



Chapter Content

Title Pharmaceutical Good Manufacturing Practice Regulations 

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Category Ministry of Health and Welfare ( 衛生福利部 )

Part 3 Good Manufacturing Practices for Medical Devices

Chapter 1 General Provisions

Article 60 In this Part, standards related to the design, development, production, installation, and servicing of medical devices are prescribed in accordance with the contents of medical device quality management system of the International Standard Organization (ISO 13485: Medical devices — Quality management systems — Requirements for regulatory purposes).

Article 61 The terms used in this Part are defined as follows:  
(1) Active medical device: means a medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;  
(2) Active implantable medical device: means an active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;  
(3) Implantable medical device: means a medical device intended to be totally or partially introduced into the human body or a natural orifice, or to replace an epithelial surface or the surface of the eye, by surgical intervention, and which is intended to remain after the procedure for at least 30 days, and which can only be removed by medical or surgical intervention;  
(4) Advisory notice: means a notice issued by the manufacturer in accordance to the regulations of central competent health authority, subsequent to delivery of the medical device, to provide supplementary information and/or to advise what action should be taken in the use of a medical device, the modification of a medical device, the return of the medical device to the organization that supplied it, or the destruction of a medical device;  
(5) Customer complaint: means a written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market.

Article 62 For Class 2, Class 3, and Class 1 medical devices that are not listed as non-sterile or without a measuring function under Attachment 2 of the Regulations Governing Management of Medical Devices, their manufacturers shall comply with the requirements in Chapter 2 of this Part.  
For Class 1 medical devices that are listed as non-sterile or without a measuring function under Attachment 2 of the Regulations Governing Management of Medical Devices, their manufacturers shall comply with the requirements in Chapter 3 of this Part.  
Requirements in Chapter 3 of this Part shall be implemented one year after the date of promulgation.

Chapter 2 Standard Mode

Section 1 Quality Management System

Article 63

Manufacturers shall establish, implement and maintain a documented quality management system that conforms to the requirements of these Regulations.

Manufacturers shall adopt the following measures:

- (1) Identifying the processes and applications needed for the quality management system;
- (2) Determining the sequence and interaction for implementation of the quality management system;
- (3) Determining criteria and methods needed for the quality management system to ensure effective operation and control of the processes;
- (4) Ensuring the availability of resources and information necessary to support the operation and monitoring of quality management system processes;
- (5) Monitoring, measuring and analyzing the processes of quality management system;
- (6) Implementing actions necessary to achieve planned results of quality management system processes and maintain the effectiveness of these processes.

Where manufacturers choose to purchase from a supplier part or whole of any process that affects product conformity with quality management system requirements, the manufacturers shall ensure control over such purchased processes.

Control of such purchased processes shall be identified within the quality management system.

Article 64 The quality management system documentation shall include the following:

- (1) Documented statements of a quality policy and quality objectives;
- (2) A quality manual;
- (3) Documented procedures required by these Regulations;
- (4) Documents needed by the manufacturer to ensure the effective planning, operation and control of its quality management system processes;
- (5) Records required by these Regulations; and
- (6) Any other documentation specified by the central competent health authority.

Where these Regulations specify that a requirement, procedure, activity or special arrangement be documented, it shall, in addition, be implemented and maintained by the manufacturers.

For each type or model of medical device, manufacturers shall establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirements.

These documents shall define the complete manufacturing process and, if applicable, installation and servicing.

Article 65 Manufacturers shall establish and maintain a quality manual, the contents of which include the following:

- (1) The scope of the quality management system;
- (2) The documented procedures established for the quality management system; and
- (3) A description of the interaction between the processes of the quality management system.

The above quality manual shall outline the structure of the documentation used in the quality management system.

Article 66 Documents required by the quality management system shall be controlled. These include but not limited to any type of documented records, which shall all be controlled according to the requirements of these Regulations.

Manufacturers shall establish a documented procedure that includes the following, to define the controls needed to:

- (1) Review and approve documents for adequacy prior to issue;
- (2) Review and update as necessary and re-approve documents;
- (3) Ensure that changes and the current revision status of documents are identified;
- (4) Ensure that applicable documents are available at points of use;
- (5) Ensure that documents remain legible and readily identifiable;
- (6) Identify documents of external origin and control their distribution; and

(7) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for necessity. Manufacturers shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function which has access to pertinent background information upon which to base its decisions.

Manufacturers shall define the period for which at least one copy of obsolete controlled documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the manufacturers, but not less than the retention period of any resulting record, or as specified by regulatory requirements.

Article 67 Manufacturers shall establish and maintain records to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable.

Manufacturers shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

Manufacturers shall retain the records for a period of time at least equivalent to the lifetime of the medical device as defined by the manufacturers but not less than three years from the date of product release by the manufacturers or as specified by other relevant regulatory requirements.

## Section 2 Management Responsibility

Article 68 Top management shall be committed to the development and implementation of the quality management system and maintain its effectiveness by providing the following evidence:

- (1) Communicating internally within the manufacturer on the importance of meeting customer as well as statutory and regulatory requirements concerning the safety and performance of the medical device;
- (2) Establishing the quality policy;
- (3) Establishing the quality objectives;
- (4) Conducting management reviews; and
- (5) Ensuring the availability of resources.

Article 69 Top management shall ensure that customer requirements are determined and are met.

Article 70 Top management shall ensure that quality policy includes the following:

- (1) Purpose that is appropriate for and conforms to the manufacturer;
- (2) Commitment to comply with requirements and to maintain the effectiveness of the quality management system;
- (3) Framework provided for establishing and reviewing quality objectives;
- (4) Communication and understanding achieved within the manufacturer's organization; and
- (5) Review of the suitability of quality policy.

Article 71 Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant

functions and levels within the manufacturer. The quality objectives shall be measurable and consistent with the quality policy.

- Article 72 Top management shall ensure the following:
- (1) The planning of the quality management system is carried out in order to meet the quality objectives, as well as the requirements of Article 63; and
  - (2) The integrity of the quality management system is maintained when changes are made to the quality management system.
- Article 73 Top management shall establish a documented procedure to ensure that responsibilities and authorities are defined, documented and communicated internally within the manufacturer.  
Top management shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.  
Manufacturers shall nominate responsible persons for activities related to monitoring experience from the post-production stage and reporting adverse events.
- Article 74 Top management shall appoint a member of the management who, irrespective of other responsibilities, shall have responsibility and authority that include the following:
- (1) Implementing and maintaining processes needed for the quality management system;
  - (2) Reporting to top management on the performance of the quality management system and any need for improvement;
  - (3) Promoting manufacturer' s awareness of regulatory and customer requirements; and
  - (4) Ensuring the safety and effectiveness of manufactured medical devices.
- The above responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.
- Article 75 Top management shall establish appropriate processes for communicating the effectiveness of the quality management system.
- Article 76 Top management shall review the manufacturer' s quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.
- Article 77 The input to management review shall include the following information:
- (1) Results of audits;
  - (2) Customer feedback;
  - (3) Process performance and product conformity;
  - (4) Status of preventive and corrective actions;
  - (5) Follow-up actions from previous management reviews;
  - (6) Changes that could affect the quality management system;
  - (7) Recommendations for improvement; and
  - (8) New or revised regulatory requirements.
- Article 78 The output from the management review shall include any decisions and actions related to the following:
- (1) Improvements to the effectiveness of the quality management system and its processes;
  - (2) Improvement of product related to customer requirements;
  - (3) Resource needs.

### Section 3 Resource Management

- Article 79 Manufacturers shall determine and provide the following resources needed to:

- (1) Implement and promote the quality management system and to maintain its effectiveness;
  - (2) Meet regulatory and customer requirements.
- Article 80 Manufacturers shall ensure their personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience.
- Article 81 Manufacturers shall establish documented procedures to implement the following:
- (1) Determining the necessary competence for personnel performing work affecting product quality;
  - (2) Providing training or taking other actions to satisfy the above needs;
  - (3) Evaluating the effectiveness of the actions taken;
  - (4) Ensuring that the personnel are aware of the relevance and importance of their activities and how to achieve the quality objectives; and
  - (5) Maintaining records of personnel education, training, skills and experience.
- Article 82 Manufacturers shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure shall include the following:
- (1) Buildings, workspace and associated utilities;
  - (2) Process equipment (both hardware and software); and
  - (3) Supporting services (such as transport or communication).
- Manufacturers shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality.
- The above records of maintenance shall be maintained.
- Article 83 Manufacturers shall determine and manage the work environment needed to achieve conformity to product requirements, including adopting the following measures:
- (1) Manufacturers shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product.
  - (2) If work environment conditions can have an adverse effect on product quality, manufacturers shall establish documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions.
  - (3) Manufacturers shall ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person.
  - (4) If appropriate, manufacturers shall establish documented special arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel.

#### Section 4 Product Realization

- Article 84 Manufacturers shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. In planning product realization, manufacturers shall determine the following:
- (1) Quality objectives and requirements for the product;
  - (2) The need to establish processes, documents, and provide resources specific to the product;
  - (3) Required verification, validation, monitoring, inspection and test

activities specific to the product and the criteria for product acceptance;

(4) Records needed to provide evidence that the realization processes and resulting product meet requirements.

The output of the above planning shall be in a form suitable for the manufacturer's method of operations.

Manufacturers shall establish documented requirements for risk management throughout product realization.

Records arising from risk management shall be maintained.

Article 85 Manufacturers shall determine the following:

(1) Requirements specified by the customer, including the requirements for delivery and post-delivery activities;

(2) Requirements not stated by the customer but necessary for specified or intended use, where known;

(3) Statutory and regulatory requirements related to the product; and

(4) Any additional requirements determined by the manufacturers.

Article 86 Manufacturers shall establish and maintain documented procedures for contract review and for the coordination of these activities.

Article 87 Manufacturers shall review the requirements related to the product. This review shall be conducted prior to the manufacturers' commitment to supply a product to the customer and shall ensure the following:

(1) Product requirements are defined and documented;

(2) Contract or order requirements differing from those previously expressed are resolved; and

(3) Manufacturers have the ability to meet the defined requirements.

Records of the results of above review and actions arising from the review shall be maintained.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by manufacturers before acceptance.

Where product requirements are changed, manufacturers shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

Article 88 Manufacturers shall determine and implement effective arrangements for communicating with customers in relation to the following:

(1) Product information;

(2) Enquiries, contracts or order handling, including amendments;

(3) Customer feedback, including customer complaints; and

(4) Advisory notices.

Article 89 Manufacturers shall establish documented procedures for design and development, and plan and control the design and development of product.

During the design and development planning, manufacturers shall determine the following:

(1) The design and development stages;

(2) The review, verification, validation and design transfer activities that are appropriate at each design and development stage. Design transfer activities during the design and development process ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications; and

(3) The responsibilities and authorities for design and development.

Manufacturers shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Manufacturers shall document planning output and update it appropriately as the design and development progress.

Manufacturers shall determine and maintain the inputs relating to product requirements, which include the following:

- (1) Functional, performance and safety requirements, according to the intended use;
- (2) Applicable statutory and regulatory requirements;
- (3) Where applicable, information derived from previous similar designs;
- (4) Other requirements essential for design and development; and
- (5) Output(s) of risk management.

Manufacturers shall review and approve inputs for adequacy.

Every requirement shall be complete, unambiguous and not in conflict with each other.

Article 91 Manufacturers shall ensure the outputs of design and development be provided in a form that enables verification against the design and development input and shall be approved prior to release. Design and development outputs shall conform to the following:

- (1) Meeting the input requirements for design and development;
- (2) Providing appropriate information for purchasing, production and for service provision;
- (3) Containing or referencing product acceptance criteria; and
- (4) Specifying the characteristics of the product that are essential for its safe and proper use.

Records of the design and development outputs shall be maintained.

Article 92 Manufacturers shall, at suitable stages, perform systematic reviews of design and development in accordance with planned arrangements and comply with the following requirements:

- (1) Evaluating the ability of the results of design and development to meet requirements; and
- (2) Identifying any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed, as well as other specialist personnel.

Records of the results of the reviews and any necessary actions shall be maintained.

Article 93 Manufacturers shall perform verification in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained.

Article 94 Manufacturers shall perform design and development validation in accordance with planned arrangements, and complete it prior to the delivery or implementation of the product to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use.

Records of the results of validation and any necessary actions shall be maintained.

Manufacturers shall perform clinical evaluation and evaluation of performance of the medical device in accordance with the regulatory requirements of central competent health authority.

Article 95 Manufacturers shall identify design and development changes and maintain their records. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of above changes and any necessary actions shall be maintained.

Article 96

Manufacturers shall establish documented procedures to ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. Manufacturers shall evaluate and select suppliers based on their ability to supply product in accordance with the manufacturers' requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

- Article 97 Purchasing information shall describe the product to be purchased, including the following:
- (1) Requirements for approval of product, procedures, processes and equipment;
  - (2) Requirements for qualification of personnel; and
  - (3) Quality management system requirements.
- Manufacturers shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. Manufacturers shall maintain relevant purchasing information, i.e., documents and records, according to the scope and extent required for traceability as set forth in these Regulations.
- Article 98 Manufacturers shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where manufacturers or their customers intend to perform verification at the suppliers' premises, the manufacturers shall state the intended verification arrangements and method of product release in the purchasing information. Records of the above verification shall be maintained.
- Article 99 Manufacturers shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include the following, as applicable:
- (1) The availability of information that describes the characteristics of the product;
  - (2) The availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary;
  - (3) The use of suitable equipment;
  - (4) The availability and use of monitoring and measuring devices;
  - (5) The implementation of monitoring and measurement;
  - (6) The implementation of release, delivery and post-delivery activities; and
  - (7) The implementation of defined operations for labeling and packaging.
- Manufacturers shall establish and maintain a record for each batch of medical devices that provides traceability to the extent specified in these Regulations and identifies the amount manufactured and amount approved for distribution. The batch record shall be verified and approved.
- Article 100 Under the following condition, manufacturers shall establish documented requirements for cleanliness of product:
- (1) Product is cleaned by the manufacturer prior to sterilization and its use;
  - (2) Product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and its use;
  - (3) Product is supplied to be used non-sterile and its cleanliness is of significance in use; or
  - (4) Process agents are to be removed from product during manufacture.

If product is cleaned in accordance with the preceding Subparagraph 1 or 2, the requirements contained in Subparagraphs 1 and 2 of Article 83 do not apply prior to the cleaning process.

- Article 101 Manufacturers shall establish documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device.  
If the agreed customer requirements allow installation to be performed other than by manufacturers or their authorized agents, the manufacturers shall provide documented requirements for installation and verification.  
Manufacturers shall maintain records of installation and verification performed by manufacturers or their authorized agents.
- Article 102 Manufacturers shall establish documented procedures, work instructions, and reference materials and reference measurement procedures, as necessary, for performing servicing activities and verifying that they meet the specified requirements.  
Records of servicing activities carried out by the manufacturers shall be maintained.
- Article 103 Manufacturers shall maintain records of the process parameters for the sterilization process which was used for each sterilization batch.  
Sterilization records shall be traceable to each production batch of medical devices.
- Article 104 Any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement, and any processes where deficiencies become apparent only after the product is in use or the service has been delivered, shall be validated by the manufacturers.  
The above validation shall demonstrate the ability of these processes to achieve planned results.  
Manufacturers shall establish arrangements for these processes, including the following as applicable:  
(1) Defined criteria for review and approval of the processes;  
(2) Approval of equipment and qualification of personnel;  
(3) Use of specific methods and procedures;  
(4) Requirements for records; and  
(5) Revalidation.  
Manufacturers shall establish documented procedures for the validation of the application of computer software, and changes to such software and its application, for production and service provision that affect the ability of the product to conform to specified requirements. Such software applications shall be validated prior to initial use.  
Records of the above validation shall be maintained.
- Article 105 Manufacturers shall establish documented procedures for the validation of sterilization processes. Sterilization processes shall be validated prior to initial use.  
Records of validation of sterilization process shall be maintained.
- Article 106 Manufacturers shall identify the product by suitable means throughout product realization, and shall establish documented procedures for such product identification.  
Manufacturers shall establish documented procedures to ensure that medical devices returned to the manufacturers are identified and distinguished from conforming product.
- Article 107 Manufacturers shall establish documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required.  
Where traceability is a requirement, the manufacturers shall control and record the unique identification of the product.

- Article 108 In defining the records required for traceability of active implantable medical devices and implantable medical devices, manufacturers shall include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements.  
Manufacturers shall require that their agents or distributors maintain records of the distribution of active implantable medical devices and implantable medical devices to facilitate the need for traceability and inspection.  
Manufacturers shall maintain the name and address of the shipping package consignee of active implantable medical devices and implantable medical devices.
- Article 109 Manufacturers shall identify the product status with respect to monitoring and measurement requirements.  
Manufacturers shall maintain the identification of product status throughout production, storage, installation and servicing of the product to ensure that only product that has passed the required inspections and tests, or released under an authorized concession, is dispatched, used or installed.
- Article 110 Manufacturers shall exercise care with customer property while it is under their control or being used by them. Manufacturers shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the manufacturers shall report to the customer and maintain records.
- Article 111 Manufacturers shall establish documented procedures or documented work instructions for preserving the conformity of product during internal processing and delivery to the intended destination.  
This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.  
Manufacturers shall establish documented procedures or documented work instructions for the control of product with a limited shelf-life or requiring special storage conditions. Such special storage conditions shall be controlled and recorded
- Article 112 Manufacturers shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.  
Manufacturers shall establish documented procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.  
Where necessary to ensure valid results, measuring equipment shall conform to the following:  
(1) Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;  
(2) Be adjusted or re-adjusted as necessary;  
(3) Be identified to enable the calibration status to be determined;  
(4) Be safeguarded from adjustments that would invalidate the measurement result;  
(5) Be protected from damage and deterioration during handling, maintenance and storage.  
In addition, manufacturers shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. Manufacturers shall take appropriate action on the equipment and any product affected. Records of the results of

calibration and verification shall be maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

## Section 5 Measurement, Analysis and Improvement

Article 113 Manufacturers shall plan and implement the monitoring, measurement, analysis and improvement processes needed to comply with the following:

- (1) Demonstrating conformity of the product;
- (2) Ensuring conformity of the quality management system;
- (3) Maintaining the effectiveness of the quality management system.

The above requirement shall include determination of applicable methods, including statistical techniques, and the extent of their use. Manufacturers shall establish and maintain documented procedures to implement and control the application of the statistical techniques.

Article 114 As one of the measurements of the performance of the quality management system, manufacturers shall monitor information relating to whether they have met customer requirements.

Manufacturers shall determine the methods for obtaining and using this information.

Manufacturers shall establish a documented procedure for a feedback system to provide early warning of quality problems and for input into the corrective and preventive action processes.

Manufacturers shall gain experience from the post-production phase in accordance with the regulations of central competent health authority, and the review of this experience shall form part of the feedback system.

Article 115 Manufacturers shall conduct internal audits at planned intervals to determine whether the quality management system conforms to the following requirements:

- (1) Conforms to the planned arrangements, to the requirements of these Regulations and to the quality management system requirements established by the manufacturers; and
- (2) Is effectively implemented and maintained.

Manufacturers shall establish an audit programme, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

Manufacturers shall define in a documented procedure the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.

Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

Article 116 Manufacturers shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. The above methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

Article 117 Manufacturers shall monitor and measure the characteristics of the product to verify that product requirements have been met.

The foregoing shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements and documented procedures.

Manufacturers shall maintain the evidence of conformity with the acceptance criteria. Records shall indicate the person(s) authorizing release of product.

Product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed.

Article 118 Manufacturers shall record the identity of personnel performing any inspection or testing of active implantable medical devices and implantable medical devices.

Article 119 Manufacturers shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

Manufacturers shall deal with nonconforming product by one or more of the following ways:

- (1) By taking action to eliminate the detected nonconformity;
- (2) By authorizing its use, release or acceptance under concession;
- (3) By taking action to preclude its original intended use or application.

Manufacturers shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met. Records of the identity of the person(s) authorizing the concession shall be maintained.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.

When nonconforming product is corrected, manufacturers shall re-verify to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, manufacturers shall take action appropriate to the effects, or potential effects, of the nonconformity.

If product needs to be reworked one or more times, manufacturers shall document the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented.

Article 120 Manufacturers shall establish documented procedures to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made.

The data analyzed shall include those generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to the following:

- (1) Feedback;
- (2) Conformity to product requirements;
- (3) Characteristics and trends of processes and products including opportunities for preventive action; and
- (4) Suppliers.

Records of the results of the analysis of data shall be maintained.

Article 121 Manufacturers shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and

preventive actions and management review.

Manufacturers shall establish documented procedures for the issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time.

Manufacturers shall maintain the records of all customer complaint investigations. If investigation determines that the activities outside the manufacturers contributed to the customer complaint, relevant information shall be exchanged between the organizations involved.

If any customer complaint is not followed by corrective and/or preventive action, manufacturers shall authorize and record the reason.

Manufacturers shall establish reporting procedures in accordance with the regulations of central competent health authority for the notification of adverse events or recall actions to the central competent health authority or its designated organization.

Article 122 Manufacturers shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. Manufacturers shall establish a documented procedure to define each of the following requirements:

- (1) Reviewing nonconformities (including customer complaints);
- (2) Determining the causes of nonconformities;
- (3) Evaluating the need for action to ensure that nonconformities do not recur;
- (4) Determining and implementing action needed, including, if appropriate, updating documentation,
- (5) Recording of the results of any investigation and of action taken; and
- (6) Reviewing the corrective action taken and its effectiveness.

Article 123 Manufacturers shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

Manufacturers shall establish a documented procedure to define each of the following requirements:

- (1) Determining potential nonconformities and their causes;
- (2) Evaluating the need for action to prevent occurrence of nonconformities;
- (3) Determining and implementing action needed;
- (4) Recording of the results of any investigations and of action taken;
- (5) Reviewing preventive action taken and its effectiveness.

### Chapter 3 Essential Mode

Article 124 Manufacturers shall appoint a member of its own management who, irrespective of other responsibilities, shall have defined authority for the following tasks:

- (1) Ensuring that a quality system is established, implemented and maintained in accordance with this Chapter;
- (2) Reporting on the performance of the quality system to the management for review and as a basis for improvement of the quality system;
- (3) Ensuring the safety and effectiveness of manufactured medical devices.

Article 125 Manufacturers shall establish and maintain a file for manufacturing procedures, installation and servicing, or referring to the location(s) of this information. Their file or information shall contain documents defining the product specifications and quality system requirements (including process and quality assurance) for each type or model of medical device.

- Article 126 All design changes and modifications of manufacturers shall be identified, documented, reviewed and approved by authorized personnel before their implementation.
- Article 127 Manufacturers shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this Chapter.
- Article 128 Manufacturers shall adopt the following measures with respect to subcontractors:
- (1) Evaluating and selecting subcontractors on the basis of their ability to meet subcontract requirements including the quality system and any specific quality assurance requirements;
  - (2) Defining the type and extent of control exercised over subcontractors depending upon the type of product, the impact of subcontracted product on the quality of final product; and, where applicable, also taking into account the quality audit reports or quality records of the previously demonstrated capability and performance of subcontractors; and
  - (3) Establishing and maintaining quality records of subcontractors. Verification by the customer shall not be used by manufacturers as evidence for their effective quality control of subcontractors.
- Article 129 Manufacturers shall require that their agents or distributors maintain and retain records of the distribution of medical devices and that such records are available for inspection.
- Article 130 Manufacturers shall identify and plan the production, installation and servicing processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. The above controlled conditions shall include the following:
- (1) Documented procedures defining the manner of production, installation and servicing, where the absence of such procedures could adversely affect quality;
  - (2) Use of suitable production, installation and servicing equipment, and a suitable working environment;
  - (3) Compliance with all types of reference codes, standards, quality plans or documented procedures;
  - (4) Monitoring and control of suitable process parameters and product characteristics;
  - (5) The approval of processes and equipment, as appropriate;
  - (6) Criteria for workmanship stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations);
  - (7) Suitable maintenance of equipment to ensure continuing process capability.
- Where the results of processes cannot be fully verified by subsequent inspection and testing of the product (including processing deficiencies that may become apparent only after the product is in use), the processes shall be carried out by qualified operators or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met.
- The requirements for any qualification of process operations, including associated equipment and personnel, shall be specified.
- Article 131 Manufacturers shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met.
- Article 132 Manufacturers shall carry out final inspection and testing and prepare records in accordance with the quality plan or documented procedures to ensure conformance of the finished product to the specified requirements.

- Article 133 Manufacturers shall establish and maintain records which provide evidence that the product has been inspected and/or tested. The above records shall include the following:
- (1) Showing clearly whether the product has passed or failed the inspections or tests according to defined acceptance criteria. Where the product fails to pass any inspection or test, the procedures for control of nonconforming product shall apply;
  - (2) Identifying the inspection authority responsible for the release of product.
- Article 134 Manufacturers shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by them to demonstrate the conformance of product to the specified requirements. The above inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.
- Article 135 Manufacturers shall identify the inspection and test status of product by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed.
- Article 136 Manufacturers shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation. The above control shall provide for identification, documentation, evaluation, segregating (when practical), disposition of nonconforming product, and for notification to the functions concerned.
- Article 137 Manufacturers shall establish and maintain documented procedures for implementing corrective and preventive action. Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered. Manufacturers shall implement and record any changes to the documented procedures resulting from corrective and preventive action. Manufacturers shall establish and maintain a documented feedback system to provide early warning of quality problems and for input into the corrective and preventive action system. Manufacturers shall gain experience from information feedback in the post-production phase, and the review of this experience shall form part of the feedback system. Manufacturers shall maintain records of all customer complaint investigations. When the investigation determines that the activities at remote premises contributed to the customer complaint, relevant information shall be communicated between the manufacturer and the remote premises. If any customer complaint is not followed by corrective and preventive action, the reason shall be recorded. Manufacturers shall establish reporting procedures to notify the central competent health authority of those incidents in which a harmful event has occurred. Manufacturers shall establish and maintain documented procedures for the issue of advisory notice for medical devices, and ensure these procedures shall be capable of being implemented at any time.
- Article 138 Manufacturers that manage the handling, storage, packaging, preservation and delivery of product shall comply with the following requirements:
- (1) Handling: Appropriate methods for handling product that prevent damage or deterioration shall be provided.
  - (2) Storage: Designated storage areas or stock rooms shall be used to

prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated. In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.

(3) Packaging: Packing and marking processes (including materials used) shall be controlled to the extent necessary to ensure conformance to specified requirements.

(4) Preservation: Appropriate methods for preservation and segregation of product shall be applied when the product is under the manufacturer's control.

(5) Delivery: Protection of the quality of product shall be arranged for after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.

Article 139 Manufacturers shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records. Quality records of manufacturers and their control shall conform to the following requirements:

(1) Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system.

(2) Pertinent quality records from the subcontractor shall be part of the records.

(3) Quality records shall be retained for a period of time at least equivalent to the lifetime of the medical device as defined by the manufacturer, but not less than two years from the date of dispatch from the manufacturer.

(4) All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

(5) Where agreed contractually, quality records shall be made available for evaluation by the customer for an agreed period.

#### Chapter 4 Medical Devices for Use in Clinical Trials

Article 140 The design, development, manufacture, processing, packaging, storage, installation method and facility of medical devices for use in clinical trials shall, unless otherwise regulated by regulations of this Chapter, be governed by regulations of Chapter 2 in this Part.

Article 141 Where manufacturers have not yet established validated manufacturing processes for medical devices for use in clinical trials, or have not yet established comprehensive manufacturing control standards, aforesaid manufacturers shall establish in writing operational procedures and keep detailed and accurate records for each batch of products manufactured and each batch of raw material used. Batch manufacturing records shall be kept until clinical trials are completed, or until at least two years after the product is completed, whichever period is longer.

Article 142 Where manufacturers provide medical devices for use in clinical trials, aforesaid devices, in addition to conforming to regulations governing labeling in the Act, must also be labeled "for use in clinical trials only", and marked with the name of the trial sponsor and a trial code sufficient to identify the trial site and research personnel involved.

Article 143 Manufacturers shall determine suitable expiration dates for medical devices for use in clinical trials based on the product properties, container characteristics and storage conditions; the expiration dates

marked on aforesaid devices may not exceed the expiration dates marked on the original product packaging.

Article 144 Where manufacturers have medical devices for use in clinical trials manufactured or tested on a contract basis, aforesaid contract shall clearly state that the product in question is for use in clinical trials only.

Article 145 Where manufacturers destroy medical devices for use in clinical trials, destruction of aforesaid devices may not take place until all clinical trials and the final report are completed; detailed records shall be kept of the destruction process, and aforesaid records shall be preserved by the manufacturers.