CERTIPHARM STANDARD

KEY WORDS

Standard Certification

ABBREVIATIONS

CPMP	Committee for Proprietary Medicinal Products
EMEA	European Agency for the evaluation of Medicinal Products
EP	European Pharmacopeia
EU	European Union (European Communities)
FP	Finished Products
GMP	Good Manufacturing Practices
ICH	International Committee on Harmonization of technical requirements for registration of pharmaceuticals for human use
IPEC	International Pharmaceutical Excipients Council's
QA	Quality Assurance
QC	Quality Control
RM	Raw Material
SF	Semi-finished Products
WHO	World Health Organization

* N.B. The term "shall" is used throughout this document to indicate those provisions which, reflecting the requirements of the standard are mandatory.
Where the term "should" is used in this requirements, it is intended to indicate those provisions which are expected to be adopted. The rationale for any variation from these requirements shall be documented.

CONTENTS

Essential elements

Good Practices

0 – INTRODUCTION

Safety of health products is strongly depending of the quality management of the producers and their suppliers.
Within an organization, quality assurance serves as a management tool.
In contractual situations, quality assurance also serves to generate confidence between parties.
There should be a documented quality policy describing the overall intentions and direction of them regarding quality, as formally expressed and authorized by their management.

Quality management shall include :

- an appropriate infrastructure or "quality system", encompassing the organizational structure, procedures, processes and resources;
- systematic actions necessary to ensure adequate confidence that a material or service and documentation will satisfy given requirements for quality.
  The totality of these actions is termed "quality assurance".

The system should cover quality assurance principles.

All the parties involved in the manufacture and supply chain must share responsibility for the quality and safety of products and services to ensure that they are fit for their intended use.

The quality system can also be built when using the HACCP (Hazard Analysis and Critical Control Points) method, a multidisciplinary approach of the processes operating in the concerned organism.

1 – OBJECT AND SCOPE OF APPLICATION

The aim of this standard is to describe the basic elements and necessary criteria to get the certificate delivered by CERTIPHARM.

Specific standards and appropriate assessment questionnaires are developed from the standard.

Should the manufacturer or services provider follow official Good Practices, this would be mentioned on the certificate.

2 – REFERENCES

1 – Pharmaceutical standards and regulations

1.1 - Codes of Public Health, if applicable
1.2 - French, European, International (WHO) Good Practices, in particular :
1.2.1 – Good Manufacturing Practices (GMP)
1.2.2 – Good Laboratory Practices (GLP) (toxicology)
1.2.3 – Good Clinical Practices
1.2.4.1 – Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
ICH Harmonised tripartite guideline - Q7A (10 nov 2000)
EU : adopted by CPMP, November 2000 issued as CPMP/ICH/1935/00
MHLW : adopted November 2, 2001, PMSB Notification N°1200
FDA : published in the federal register, Vol.66, N°186, September 25, 2001, Pages 49028 to 49029
1.2.4.2 – European Directive 2003/94/EC – 8 Oct 2003.
Annex 18 (July 2001)
1.2.5 – OMS WHO Technical Report Series
32nd, 33rd, 34th, 36th, 38th, 908 - 2003

2 – International and national standards

2.1 – NF EN ISO 9000 - December 2000
Quality management systems : fundamentals and vocabulary
2.2 – NF EN ISO 9001 – December 2000
Quality management systems : requirements.

3 - Bibliography

3.1 – Ateliers Nationaux de la Qualité (Tours – France)
(National Quality Workshop) 1990 – 2003.
3.2 – EOQ paper on assessing suppliers
(European Organization for Quality Section for Quality in the Pharmaceutical Industry – P.O. Box 5032 – CH-3001 BERN).
3.3 – STP Pharma Pratiques 5(4) 260-270 - 1995
« Guide for writing the quality manual for a company manufacturing drugs »
French version 5(4) 260-279 - 1995
English version 6(3) 229-249 - 1996
3.4 – STP Pharma Pratiques 1(3) 224-226 – 1991
The supplier partnership approach.
3.5 – STP Pharma Pratiques 4(1) 37-43 – 1994
« Supplier quality assurance »
3.6 – STP Pharma Pratiques 9(4) 271-285 – 1999
« Supplier's quality assurance product plan ».

3 – DEFINITIONS (alphabetical order)

3.1 Analysis certificate

A document reporting analysis criteria, the corresponding standards, the results obtained and which signifies the status of verifications and tests (approval, in compliance, accepted, etc…).

3.2 – Audit – ISO 9000:2000

Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

3.3 – Audit findings

3.3.1 – ISO 19011
Results of the evaluation of the collected audit evidence against audit criteria.

3.3.2 - CERTIPHARM
The following definitions are used :

- **Critical deviation**
  Non satisfaction of a standard's requirement, concerning the organization, application and formalization of quality system and leading risk for organism's customers or final users of product / service of this organism.
  Note : Such deviation requires an immediate correction.

- **Major deviation**
  Non satisfaction of a standard's requirement, concerning the organization, application and formalization of quality system and not leading risk for organism's customers or final users of products / service of this organism.
  Note : Such deviation requires correction at middle course (date to precise).

- **Minor deviation**
  Non satisfaction of a standard's requirement without particular risk.
  Note : Such deviation requires starting improvement of quality system (to verify next audit).

3.4 – Certificate of conformity

A document to testify that an operation or a series of operations has been carried out and that the process has been monitored (including in-process controls).

3.5 – Characteristics card (for a service)

Document describing precisely the service to supply.

3.6 – Customer – ISO 9000:2000 – 3.3.5

Organization or person that receives a product.

3.7 – In-process control

Checks performed during the process in order to monitor and, if necessary, to adjust the process to ensure that the product conforms its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.

3.7 – Inspection (Testing)

Activity such as measuring, examining, testing or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformity is achieved for each characteristic.

3.9 - Monitoring plan

A document describing the specific arrangements for assessing the conformity of the considered product, process or service.

3.10- Organization – ISO 9000:2000 – 3.3.1

Group of people and facilities with an arrangement of responsibilities, authorities and relationship.

3.11 - Process – ISO 9000:2000 – 3.4.1

Set of interrelated or interacting activities which transforms inputs onto outputs.

3.12 – Product - ISO 9000:2000 – 3.4.2

Result of process.

3.13 – Product or service quality assurance plan

A document describing the specific arrangements implemented for quality assurance.

3.14.1 – Quality assurance – ISO 8402:1994 – 3.5 (obsolete, for memory only)

All the planned and systematic activities implemented within the quality system and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality.

3.14.2 – Quality assurance – ISO 9000:2000 – 3.2.11

Part of quality management focused on providing confidence that quality requirements will be fulfilled.

3.15 – Quality assurance manual

Part of the quality manual which can be given out of the company.

3.16 – Quality audit – ISO 8402:1994 – 4.9 (obsolete, for memory only)

Systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
Note 4 – Quality audits are performed either for internal or external purposes.

3.17.1 – Quality control
Commission directive 2003/94/EC of 8 October 2003 lying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use. extracted from annexed Guide to Directive 91/356 EEC

"…Quality control is the part of GMP concerned with sampling, specifications, and testing and with the organization, documentation, and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory…"

3.17.2 – Quality control – ISO 8402:1994 – 3.4 (obsolete, for memory only)

Operational techniques and activities that are used to fulfil requirements for quality.

1 – Quality control involves operational techniques and activities aimed both at monitoring a process and at eliminating causes of unsatisfactory performance at all stages of the quality loop in order to achieve the best economic effectiveness.

2 – Some quality control and quality assurance actions are interrelated.

3.17.3 – Quality control – ISO 9000:2000 – 3.2.10

Part of quality management focused on fulfilling quality requirements.

3.18 – Quality manual – ISO 9000:2000 – 3.7.4

Document specifying the quality management system of an organization.

NOTE – Quality manuals can vary in detail and format to suit the size and complexity of an individual organization.

3.19 - Service

Prestation associated with the design, the production, the testing or the distribution of an entity, one of its components or the control of equipment and the processes involved.

3.20 – Supplier – ISO 9000:2000 – 3.3.6

Organization or person that provides a product.

3.21 – Traceability – ISO 9000:2000 -

Ability to trace the history, application or location of an entity by means of recorded identifications.

3.22 – Validation

3.22.1 – **ISO 8402:1994 – 2.18 (obsolete, for memory only)**
Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

3.22.2 – **Origin : see 3.17.1**
Action of proving, in accordance with the principles of Good Manufacturing Practices, that any procedure, process, equipment, material, activity or system actually leads to the expected results.

3.22.3 – ISO 9000:2000 – 3.8.5
Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.
Note 1 – The term "validated" is used to designate the corresponding status.
Note 2 – The use conditions for validation can be real or simulated.

4 – PRESENTATION OF THE ORGANIZATION

The organization shall be correctly identified so as to establish necessary relationship for certification.

Following elements shall be defined :

1 – Contacts (head office, plants, offices, distribution sectors, commercial sectors, etc…)

2 – Administrative and legal situation, and any element concerning organization's activities.

3 – Assigned responsibilities. An up-to-date organization chart shall be presented showing hierarchical and functional links related to quality.

4 – Commercial elements and the work-time organization for activities related to product and/or service concerned by Certipharm standard.

5 – PRODUCTS OR SERVICES SITE

Products provider

Following elements shall be described :

- location of the site or sites concerned by products,
- hierarchical and functional responsibilities,
- site drawings (location map); layout of premises, including knowledge of environment,
- schematic description of process and corresponding categories of products manufactures,
- flow of personnel, materials, intermediary products and finished products and any other flow which can have an influence on quality,
- all premises including those with controlled environment, social premises, cloakrooms and toilets, support (services areas, etc…

Associated with these elements, there shall be coded information to identify the type and direction of flows on drawings.

Services provider

Following elements shall be described :

- location of site or sites of service
- hierarchical and functional responsibilities
- type of services carried out on site or elsewhere
- premises which may have an influence on quality.

6 – QUALITY ASSURANCE

Current good manufacturing practices describe requirements in terms of quality assurance for pharmaceutical companies.
Successive updating operations specify and extend scope of their application.

Certipharm standard describes requirements in terms of quality assurance for companies, which, although they are not, strictly speaking, under the authority of GMP, participate in developing the manufacture of public health products (pharmaceutical products, medical devices …) or services.

Organizations shall have an operational quality assurance system.

7 – QUALITY CONTROL

Products provider

Quality control and testing function shall be described. The way of releasing products shall be documented. Responsibility for releasing shall be defined.

Following elements can be taken into account :

- sampling inspection and testing procedures, including in-process control which should enable the specified final product quality to be assessed
- classification and regular survey of defects and non-conformances in products and services
- examination of batch manufacturing records, associated with external elements, as necessary (supplier certificates), records or batch records
- knowledge of the related validation results
- fate of rejected products
- way of archiving and storing products and documents, the reserve sample room
- traceability in terms of used materials, production and verification means, conditions for dispatching, transportation and staff.

A report shall be written for all verification operations carried out during process.

A certificate of conformity or an analysis certificate shall be remitted to the customer on each delivery of final product.

Services provider

Quality control function for services shall be described.

Service shall be defined by its "characteristics card" which shall specify elements taken into consideration in quality assessment or control of service.

Responsibilities associated with each point of control, and all documents relating to it shall be described in characteristics of service.

8 – IN-PROCESS CONTROLS

Responsibilities shall be described for :

- acceptance of in-process control
- decision-making concerning shutdown or pursuit of a process or service
- modification to sampling or assessment plans; any reincorporation of samples into production line (for products), where acceptable i.e. when there is no risk of confusion or deterioration or heterogeneity.

In-process controls shall be laid down in writing and mentioned in the product or service quality assurance plan.

Verification methods used shall be described and validated.

Samples used for the verifications shall be the object of representative and documented sampling plans.

Results of the tests shall be recorded.

9 – CONTRACT REVIEW

Contract review procedure is a general procedure of quality system.

It takes into consideration :

- a new product or service
- a modified product or service
- a "standard" product or service.

Its major features are :

- detecting customer requirements
- study of the feasibility of the order of contract
- processing discrepancies between offer and demand and answer sent to customer
- behaviour to adopt in the event of an order modification before or after having acknowledged receipt of the order.

There can be no relationship between customer placing order and supplier (provider) without a contract including at the least the following elements :

- technical specifications of the product or description of the service
- conditions under which the product is to be produced or the service supplied
- distribution of responsibilities between various stages in process
- conformity assessment modes for the product or service.

10 - VALIDATION

Each validation operation shall be defined, planned, documented and used. In the case of validation operations using equipment, the equipment concerned shall be previously qualified. The qualification and validation operations shall be carried out at defined intervals so as to guarantee control over the process.

There shall be a structure to define the methodologies, monitor the actions and comment on the results, in agreement with customers and their professional or normative current practices, particularly concerning the following points :

- managing validations (experts, planification, budget, methods, etc…)
- defining the critical points of the process or of the service and their parameters
- managing of modifications (e.g. minor, major or critical modifications) : change controls and periodical revalidation.

A validation shall include :

- description of the process or service
- check points (parameters, limits …)
- methods and means for verification, test or assessments (by the customer or the supplier)
- sampling or sounding/random plans
- results of verification, tests or assessments
- decision and responsibilities taken
- associated correction and monitoring plan.

Validation operations shall be performed by a trained and qualified personnel.

11 – COMPUTERIZED SYSTEM

Existence of a computerized system in production process or service supply process requires the knowledge and description of :

- its general operational set-up with demonstration
- hierarchical and functional responsibilities for quality in terms of the computerized system
- security and back-up devices to protect from any accidental or voluntary modification, suppression or deterioration of the data or programs (including an emergency plan)
- influence of computerized system on quality
- training of staff to use the system with traceability in their files
- validations carried out as soon as the development started, within limits of technical possibilities and computer field of application in process environment of product or service
- sets of tests
- change control.

It implies the close cooperation of specialized departments and quality functions to study the impact of computers on the specified quality of the product or the service.

12 – HANDLING OF NON CONFORMITIES, COMPLAINTS AND PRODUCT RECALL

There shall be an effective and early examination of non conformities.

Non conformities shall be documented, issued and archived, whether they are or internal or external origin.

Conditions for not taking into account a non suitable result shall be stated in writing. Conditions of an eventual retesting shall be pre-established in writing.

Pre-defined rules shall be written, including the type of responsibility for recording, monitoring and prompting corrective action plans.

All recovery and reprocessing operations for internal non conformities shall be described and known to operators and participants, including quality control :

- for products : recycling, reprocessing, reintroduction, downgrading, delivery by waiver
- for services : discontinuation and resuming of the service, amendments.

Complaints shall be managed systematically.

Recalls of goods shall be organized by a written procedure which shall enable all the customers concerned by the same batch or the same product series to be identified.

13 – INTERNAL QUALITY AUDIT

Supplier shall establish written procedures for planning and conducting internal quality audits and keep them up-to-date, so as to verify if activities relative to quality and corresponding results are in compliance with the planned arrangements and to assess the effectiveness of quality system.

Internal quality audits shall be programmed in accordance with nature and importance of the activity being subjected to the audit.
They shall be conducted by persons other than those who have direct responsibility for activity being audited, and trained for this type of activity.

Results of audits shall be recorded and brought to the knowledge of people who have responsibility for the field being audited.
Those in charge of this field shall engage corrective action in due course so as to correct for the deficiencies found in audit.

14 – PERSONNEL

Personnel organization is crucial for quality management; the personnel shall be described in detail to present its background, its allocation and its activities.

Personnel allocation shall be known so as to establish the level of skills and responsibility for operations or service interventions.

Key position which have an influence on the quality of a product or service shall be the object of a pre-defined organization to adapt the training to the type of position concerned, or for emergency replacement or regular personnel.

Functions shall be defined, written and the supplier or service provider shall have a training programme in his possession.

Training for specific tasks and tasks in relation with the control of processes and services is necessary. It should be accompanied by habilitation in accordance with a written programme and procedures, including those for periodical reassessment.

Organization of working time shall be known and applied and shall not represent a risk for quality control of the product or the service.

Name of persons shall appear on documents used in the company.

15 – PREMISES

Product suppliers

Suitability of the nature of the premises for their use or destination shall be assessed using criteria concerning the surfaces, physical separations, general maintenance, particularly for :

- cloakrooms and toilets
- production workshops
- laboratories
- warehouses and storage areas
- utilities production units and maintenance workshops
- social premises
- offices.

Access rules to the rooms shall be known and formalized.

Premises shall be maintained in accordance with defined cleaning and maintenance instructions.

Maintenance programmes for the premises shall be adapted to the risks of contamination of the products.

They shall cover :

- cleaning and decontamination
- general and specific maintenance
- insects, rodents and intruders prevention
- decontamination in the event of accidental or unexpected pollution or contamination.

Rules of hygiene and safety shall be respected in compliance with the regulation in force.

Service providers

The nature of the premises and their maintenance do not involved the same obligations when services are involved.

Two cases can be identified :

- Premises which are not involved in the accomplishment of the service (missions carried out on the customer's premises, or a third part).
  In this case, there is no particular requirement concerning the premises apart from the fact that they should be suitable for use as offices.
- Premises which are involved in the accomplishment of the service (missions carried out on the supplier's premises, technical operations on the shopfloors, in laboratories, training rooms, premises used for transportation purposes, etc…).
  In this case, the requirements are the same as those described in the "product supplier's" chapter.

16 – EQUIPMENT

Equipment having an influence on the quality of the product or the service shall be itemized, located on the drawings and information shall be present concerning :

- capacities
- use modes
- maintenance modes
- safety and hygiene rules
- general conditions and appearance
- the type of used material if necessary

All pieces of equipment shall be qualified for their use and measurement instruments impacting on the quality of the products, shall be gauged, calibrated depending on their importance, at appropriate defined intervals.

Monitoring plans for these operations shall be written and the result shall be documented, kept and taken into account.

The impact of any type of technical intervention on equipment concerning quality shall be assessed and monitored.

Equipment and spare parts management shall also be ensured.

Any operations that are sub-contracted shall be the object of files for specification, maintenance operations, records.

There shall be procedures in order to consider the fate of products manufactured during technical interventions or dysfunctions.

Each piece equipment which has direct effects on the quality of the product or the service shall have a life-cycle docket.

Types of equipment and systems concerned are those of production, hot or cold treatment, weighing, maintenance laboratories including tooling, fluid and energy source treatment systems, whether they are used for production, monitoring, assessment, approval or maintenance of a manufacturing, conditioning, storage process…

17 – SUPPLIES AND RAW MATERIALS

"Secondary suppliers", i.e. those of the organization being audited, shall be identified and assessed according their impact on the quality of the process and of the product.

There shall be clear specifications to describe :

- the statute (approved or qualified) of the secondary suppliers
- the nature of supplies and raw materials and other materials having an impact on the quality of the manufactured products
- sampling policies
- identification methods
- the type of testing (methods, standards, status …)
- what happens to raw materials and supplies that are rejected.

Ordering and reception procedures, flow of raw materials and supplies, their status and the conditions for delivery to the production department shall be described (reception, quarantine, sampling, approval or rejection, reserve sample room, delivery and returns of supplies and raw materials).

Storage conditions shall be suitable in terms of premises, flows and damage prevention.

18 – SCRAP AND WASTE

Products

Scrap and waste resulting from the processes or verifications shall be identified.

The process undergone to transform them into unusable products inside the organization shall be described, documented and traceability should be assured.

Responsibility for the disposal of scrap and waste shall be defined and formalized.

Services

In the normative sense of the word, there is no waste resulting form services. Scrap corresponds to services which are not in compliance, not usable and abandoned.

Decisions taken and the traceability of the service shall be documented.

Responsibility for the disposal of scrap and waste shall be defined and formalized.

19 – DOCUMENTATION CONTROL

Apart the quality manual or similar like Quality Assurance Plans, there are three categories of documents :

- general organizational procedures
- operational procedures, work instructions
  (operating protocols, position sheets, missions sheets, printed forms …)
- records
  (control charts, life-cycle sheets, monitoring sheets, mission reports, lists …).

Responsibilities for the management of documents shall be defined for each level of documents and also from an overall point of view.
Quality department shall be involved in document management.
Flows of documents, from the contact right up to the delivery form of the work report, shall be described.
Working documents shall be available at the place where they are used.
Documents shall be updated, as necessary.
Drafting, approval, diffusion and archiving of documents shall be formalized, eventually on computerized supports.

It shall be possible to track documents in terms of :

- production or service means
- verification of production or service
- maintenance or monitoring
- logistics
- supports of materials or services

- personnel.

20 – DESIGN CONTROL – DEVELOPMENT

1 – General points

Any defective design may entail significant quality issues. Therefore the different stages are to be controlled, which have common features :

- work programmes
- assigned responsibilities, defined relations and interfaces
- inspection/evaluation of documents and procedures so that participants are informed, make or apply decisions during this long process.

Each stage mentioned thereafter requires a validation prior to dealing with the next stage.

2 – Preparation and planning

The company has to specify :

- stages of the design/development process such as setting up of the functional agreement, feasibility study, technical agreement, data validation, final design review
- activities relating to the assessment of each stage (project review …)
- management of communication between groups of contributors
- working procedures necessary to the progress of the studies and to the elaboration of proofs (instructions, reports, minutes).

3 – Input components for the design/development

Requirements relating to the product shall be :

- defined (relating to characteristics, functions, performances, safety, reglementation…),
- documented (put together in an explanatory booklet),
- quantified,

- re-evaluated as to their suitability (possible incomplete or ambiguous, contradictory requirements),
- resting, if the case arises, on previous similar designs.

4 – Output components for design/development

During design/development, the prior requirements are expressed into output data to allow their verification and conformity in relation to the input data. These output data supply information necessary to achievement of product, contain product acceptance criteria, define key characteristics for its use (specifications, drawings, softwares, directions for use …).

5 – Design/development review

Output components as well as input ones are subjected to a formal validation named "design review". These methodical examinations – with persons involved in previous steps – offer possibility to assess the ability to meet requirements, to identify difficulties in order to find solutions. These reviews complemented with tests, trials, prototypes, shall enable to gain control of the design (knowledge of implications, of consequences coming from the decision taken) and implement the industrial stages for the manufacture of the product.

6 – Final design/development review

This validation is performed to confirm ability of the product – resulting from the previous steps – to meet the requirements for the intended use.
Checks are achieved : all stages have been addressed, decisions have been put into effect. This recorded check is conducted by one or several qualified persons who did not participate in the progress of the analysed project. When possible, validation shall be completed before the delivery or use of the product.

7 – Change control

Changes (issues, omissions, new requirements …) are identified, documented, tested, approved before their implementation.

Consequences on the results of the design verifications – previously approved – are analysed. Way changes which can affect constituent elements of the product, are assessed.

21 – PRODUCTION

There shall be a description of production or service providing.
Documents present at the work stations shall be clear and up-to-date. They include general and operational procedures, work instructions (operating procedures, position sheets, etc …) records of the results of verifications or interventions.

Critical points of the process or of the service shall be identified so as to enable definition of :

- prospective or retrospective validation, which is periodically reassessed
- analysis of the reliability of process and of verifications (study of drift, capability of the processes, etc …), as well as the alert and non-conformity limits
- final assessment methods for specified quality of product or service.

A batch file or, if not possible, an appropriate documentation shall be established and available. Responsibilities in terms of monitoring, use (or even release), archiving, diffusion, etc… shall be identified.
For services, a contract file (corresponding to the batch record for a product) is required; it shall include all elements necessary for executing, monitoring and assessing for a given customer.

<u>Product production</u>
For products concerned, production steps shall be described, as well as equipment used in the production lines, shopfloors or sets of shopfloors.
All process steps shall be summarized in a document.
Descriptions of the production lines and the production flows shall include notion of :

- versatility or dedicated product lines
- continuous or discontinuous operations
- partial or occasional subcontracting.

Service providing

There shall be a description of the service which shall specify :

- nature of the service (its characteristics)
- references of the people involved, if necessary,
- technical, administrative and logistic arrangements made in order to execute the service
- notion of partial or occasional subcontracting.

22 – PREVENTION OF MIX-UPS, CONTAMINATION, CONFUSION AND DETERIORATION

Products production

All necessary arrangements shall be made by the supplier to avoid any form of contamination, mix-ups of products, confusion and deterioration by :

- identifying products and equipment during the processing at each stage of the process
- observance of specifications
- if necessary, workshops dedicated to one given product or having appropriate partition
- environmental control (absence of cross-contamination, temperature, relative humidity, overpressure / underpressure, lighting, …)
- workshops, production lines or machine clearance operations
- installations cleaning.

The organization thereby guarantees :

- that personnel has received training (on respect of hygiene regulations, labelling, data recording, changing …)
- consistency in the production flows (logical diagrams)
- production lines and workshops clearance between different production sessions, different batches or series of the same production
- start-up and shut-down operations on production line concerned are recorded with control of recorders and automatisms

- respect of shelf life of products, of operating steps duration
- qualification of air treatment, if necessary
- prevention of mix-ups by restricted accesses, zones partitions or appropriate physical or administrative management mode

- that cleaning operations are efficient
- management of the potential excess delivery in comparison with a supply order
- evaluation of the production yields all along the process
- management of return goods coming back from the customer
- management of non conforming products
- management of process samples.

Service providers

This chapter is not applicable to the supply of services, except within framework of a technical mission (work on a machine while running, subcontracting, transportation).

In this case, operations carried out and equipment used shall not interfer with the activity concerned by this service.

Personnel carrying out the service shall not have a negative influence on the quality of the activity concerned.

23 – CHANGE CONTROL

Any modification which has a real or potential impact on quality of the product or service, involving process, equipment, materials, testing or any other specification or characteristics shall be documented and shall generate tests to evaluate the consequences, if necessary.

Nature of each modification may be different (e.g. critical, major, minor) : the organization shall justify the classification of these modifications.

The customer shall be previously informed of modifications when they have an impact on the specified quality of the product or service. If necessary, the formal approval of the customer shall be previously requested.

At least, the previous version before any type of modification shall be archived.

24 – LABELLING – PACKAGING

Each packaging unit shall be identified.
The used labelling methods shall be described and ensure that products are identified, taking into account, if appropriated, the notion of batch.
They shall be in compliance with reference texts and models accepted by authorized personnel.

Errors prevention is an essential point of the packaging operations: text accuracy, no confusion between printed materials and products to be packaged.

Various final packaging methods for the product shall guarantee that specified quality criteria are maintained and preserve the integrity of the containers.

Customer shall be aware of the system of identification for packaging.

In all cases where regulations require so, labelling and packaging methods shall strictly respect these obligations.

25 STORAGE – PACKING – DISPATCH

This chapter is applicable for products as well as pieces of equipment used for services.

Quarantine methods shall be described as shall identification, storage, taking out of stock and delivery systems.

Special storage conditions shall be periodically checked (appearance, maintenance, temperature, relative humidity, identifications and status of verifications).

Wrapping shall be conceived in such a way that product is protected until it reaches the customer. More severe transport and storage conditions shall be taken into account (shocks, falls, climate, malevolence, thefts…)

Verifications shall be carried out at dispatch stage to ensure the conformity of product (integrity, status…).

It shall be possible to trace documents, personnel and transportation means.

Transportation conditions shall enable the specified quality criteria to be maintained, to prevent mix-ups of products : for this purpose, transport services and providers shall be assessed by the organization.