulated by the IFRA Code of Practice. Many national regulations refer to these recommendations, particularly with regard to concentrations and the use of perfumes. In order to comply with these regulations, your fragrance manufacturer must provide you with an IFRA certificate.

### 1.2 Benefits

Some benefits of ISO 22716 certification:

- preparing and facilitating legal inspections (health authorities)
- validate the compliance of your quality and safety management system with Good Manufacturing Practice (GMP) recommendations
- improved confidence of your customers and customers (ability to deliver safe, healthy and environmentally friendly cosmetic products)
- facilitate access to European and international markets (internationally recognized benchmark)
- your team is made aware around a rewarding project
- always produce products with the quality required for the intended use
- improve the efficiency of your company
- heightened competition
- compliance with legal requirements

***True story***

*L'Oréal, one of the world leaders in the cosmetics industry, has implemented ISO 22716 to guarantee the quality of its products and the safety of consumers. The standardization of procedures and the establishment of a quality culture have made it possible to reduce manufacturing defects and improve the reliability of cosmetic products.*

*L'Oréal has recorded a significant improvement in the quality of its products, demonstrating the company's commitment to consumer safety and the positive impact of ISO 22716 on financial performance.*

### 1.3 Application

Compliance with Good Manufacturing Practices (GMP) concerns the entire branch of the cosmetics industry:

- producers (manufacturers) of finished products
- importers/exporters
- distributors (see Annex 01 and also Articles 6 and 26 of the Cosmetic Regulation)

The processes within the scope of ISO 22716 are manufacturing, storage, packaging, testing and transport.

The end user can be the consumer or a professional (hairdresser, beautician).

Since 11 July 2013, all cosmetic products on the European market are (must be) compliant with Good Manufacturing Practices (GMP), according to the ISO 22716 standard.

The ISO 22716 standard does not apply to research and development activities or to the distribution of finished cosmetic products.

A product intended to be ingested, inhaled, injected or implanted into the human body cannot be considered a cosmetic product.

A cosmetic product may not be represented as having curative or preventive properties with respect to human disease. In this case the product is a medicinal product within the meaning of Article L.5111-1 of the Public Health Code.

But some products (such as some soaps) can be considered as both cosmetics and drugs at the same time (see the FDA Cosmetics & U.S. Law).
The ISO 22716 standard has been approved and accepted by many global regulatory bodies such as the FDA (Food & Drug Administration), the ICCR (International Cooperation on Cosmetics Regulation) and the European Committee for Standardization (ECS).

### 1.4 Standards, definitions and books

#### 1.4.1 Standards

Some ISO standards on cosmetics:

- ISO 22716:2007, Cosmetics - Good manufacturing practices (GMP) – Guidelines on Good manufacturing practices
- ISO 17516:2014, Cosmetics - Microbiology - Microbiological limits
- ISO 18416:2015, Cosmetics - Microbiology - Detection of Candida albicans
- ISO 21150:2015, Cosmetics - Microbiology - Detection of Escherichia coli
- ISO 22718:2015, Cosmetics - Microbiology - Detection of Staphylococcus aureus
- ISO 16128-1:2016, Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products — Part 1: Definitions for ingredients
- ISO 16128-2:2017, Cosmetics — Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients — Part 2: Criteria for ingredients and products
- ISO 16212:2017, Cosmetics - Microbiology - Enumeration of yeasts and moulds
- ISO 18415:2017, Cosmetics - Microbiology - Detection of specified and unspecified microorganisms
- ISO 21149:2017, Cosmetics - Microbiology - Enumeration and detection of mesophilic aerobic bacteria
- ISO 29621:2017, Cosmetics - Microbiology - Guidelines for risk assessment and identification of products with low microbiological risk
- ISO 11930:2019, Cosmetics - Microbiology - Evaluation of the antimicrobial protection of a cosmetic product

All of these standards and referential can be ordered (in electronic or paper format) on the ISO website.

More than 28,000 standards (in English and other languages) are available free of charge on the Public.resource.Org website.

The ISO 22716 certification is necessary to produce cosmetic products because the Cosmetic Regulation 1223/2009 indicates that the ISO 22716 attestation must be added to the Product Information File (PIF) of your cosmetic product. The placing on the market of a cosmetic product must comply with the rules (requirements) of the Cosmetic Regulation.

The ISO guide "The integrated use of management system standards" of 2018, contains relevant recommendations on the integration of management systems.

Some useful sites related to cosmetics:

- ANSM - National Agency for the Safety of Medicines and Health Products
- Cosmetic ingredient database - European Commission database for information on cosmetic substances and ingredients
- Ministry of Solidarity and Health France
- DGCCRF - Directorate-General for Competition, Consumer Affairs and Fraud Control
- Le flacon - the composition of your cosmetic products under the magnifying glass
- Cosmetic valley - the world's leading resource centre for cosmetic perfumery in terms of know-how, research and training
- FEBEA - federation of beauty companies
- Ecomundo - experts on chemical substances and their regulatory framework

### 1.4.2 Definitions

**The beginning of wisdom is the definition of terms. Socrates**

As seen in paragraph 1.1 ISO 22716 is a standard and at the same time they are guidelines. The verb "should" seems to be more flexible than the verb "shall". But to comply with either verb is to achieve the same end (to meet/fulfill a recommendation or requirement).

Some specific quality and cosmetic terms:

**Acceptance criteria**: *everything that is compared to the requirements to assess compliance*
**ANSM:** *National Agency for the Safety of Medicines and Health Products*
**Audit:** *a systematic and independent examination to determine whether activities and results meet pre-determined arrangements and are capable of achieving objectives*
**Batch**: *quantity of a cosmetic product manufactured in a homogeneous operation cycle*
**Bulk product (semi-finished)**: *any intermediate product of a process or activity*
**Calibration**: *the set of operations for establishing the relationship between the values indicated by the instrument and the known values of a reference standard*
**Cleaning**: *any operation to separate and remove dirt by means of chemical, mechanical or temperature action*
**Conformity**: *fulfillment of a specified requirement*
**Contamination**: *presence of undesirable substances in the product*
**Control (inspection)**: *actions of measuring, testing, and examining a product, service, process or material to determine compliance with requirements*
**Corrective action**: *action to eliminate the causes of nonconformity or any other undesirable event and to prevent their recurrence*
**Cosmetic product**: *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 (Article 2, 1a of Cosmetic Regulation)*
**CPNP**: *Cosmetic Products Notification Portal*
**CSSC**: *Scientific Committee on Consumer Safety*
**Customer**: *anyone who receives a product*

**Document**: *any support allowing the treatment of information*
**Effectiveness**: *capacity to realize planned activities with minimum effort*
**Efficiency**: *financial relationship between achieved results and used resources*
**Finished product**: *any end result of a process or activity*
**Maintenance (preventive)**: *a set of planned preventive actions to maintain e-quipment in perfect condition and ensure the specified service*
**Making available on the market**: *any supply of a cosmetic product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge (Article 2, 1g of Cosmetic Regulation)*
**Management system**: *set of processes allowing objectives to be achieved*
**Nonconformity**: *non-fulfillment of a specified requirement*
**Organization (company)**: *a structure that satisfies a need*
**Performance**: *measurable and expected results of the management system*
**PIF**: *product information file*
**Process**: *activities that transform inputs into outputs*
**Product (or service)**: *every result of a process or activity*
**Quality management**: *activities allowing the control of a company with regard to quality*
**Quality**: *aptitude to fulfill requirements*
**Recall**: *any measure aimed at achieving the return of a cosmetic product that has already been made available to the end user (Article 2, 1r of Cosmetic Regulation)*
**Requirement**: *explicit or implicit need or expectation*
**Risk**: *likelihood of occurrence of a threat or an opportunity*
**Sanitization**: *any operation to reduce undesirable invisible contaminants*
**Subcontractor (supplier)**: *an entity that provides a product*
**SUE (serious undesirable effect)**: *an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalization, congenital anomalies or an immediate vital risk or death (article 2, 1p of the Cosmetic Regulation)*
**Top management**: *group or persons in charge of the company's control at the highest level*
**Undesirable effect**: *an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product (article 2, 1o of the Cosmetic Regulation)*
**Waste**: *anything that is destined for disposal*
**Withdrawal**: *any measure aimed at preventing the making available on the market of a cosmetic product in the supply chain (Article 2, 1q of Cosmetic Regulation)*

In the terminology of quality management systems, do not confuse:

- anomaly, defect, dysfunction, failure, nonconformity, reject and waste:
  - anomaly is a deviation from what is expected
  - defect is the non-fulfillment of a requirement related to an intended use
  - dysfunction is a degraded function that can lead to a failure
  - failure is when a function has become unfit
  - nonconformity is the non-fulfillment of a requirement in production
  - reject is a nonconforming product that will be destroyed
  - waste is when there are added costs but no value
- audit program and plan
  - an audit program is the annual planning of the audits
  - an audit plan is the description of the audit activities
- audit, inspection, auditee and auditor
  - an audit is the process of obtaining audit evidence
  - an inspection is the conformity verification of a process or product
  - an auditee is the one who is audited
  - an auditor is the one who conducts the audit

- control and optimize
  - control is meeting the objectives
  - optimize is searching for the best possible results
- customer, external provider and subcontractor
  - a customer receives a product
  - an external provider provides a product on which specific work is done
  - a subcontractor provides a service or product on which specific work is done
- effectiveness and efficiency
  - effectiveness is the level of achievement of planned results
  - efficiency is the ratio between results and resources
- follow-up and review
  - follow-up is the verification of the obtained results of an action
  - review is the analysis of the effectiveness in achieving objectives
- inform and communicate
  - to inform is to give someone meaningful data
  - to communicate is to pass on a message, to listen to the reaction and discuss
- objective and indicator
  - an objective is a sought after commitment
  - an indicator is the information on the difference between the pre-set objective and the achieved result
- organization and enterprise, society, company
  - organization is the term used by the ISO 9001 standard as the entity between the supplier and the customer
  - an enterprise, society and company are examples of organizations
- process, procedure, product, activity and task
  - a process is how we satisfy the customer using people to achieve the objectives
  - a procedure is the description of how we should conform to the rules
  - a product is the result of a process
  - an activity is a set of tasks
  - a task is a sequence of simple operations
- recall and withdrawal
  - recall is a measure to prevent consumption after distribution
  - withdrawal is a measure to prevent distribution

*Remark 1: the use of ISO 9000, ISO 22716 and Cosmetic Regulation definitions is recommended. The most important thing is to determine a common and unequivocal vocabulary for everyone in the company.*

*Remark 2: the customer can also be the user, the beneficiary, the trigger, the ordering party or the consumer.*

*Remark 3: documented information is any information that we must maintain (procedure*  *) or retain (record*  *).*

For other definitions, comments, explanations and interpretations that you don't find in this module and in annex 06, you can consult: 

- M. Varinia Michalun, Joseph C. DiNardo, Skin Care and Cosmetic Ingredients Dictionary, Milady, 2014

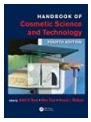
### 1.4.3 Books

**When I think of all the books still left for me to read, I am certain of further happiness. Jules Renard**

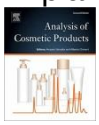
To go further, here are some books related to cosmetics:

Cosmetics, good manufacturing practices, guidelines on GMPs: the ISO 22716:2007 standard, Questions and answers, 2008 (pdf in French and English)


Marie Gale, Good Manufacturing Practices for Soap and Cosmetic Handcrafters, Cinnabar Press, 2013

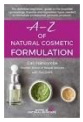

André O. Barel et al, Handbook of Cosmetic Science and Technology, CRC Press, 2014


Marie Gale, Soap and Cosmetic Labeling: How to Follow the Rules and Regs Explained in Plain English, Cinnabar Press, 2015


Amparo Salvador et Alberto Chisvert, Analysis of Cosmetic Products, Elsevier Science, 2017


Suzanne Carpenter, Soap and Cosmetic Packaging & Labeling Rules and Regulations Handbook: How to Implement Good Manufacturing Practices, CreateSpace Independent Publishing Platform, 2017


Brendan Cooper, GMP Audit Trainer: Good Manufacturing Practices Made Easy, CreateSpace Independent Publishing Platform, 2017


Gail Francombe and al, A-Z of Natural Cosmetic Formulation: The definitive beginners' guide to the essential terminology, theories and ingredient types needed to formulate professional cosmetic products, Goodness & Wonder, 2019


John Fauquembergue, SETS UP HIS BIO-COSMETIC BIO-PHARMACEUTICAL COMPANY: Beauty seduces the flesh to get permission to pass to the soul. . ., John, 2020

### 1.5 Principles and steps

**Quality is anything that can be improved. Masaaki Imai**

The quality approach is a state of mind which starts with top management as a priority strategic decision and extends to all employees.

Quality is almost free when customers are satisfied: they remain loyal to us. It's only when the customer is not fully satisfied that quality becomes very expensive to us: sooner or later the customer will go to a competitor.

**Quality remains long after the price has been forgotten**

The seven quality management principles (cf. figure 1-1) will help us achieve sustained success (cf. ISO 9000: 2015, sub-clause 2.3).

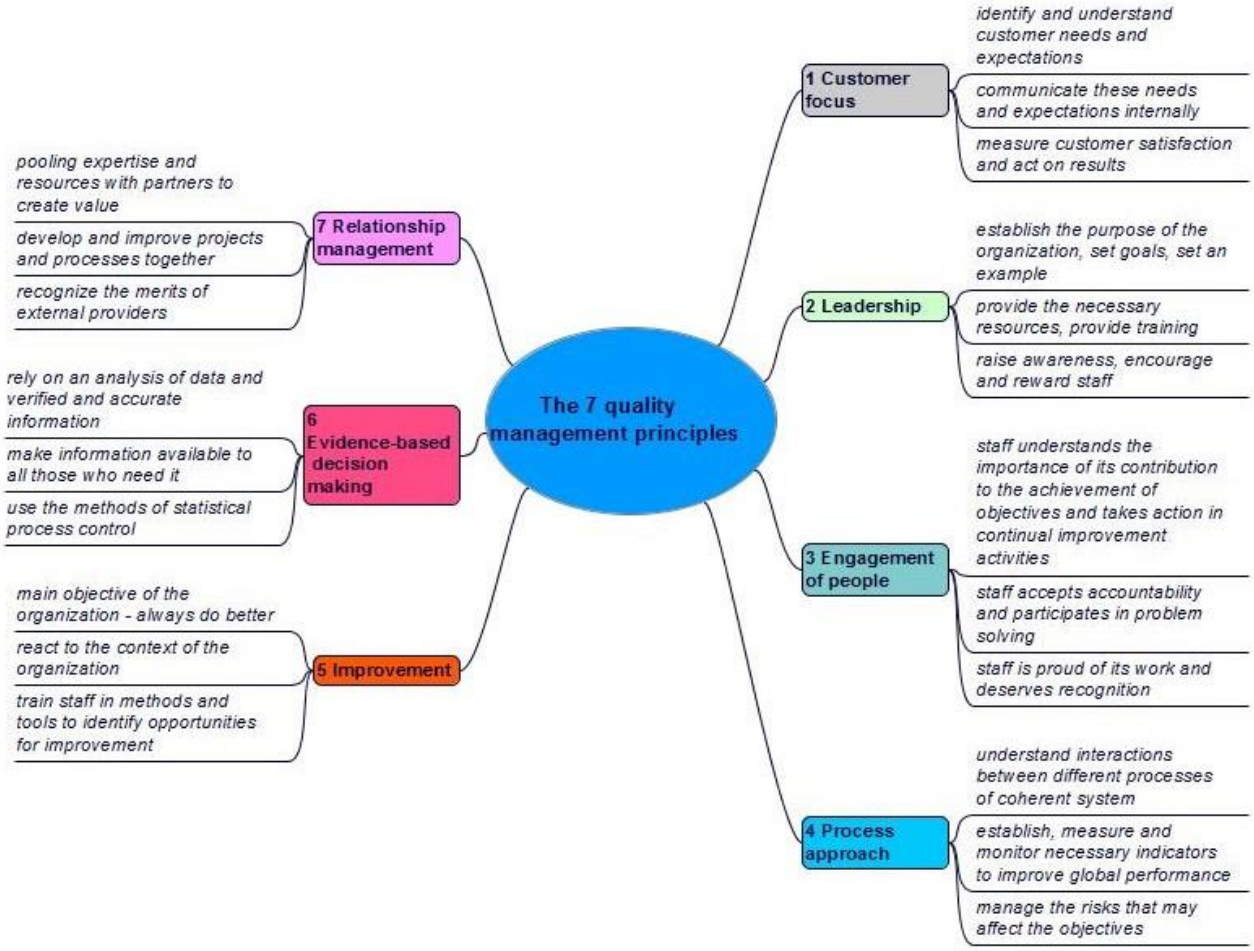



*Figure 1-1. The 7 quality management principles*

The Deming cycle (figure 1-2) is applied to control any process. The PDCA cycles (Plan, Do, Check, Act) are a universal base for continual improvement.

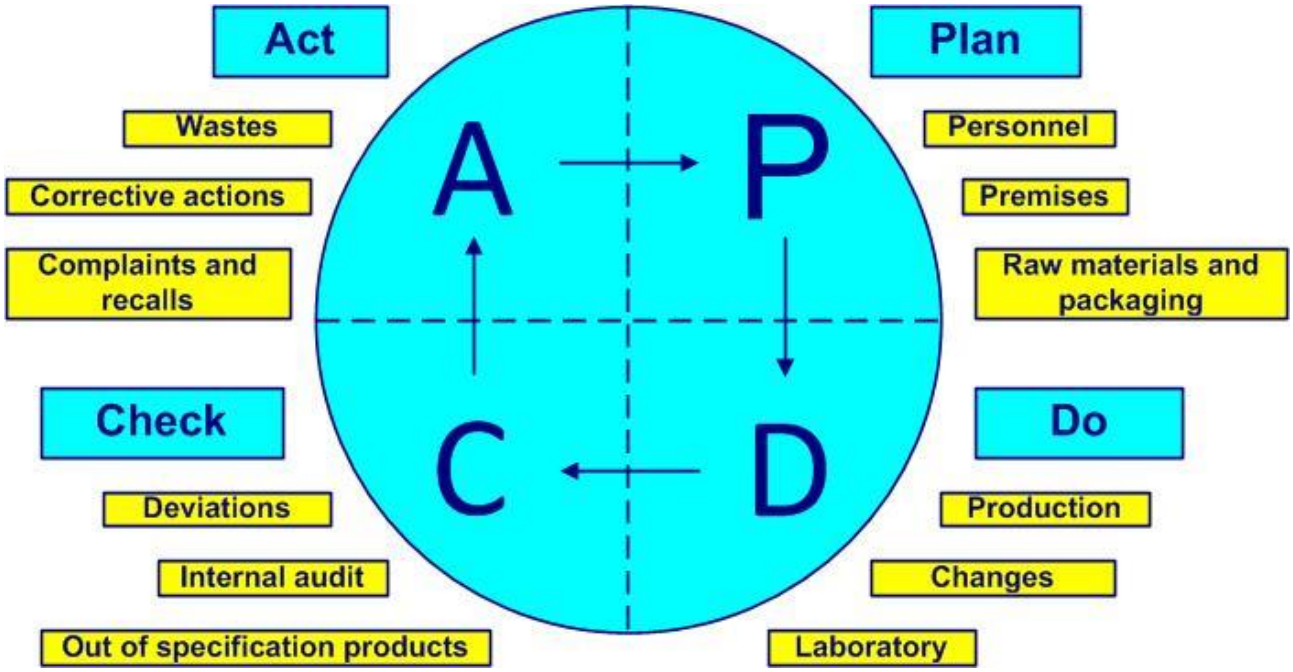



*Figure 1-2. The Deming cycle*

- Plan - planning, managing personnel, premises, raw materials, packaging materials and equipment (ISO 22716, clauses 3, 4, 5 and 6)
- Do - process, manufacture the product, manage finished products, control laboratory activities, manage subcontracting, changes and documentation (ISO 22716, clauses 7, 8, 9, 12, 15 and 17)
- Check - control out-of-specification products, manage deviations and audit (ISO 22716, clauses 10, 13 and 16)
- Act – improve, implement corrective actions, manage waste, complaints and recalls, find new improvements (new PDCA) (ISO 22716 articles 11 and 14)

For more information on the Deming cycle and its 14 points of management theory, you can consult the classic book "Out of the crisis", W. Edwards Deming, MIT press, 1982.

The 311 requirements (recommendations) of ISO 22716 in clauses 3 to 17 are shown in figure 1-3:


*Figure 1-3. ISO 22716 requirements*

## A well-prepared approach is half way to success

The approach to implement a management system in compliance with good cosmetic manufacturing practices according to ISO 22716 involves several steps. An example of preparation is shown in Figure 1-4, see also the certification project plan shown in Annex 02.

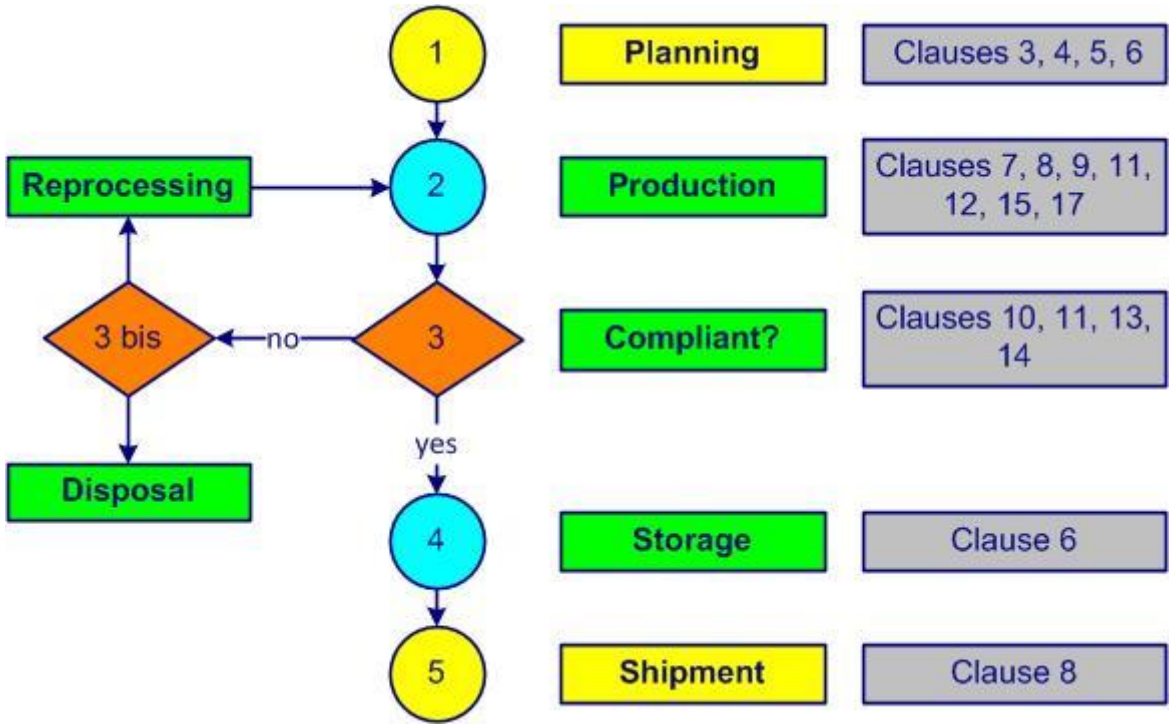



*Figure 1-4. Implementation of GMP*

**Step 1** in the implementation of cosmetic Good Manufacturing Practices is planning. Resources (financial and personnel) are confirmed by top management. A representative of management (often the quality manager) is appointed to be responsible for the project to obtain ISO 22716 certification. If you do not yet have a copy of the ISO 22716 standard, now is the time to obtain it (ISO website).

Some recommendations related to the activities of this phase:

- staff is adequately trained in good manufacturing practices for the production, control and storage of cosmetic products
- the premises ensure the protection of the product and allow efficient maintenance
- the equipment is adapted to the intended use and allows efficient maintenance
- the raw materials and packaging materials meet the acceptance criteria
- the (quality) management system documentation is in place

The activities of **step 2**, manufacturing, packaging, storage and shipment of the product, ensure that the finished products meet the acceptance criteria. The laboratory carries out controls and tests in order to guarantee this quality of materials and finished products.

Refusals (raw materials, packaging materials, bulk products and finished products) are investigated (step 3) and a decision (step 3 bis) is taken by authorized personnel. The waste is disposed of in accordance with defined sanitary provisions. Authorised personnel establish and maintain the documentation system and manage the required changes.

**Have confidence: success will come with the involvement and effort of all!**

Storage activities are carried out in **step 4**. Storage concerns:

- raw materials
- packaging materials
- bulk products
- consumables
- finished products

The last **step 5** concerns the shipment of the finished products corresponding to the defined acceptance criteria.

A relevant method to evaluate the performance level of your quality management system is the RADAR logic of the EFQM (European Foundation for Quality Management) excellence model with its nine criteria and its global score out of 1000 points.

## 2 Process approach

**If you cannot describe what you are doing as a process, you do not know what you're doing. Edwards Deming**

### 2.1 Process

The word process comes from the Latin root procedere = go, development, progress (Pro = forward, cedere = go). Each process transforms inputs into outputs, creating added value and potential nuisances.

A process has three basic elements: inputs, activities and outputs. 

A process can be very complex (launch a rocket) or relatively simple (audit a product). A process is:

- repeatable
- foreseeable
- measurable
- definable
- dependent on its context
- responsible for its suppliers

A process is, among other things, determined by its:

- title and type
- purpose (why?)
- beneficiary (for whom?)
- scope and activities
- initiators
- documented information
- inputs
- outputs (intentional and not intentional)
- constraints
- people
- material resources
- objectives and indicators
- person in charge (owner) and actors (participants)
- means of inspection (monitoring, measurement)
- mapping
- interaction with other processes
- risks and potential deviations
- opportunities for continual improvement

A process review is conducted periodically by the process owner.

**Review**: *a survey of a file, product or process so as to verify if pre-set objectives are achieved*

The components of a process are shown in figure 2-1: 

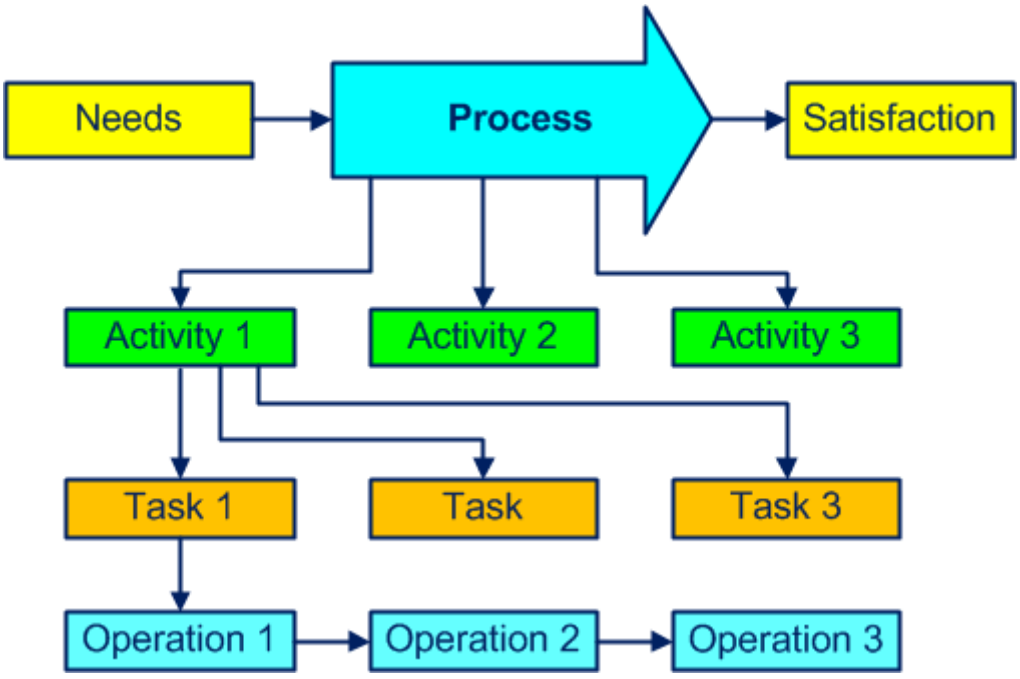



*Figure 2-1. Components of a process*

Figure 2-2 shows an example that helps to answer some questions:

- which materials, which documents, which tooling? (inputs)
- which title, what objective, which activities, requirements, constraints? (process)
- which products, which documents? (outputs)
- how, which inspections? (methods)
- what is the level of performance? (indicators)
- who, with what competence? (people)
- with what, which machines, which equipment? (material resources)

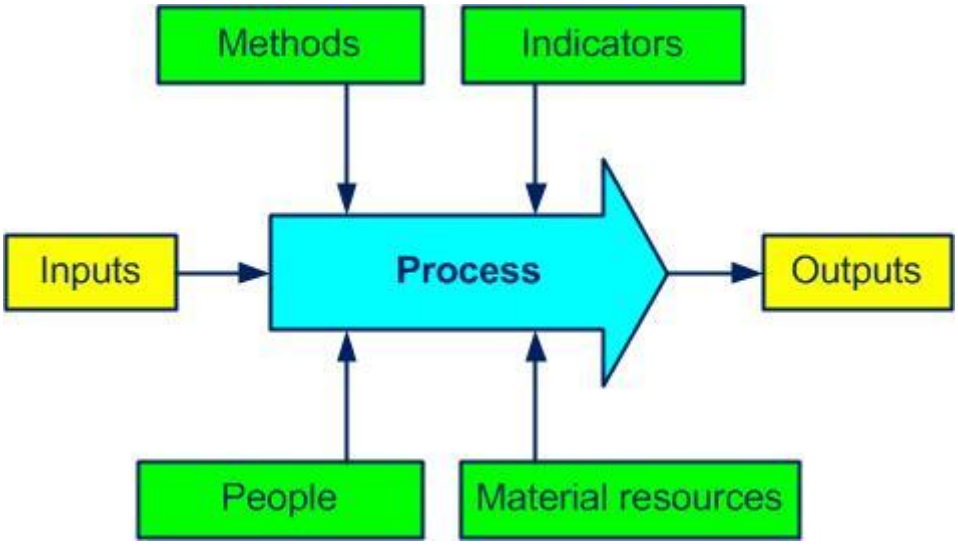



*Figure 2-2. Some elements of a process*

Often the output of a process is the input of the next process.

You can find some examples of process sheets in the document pack D 02 and a list of processes in annex 03.

Any organization (company) can be considered as a macro process, with its purpose, its inputs (customer needs and expectations) and its outputs (products/services to meet customer requirements).

Our preference is to identify a process using a verb (buy, produce, sell) instead of a noun (purchases, production, sales) to differentiate the process from the company's department or documented information to maintain and recall the purpose of the process.

The processes are (as we shall see in the following paragraphs) of management, realization and support types. Do not attach too much importance to process categorizing (sometimes it's very relative) but ensure that all the company's activities at least fall into one process.

### 2.1.1 Management processes

Management processes are also known as piloting, decision, key or major processes. They take part in the overall organization and include elaboration of the policy, deployment of the objectives and all needed checks. They are the glue of all the realization and support processes.

The following processes can be part of this family:

- develop strategy
- establish policy
- plan
- address risks
- communicate
- acquire and manage resources
- negotiate contract
- establish process ownership
- conduct an audit
- improve

A list of risks is shown in Annex 04 and the establishment of risk levels is shown in Annex 05. 

The risk approach (cf. ISO 31000) is a process with some distinct activities: 

- identification (list)
- analysis (impact)
- assessment (type and level)
- processing (options)
- monitoring and review (effectiveness)

The "Manage risk" process is shown in Annex 07. An example of the "Risk Management" procedure is shown in Annex 08. A risk mitigation action plan is shown in Annex 09. 

### 2.1.2 Realization processes

The realization (operational) processes are related to the product, increase the added value and contribute directly to customer satisfaction.

They are mainly:

- receive, store and deliver
- control suppliers
- purchase components
- produce and package products
- clean and maintain equipment
- implement traceability
- analyze and test
- inspect production
- sell products
- control nonconformities
- implement corrective actions

### 2.1.3 Support processes

The support processes provide the resources necessary for the proper functioning of all other processes. They are not directly related to a contribution of the product's added value, but are still essential.

The support processes are often:

- control documentation
- provide information
- manage staff
- provide training
- keep accountability
- acquire and maintain infrastructure
- manage inspection means

## 2.2 Process mapping

Par excellence process “mapping” is a multidisciplinary work. This is not a formal requirement of the ISO 22716 standard but is always welcome.

The three types of processes and some interactions are shown in figure 2-3 and annex 10.

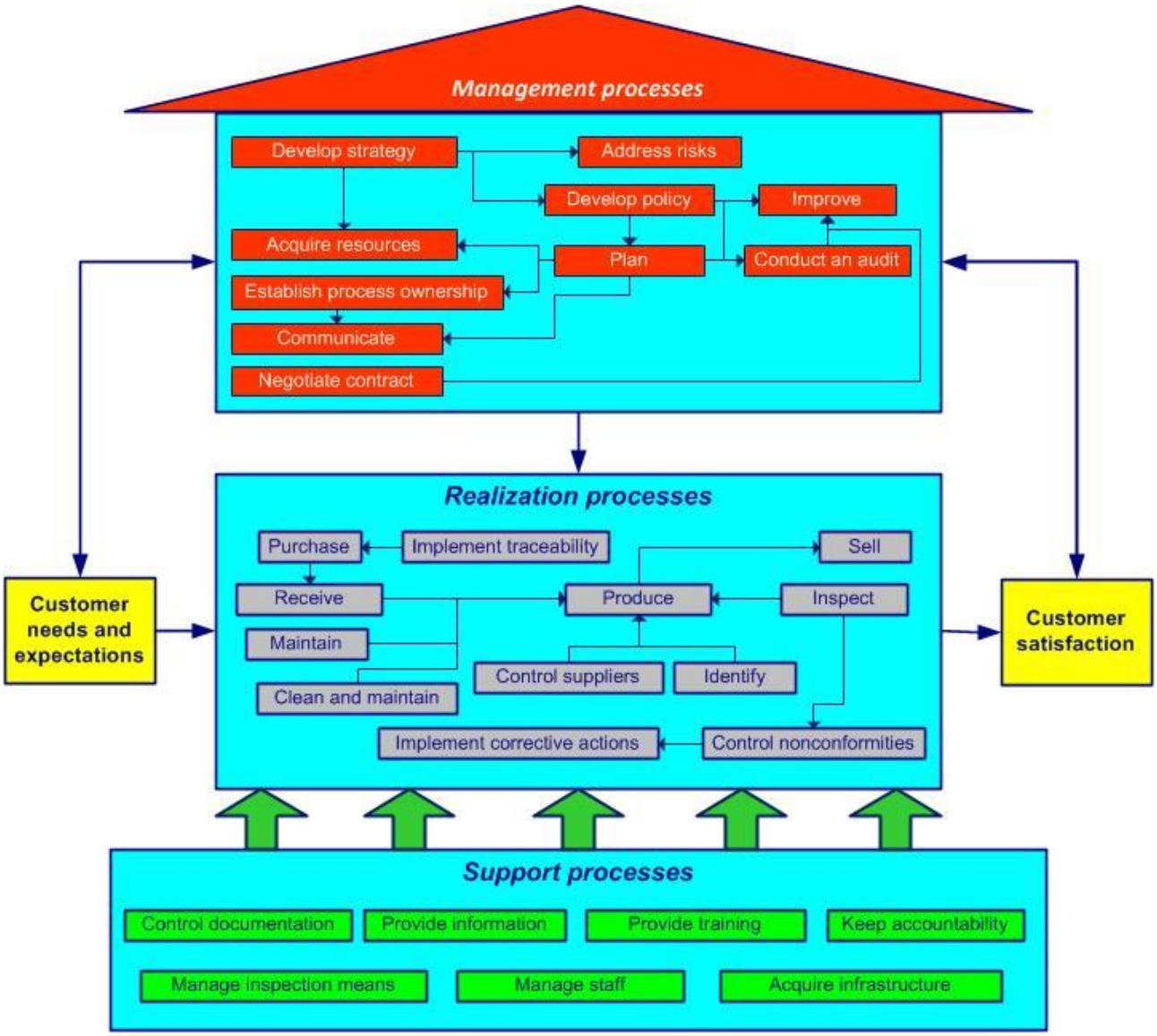



*Figure 2-3. The process house*

Mapping, among other things, allows you to:

- obtain a global vision of the company
- identify the beneficiaries (customers), flows and interactions
- define rules (simple) for communication between processes

To obtain a clearer picture, you can simplify by using a total of about 15 core processes. A core process can contain several sub-processes: for example, the process "develop a quality management" can involve:

- develop strategy
- establish policy
- plan
- establish process ownership
- address risks
- communicate
- acquire resources
- deploy objectives
- conduct an audit

- improve

Another example (“produce” process, figure 2-4):

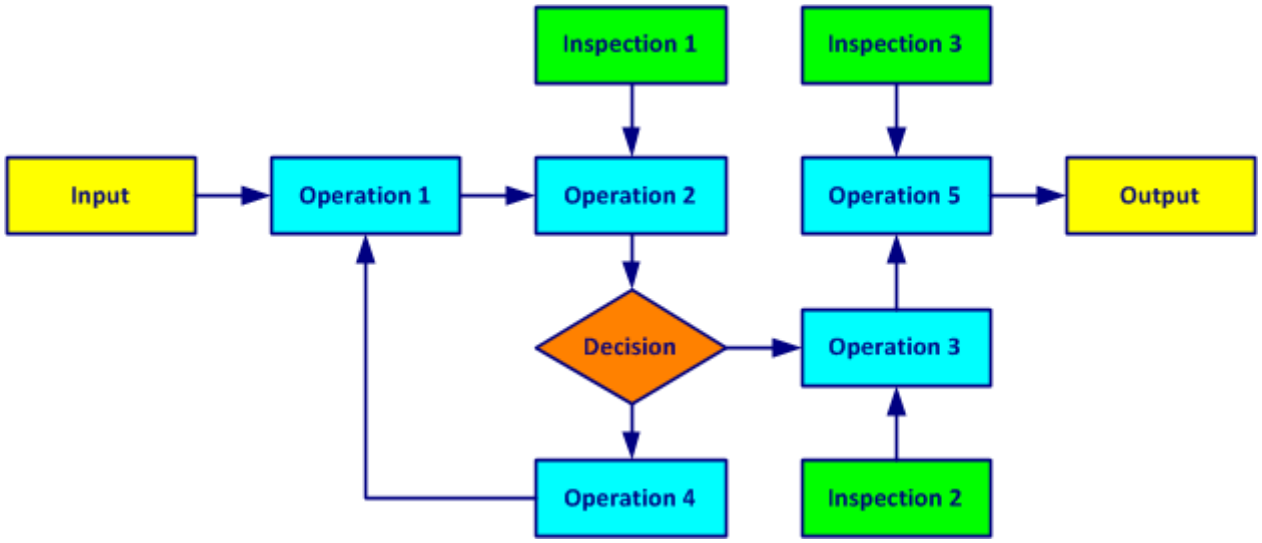



*Figure 2-4. Produce process*

## 2.3 Process approach

**Simple solutions for now, perfection for later**

The process approach contributes enormously to the efficient management of the company (cf. annex 11).

**Process approach**: *management by the processes to better satisfy customers, improve the effectiveness of all processes and increase global efficiency*

The process approach:

- emphasizes the importance of:
  - understanding and complying with customer requirements
  - prevention so as to react to unwanted elements such as:
    - customer returns
    - waste
  - measuring process performance, effectiveness and efficiency
  - permanently improving objectives based on pertinent measurements
  - process added value
- relies on:
  - methodical identification
  - interactions
  - the sequence and
  - process management, which consists of:
    - determining objectives and their indicators
    - piloting related activities
    - analyzing obtained results
    - permanently undertaking improvements
- allows one to:
  - better view inputs and outputs and their relationship

    - clarify roles and responsibilities
    - judiciously assign necessary resources
    - break down barriers between departments
    - decrease costs, delays and waste
- and ensures in the long run:
    - control
    - monitoring and
    - continual improvement of processes

The process approach **is not**:

- crisis management ("You will not solve the problems by addressing the effects")
- blaming people (“Poor quality is the result of poor management." Masaaki Imai)
- prioritizing investments (“Use your brain, not your money." Taiichi Ohno)

## 3 Personnel

### 3.1 Principle

*Requirement 1*

**The right person, in the right place, at the right time**

All persons involved in the activities of material reception, production, packaging, inspection, storage and shipping of cosmetic products have appropriate training and experience and are aware of ISO 22716 Good Manufacturing Practices. See also Articles 4, 5 and 25 of the Cosmetic Regulation.

### 3.2 Organization

*Requirement 2 to 7*

**When you sweep the stairs, you start at the top. Romanian proverb**

The organization chart of the company shows the structure, organization and some of the links between the different departments, for example in Figure 3-1:

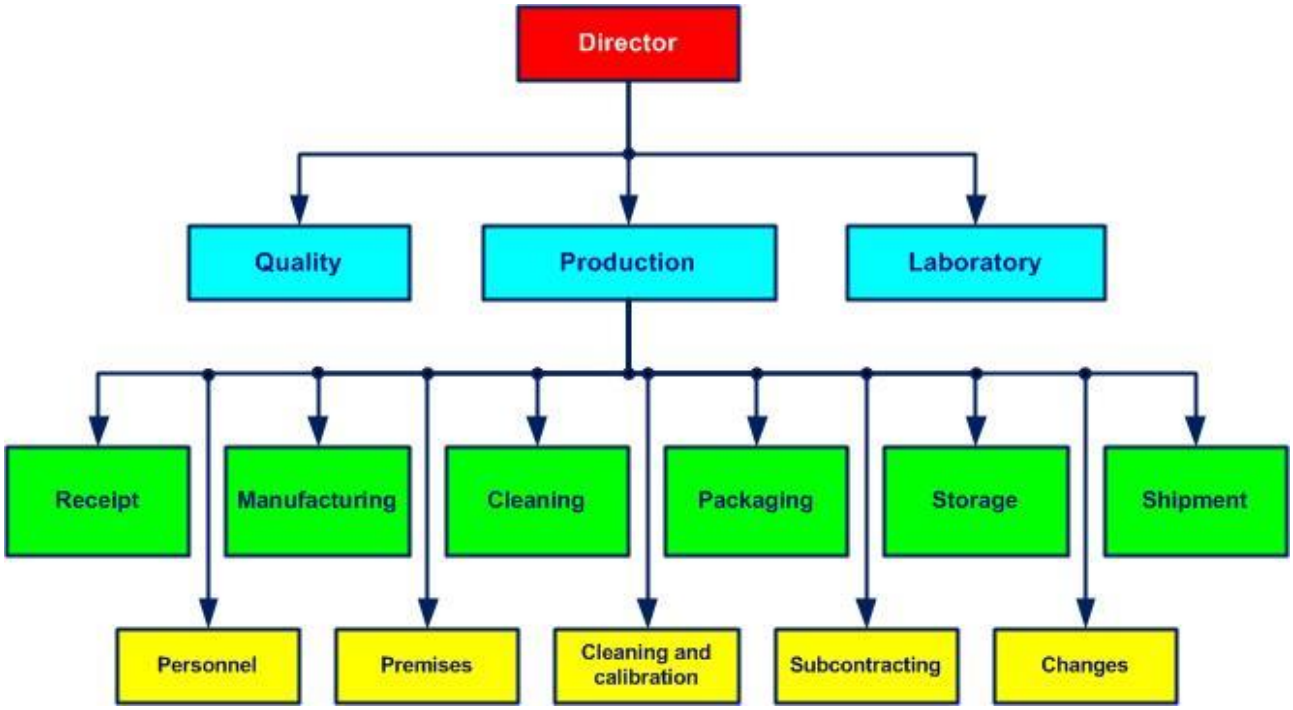



*Figure 3-1. Organization chart of a company*

The organization chart is adapted to the size of the company and the products manufactured. Top management ensures the availability of the necessary personnel for each activity.

Job descriptions clearly establish the responsibilities and authorities of each position (function, person). Some 30 examples can be found in set D 01.

The independence of each unit (department) is clearly shown in the organization chart, especially for the quality, production and laboratory departments. The organization chart is validated by the director.

### 3.3 Responsibilities

*Requirements 8 to 17*

**Responsibility cannot be shared. Robert Heinlein**

The participation and commitment of the staff in the implementation of cosmetic Good Manufacturing Practices is supported by top management (senior executives).

A document identifies the access to the different areas. This document is communicated to all staff. This activity is part of the "Communicate internally and externally" process. 

The organization chart, job descriptions and other specific documents enable staff to:

- know its place in the structure of the company
- identify its responsibilities, authorities and rights by having access to the necessary documents
- be informed and to follow the requirements of personal hygiene
- report without fear any nonconformity encountered

The "Address risk" process sets out how to identify hazards, assess and deal with risks. 

Job descriptions identify the responsibilities, authorities and duties of each individual. 

### 3.4 Training

*Requirements 18 to 26*

**Tell me and I'll remember for an hour; show me and I'll remember for a day; but let me do it and I'll remember forever. Chinese Proverb**

The personnel have the necessary skills appropriate to the responsibilities and activities carried out on the basis of the training received and the experience gained. Training in good cosmetic manufacturing practices is provided to all personnel. Appropriate training is provided for persons coming into contact with hazardous materials.

A training program is put in place to meet the needs of personnel. Training activities are adapted to the positions, duties and responsibilities and take into account the knowledge and experience of the persons to be trained. An evaluation of the know-how acquired by the personnel is carried out both hot (at the end of the training) and cold (two to three months later). The result of the evaluation of training effectiveness is documented. 

Training is conducted internally, when resources are available, or with the help of external trainers.

The "Provide training" process is a process that is continually being improved. 

Newly recruited persons receive, in addition to training on cosmetic good manufacturing practices, training on assigned activities. 

Since 2008 (cf. articles L4141-1 to 4 of the French Labour Code) training in terms of safety at the workstation is a legal obligation. The mandatory safety and specific training courses are shown on the INRS site and in the ED 6298 brochure.

Article L6312-1 of the French Labor Code states: “Employee access to continuing professional training is guaranteed:

1° At the initiative of the employer, where appropriate, as part of a training plan;
2° At the employee's initiative, in particular in the context of individual training leave as defined in Article L. 6322-1;
3° At the initiative of the employee with the agreement of his employer within the framework of the individual right to training provided for in Article L. 6323-1 ;
4° As part of the periods of professionalization provided for in Article L. 6324-1;
5° As part of the professionalization contracts provided for in Article L. 6325-1.”

### 3.5 Hygiene

*Requirements 27 to 33*

Hygiene program are adapted to the context of the company, see Annex 12. Hygiene requirements are fully understood and strictly adhered to by the staff. 

Personnel follow the instructions for using the hand washing facilities to the letter before each entry into a production area. 

Personnel entering the areas of production, inspection and storage of cosmetic products shall wear appropriate and protective clothing to avoid contamination (e.g. uniform, gloves, goggles, hair cover). In these areas it is forbidden (strongly not recommended) to eat, drink, smoke or possess food, beverages, tobacco or medicines. Any unhygienic practices that may deteriorate the product are prohibited.

Persons with apparent illness or with uncovered wounds are excluded from direct contact with cosmetic products. The measures taken to exclude this direct contact are maintained until the medical staff certifies that the danger has been eliminated (the person is in good health).

### 3.6 Visitors

*Requirements 34 to 36*

Visitors and untrained personnel should not access the production, inspection and storage areas. When this cannot be avoided, they should be accompanied and informed about hygiene requirements and protective clothing. 

 Minute of relaxation. Cf. joke “Gold contract”.

*Good practices*

- *the organization chart shows the independence of the quality department*
- *the job description of the quality manager includes the task of raising staff awareness of good manufacturing practices*

- *cold and hot staff evaluations for the training courses provided are up-to-date*
- *new recruits are informed and have assimilated the induction program*
- *clothing is always clean (reserve clothing is available)*

## *Bad practices*

- *the dependency of the production quality department is not defined*
- *the job description of the quality manager is not up-to-date*
- *the authority to stop production is not included in the quality manager's job description*
- *there is no document on staff awareness of good manufacturing practices*
- *the evaluation of training courses taken is not recorded*
- *new recruits are not informed about the induction course*
- *personal hygiene rules are not always followed (dress code not applied for the production area)*


## 4 Premises

### 4.1 Principle

*Requirements 37 to 40*

The premises efficiently provide:

- the protection of the product
- maintenance, cleaning and sanitization
- reduction the risk of mix-up of:
  - products
  - raw materials
  - ingredients
  - packaging items
  - containers
  - consumables

Decisions on the design of the premises take into account the type of cosmetic product manufactured, the existing environment, and the cleaning and sanitization methods used.

### 4.2 Areas

*Requirement 41*

Receiving, production, inspection, storage, shipping, ancillary, toilet and sanitary areas are identified, defined and separated.

### 4.3 Space

*Requirement 42*

Necessary and preferably separate space is provided for all activities related to the cosmetic product such as:

- receipt
- sampling
- quarantine
- storage in reception
- measurement and weighing in production
- distribution
- transformation
- storage of bulk products
- laboratory
- packaging
- inspection
- storage of finished products
- maintenance
- shipment

### 4.4 Flow

*Requirement 43*

The flow of materials, products and personnel is clearly established. Establishing and adhering to one way flow greatly reduces the possibility of contamination.

**4.5 Floors**
*Requirements 44 to 50*

The floors, walls, ceilings and windows of the production rooms facilitate cleaning and sanitization to keep them clean and in good repair.

When ventilation is adequate the windows do not open. If the windows do open a screen is put in place.

New constructions allow efficient cleaning and maintenance. It is preferable to use smooth surfaces that are resistant to the corrosive action of cleaning and sanitizing agents.

**4.6 Toilet facilities**
*Requirements 51 to 53*

Toilets and washrooms are kept regularly clean and ventilated. Toilets and sanitary facilities are separated from production areas. Shower rooms may be provided.

**4.7 Lighting**
*Requirements 54 to 56*

The lighting is adequate and sufficient for all areas of the company. The lighting is such that in the event of breakage, the containment of debris is ensured and the product is protected in all circumstances.

**4.8 Ventilation**
*Requirements 57 to 58*

Ventilation is adequate to guarantee production activities and the product is protected in all circumstances. Particular attention is paid to the treatment of dust-generating products, such as compact powders or talcum powder.

**4.9 Pipework**
*Requirements 59 to 63*

Pipework, drains and ducts do not permit the contamination of materials, products, surfaces and equipment by leakage or condensation.

Drainage lines are kept clean and are sloped sufficiently to prevent back flow.

When designing consider:

- avoid exposed overhead roof beams, pipes and ducts
- keep exposed pipes away from walls to allow for cleaning
- in all circumstances protect the product

**4.10 Cleaning**
*Requirements 64 to 67*

Premises for receiving, production, inspection, storage and dispatch activities are regularly maintained in a clean condition to protect cosmetic products. Cleaning and sanitizing agents are specified and effective. Cleaning and sanitizing programs for each area are established and adhered to.

The process "Clean and sanitize premises and equipment" describes the activities related to the cleaning and sanitization of premises and equipment. 

In order to avoid contamination, cleaning methods such as vacuuming and wet wiping are preferred over compressed air or brushes.

### 4.11 Maintenance

*Requirement 68*

The maintenance in a good state of repair of the premises for the activities of reception, production, inspection, storage and shipment is established and followed. 

### 4.12 Consumables

*Requirement 69*

Consumables used for cleaning, sanitization and maintenance of the premises for receiving, production, inspection, storage and shipment do not affect the quality of the products manufactured.

### 4.13 Pest control

*Requirements 70 to 72*

Premises for receiving, production, inspection, storage and shipment activities are designed, constructed and maintained to limit the access of insects and pests. A cleaning and checking program is established and regularly monitored. Measures are taken to ensure that pests are not allowed to enter the premises. 

*Good practices*

- *all areas are segregated, ventilated and adequately lit*
- *the cleaning program is applied and followed*
- *consumables for hand washing and room cleaning are appropriate*
- *the temperature of the raw material storage room is continuously monitored*
- *the pest control system is effective*

*Bad practices*

- *the production premises are not suitable (not enough space)*
- *the lighting in some production areas is not strong enough (intense) and cannot be moved to a specific location*
- *the storage premises are poorly maintained*
- *there is no separation between the production and storage areas for finished products*
- *the identification of certain areas is not carried out*
- *the frequency of cleaning of some premises is not adapted to the product*
- *the pest protection program does not include regular cleaning*
- *the floor material is not suitable for easy cleaning*
- *the one way flow of the product is not carried out (danger of contamination)*
- *the layout of the premises does not favor meeting staff hygiene rules*
- *ventilation in the weighing area is not sufficient*