Ministry of Health - MS
National Health Surveillance Agency – ANVISA

COLLEGIATE BOARD RESOLUTION - RDC No. 665, OF MARCH 30, 2022

(Published in DOU No. 62, of March 31, 2022)

Provides for Good Manufacturing Practices of Medical Devices and In Vitro Diagnostic Devices.

The **Collegiate Board of the National Health Surveillance Agency**, in the exercise of the attribution granted by Article 15, III and IV, allied to Article 7, III and IV, of Law No. 9.782, of January 26, 1999, and to Article 187, VI, § 1 of the Internal Regulations approved by the Collegiate Board Resolution – RDC n. 585, of December 10, 2021, resolves to adopt the following Resolution, as resolved in Extraordinary Meeting – RExtra n. 6, held on March 30, 2022, and I, the President-Director, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Objective

Art. 1° This Resolution provides for Good Manufacturing Practices (GMP) for Medical Devices and In Vitro Diagnostic Devices, establishing the requirements that describe the GMP for methods and controls used in the design, purchasing, manufacturing, packaging, labeling, storage, distribution, installation, and servicing applicable to the manufacturing of medical devices and in vitro diagnostic devices.

§ 1° The requirements mentioned in the caput of this article are intended to ensure that medical devices and in vitro diagnostic devices are safe and effective.

§ 2° This Resolution incorporates into the national legal system the MERCOSUL Common Market Group (GMC) Resolution n. 20, of November 17, 2011, MERCOSUL/GMC/RES. N. 20/11, "MERCOSUL Technical Regulation on Good Manufacturing Practices for Medical Devices and In Vitro Diagnostic Devices (revocation of GMC Res. N. 04/95, 38/96, 65/96, 131/96)".

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

Section II

Scope

Art. 2° This Resolution applies to manufacturers, distributors, storers and importers of Medical Devices and In Vitro Diagnostic Devices that are marketed in Brazil.

§ 1° When the manufacturers mentioned in the caput of this Article conclude that certain requirements established in this Resolution are not applicable to their processes, they shall document the justification of such understanding.

§ 2° Distributors of Medical Devices and In Vitro Diagnostic Devices must comply, as a minimum, with the following requirements of this Resolution:

I - Chapters I, VII and VIII, entirely;

II - Chapter II, entirely, except Section IV;

III - Chapter III, Section I;

IV - Chapter V, articles 67, 68, 69, 70, 71, 72, 73, 74, 75, 76 e 77, in addition to Section IV; and

V - Chapter VI, entirely, except art. 119.

§ 3 Storers of Medical Devices and In Vitro Diagnostic Devices must comply, as minimum, with the following requirements of this Resolution:

I - Chapters I and VII, entirely;

II - Chapter II, entirely, except Section IV;

III - Chapter III, Section I;

IV - Chapter V, articles 67, 68, 69, 70, 71, 72, 73, 74, 75, 76 e 77; and

V - Chapter VI, entirely, except art. 119.

§ 4° Importers of Medical Devices and In Vitro Diagnostic Devices must comply, as minimum, with the following requirements of this Resolution:

I - Chapter I, II, VII, VIII and IX, entirely;

II - Chapter III, Section I and Section III;

III - Chapter IV, art. 63, items III, IV and V;

IV - Chapter V, articles 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 85, 86 and 87, in addition to Sections III and IV; and

V - Chapter VI, entirely, except art. 119.

§ 5° Companies that carry out more than one activity must comply with

the specific requirements defined for each activity.

§ 6° The minimum requirements to be complied with, defined in §§ 2°, 3° and 4° of this article, are applicable to distributors, storers and importers, even if the device mentions only the word manufacturer.

Section III

Definitions

Art. 3. For the purpose of this Resolution, the following definitions are adopted:

I - servicing: maintenance or repair of a finished product in order to return it to its specifications;

II - quality audit: an established, systematic, and independent examination of a manufacturer's entire quality system, performed at regular intervals and with sufficient frequency to ensure that both the activities of the quality system and its results meet the procedures specified in its quality system;

III - component: raw material, substance, piece, part, software, hardware, package, label or instructions for use used during the manufacturing of a medical device and in vitro diagnostic device, intended to be included as part of the finished product;

IV – design input: descriptions of physical attributes, indication of use, performance, compatibility, safety, efficacy, ergonomics, usability, information from previous designs and results of risk management, among other requirements of a medical device or in vitro diagnostic device that are used as the basis for the design;

V - design output: result of the work in each phase of the design and its final result, which when finalized is the basis for the device master record (DMR);

VI - damage: physical lesion or injury to the health of a person, or injury to property or environment;

VII - specifications: requirements to which products, components, production activities, servicing, services, quality system or any other activity shall conform;

VIII - establish: define, document by written or electronic means and implement;

IX - manufacturer: any person who designs, manufactures, assembles or processes a finished product, including those who perform functions by contract for sterilization, labeling and packaging;

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

X - Executive Management: high management of the company, responsible for providing resources, with authority to establish or amend the policy and the quality system of the company;

XI - risk management: systematic application of management policies, procedures and practices to the tasks of analysis, assessments, controls, and monitoring of risks associated with a particular product or process;

XII - lot or batch: quantity of a product produced in a manufacturing or sterilization cycle, whose fundamental feature is the homogeneity;

XIII - manufacturing material: material or substance employed in the process of manufacturing or to facilitate this process, including cleaning agents, mold detach agents, lubricating oils, sterilizing agents, or other byproducts of the manufacturing process;

XIV - non-conformity: failure to comply with a previously specified requirement;

XV - serial number or batch: combination of different letters or numbers, or both, from which can be determined the full history of purchasing, manufacturing, packaging, labeling and distribution of finished products;

XVI - hazard: potential source of harm;

XVII - quality policy: all intentions and guidelines of an organization with respect to quality, expressed by the executive management;

XVIII - special process: any process whose outcome cannot be fully verified by inspections and subsequent tests;

XIX - production: all operations involved in the manufacturing of a particular product, from receipt of components, through processing and packaging, until obtaining the finished product;

XX - finished product: any product or accessory suitable for use, packaged and labeled;

XXI - quality: totality of aspects and characteristics that enable a medical device or in vitro diagnostic device to meet the requirements of suitability for use, including safety and performance;

XXII - complaint: written, oral or electronic communication regarding the non-acceptance of identity, quality, durability, reliability, safety, effectiveness or performance of a product;

XXIII - record: physical or electronic document, which evidence data, facts, specific events and results achieved in relation to compliance of procedures and standards of the quality system;

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

XXIV - device history record: compilation of records containing the full production history of a finished product;

XXV - design history file: compilation of documents containing the full design history of a finished product;

XXVI - device master record (DMR): compilation of documents containing specifications, instructions and procedures for obtaining a finished product, as well as for its installation, servicing and maintenance;

XXVII - rework: partial or total manufacturing operation intended to correct a non-conformity of a component, intermediate product or finished product, so that it meets the specifications defined in the DMR;

XXVIII - design review: documented, systematic and complete examination performed during the design development to assess its suitability to the planning and the objectives established;

XXIX - risk: combination between probability of occurrence and severity of a damage;

XXX - quality system: organizational structure, responsibilities, procedures, specifications, processes and resources needed for quality management;

XXXI - validation: confirmation by analysis and objective evidence that the requirements defined for a particular purpose consistently lead to the expected result;

XXXII - verification: confirmation by analysis and submittal of objective evidences that the specified requirements have been met, including the process of examining the results of an activity to determine the compliance to the specifications established; and

XXXIII – shelf life: period of time estimated by the manufacturer during which the product correctly meets the functions for which it was designed.

§ 1° The procedures referred to in item II of the caput of this article must be implemented efficiently and adequate to achieve the objectives of the quality system.

§ 2° The quality audit referred to in item II of the caput of this article is different from other activities of the quality system required by this Resolution.

§ 3° With relation to a design, the validation referred to in item XXXI of the caput of this article means establishing and documenting objective evidences that the product specifications meet the user's needs and its intended use.

§ 4° With relation to a process, the validation referred to in item XXXI of the caput of this article means establishing and documenting objective evidences that the process will consistently produce a result that satisfies the predetermined specifications.

CHAPTER II

GENERAL QUALITY SYSTEM REQUIREMENTS

Section I

General Requirements

Art. 4° Each manufacturer shall establish and maintain a quality system to ensure that the requirements of this Resolution are met and that the products manufactured are safe, effective and suitable for their intended use.

Single paragraph. As part of its activities in the quality system mentioned in the caput of this article, each manufacturer shall:

I - establish and maintain effective procedures and instructions of the quality system according to the requirements of this Resolution; and

II - establish procedures to comply with the legal provisions provided for in the current health surveillance legislation.

Section II

Management responsibility

Subsection I

Quality Policy

Art. 5° The executive management of each manufacturer shall establish its policy and its quality commitment objectives, which shall be measurable and coherent with the established policy.

Art. 6° The executive management shall keep the policy at all levels of the organization.

Art. 7° The executive management shall ensure that the policy is described in a quality manual and understood by all the employees that may affect or influence the product quality.

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

Subsection II

Organization and responsibilities

Art. 8° Each manufacturer shall:

I - establish and maintain an appropriate organizational structure, represented by organization chart, with sufficient personnel to ensure that the products are manufactured in accordance with the requirements of this Resolution;

II – establish the responsibility, authority, and interrelationship of all personnel who manage, perform and verify the work related to quality, with the necessary independence to perform their responsibilities; and

III - establish functions for verification activities, provide appropriate resources and designate trained personnel to perform the activities of verification.

Art. 9° The executive management of each manufacturer must designate an individual from its own executive management who, independently of other functions, has the authority and responsibility for:

I - ensure that quality system requirements are established and maintained in accordance with this Resolution; and

II - report the performance of the quality system to the executive management for review and provide information on improvements of the quality system.

Single paragraph. The designation referred to in the caput of this article must be documented.

Subsection III

Management review

Art. 10. The executive management of each manufacturer shall evaluate the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency to ensure that the quality system meets the requirements of this Resolution and complies with the objectives of the quality policy established.

Art. 11. The management review shall be conducted according to established review procedures and the results of each quality system review shall be documented.

Art. 12. Audit results, post-marketing information, process performance and product conformity, status of corrective and preventive actions, changes that may affect the quality system or product conformity, regulatory requirements, and other data shall be considered as inputs for management reviews.

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

Section III

Personnel

Art. 13. Each manufacturer shall have a sufficient number of personnel with instruction, expertise, training and practice compatible with the assignments of the position, in order to ensure that all the activities provided for in this Resolution are properly performed.

Art. 14. It shall be documented descriptions defining authority, responsibility and necessary requirements of all personnel for the various tasks of the company.

Art. 15. Each manufacturer shall ensure that all personnel are trained to adequately perform the tasks assigned to them.

§ 1° The training referred to in the caput of this article shall be conducted in accordance with procedures established by qualified persons to ensure that employees have a proper understanding on their regular functions and on the requirements of these Resolution applicable to their functions.

§ 2° As part of the training referred to in the caput of this article, all employees shall be warned of defects in products that may occur as a result of improper performance of their specific functions.

§ 3° The training of personnel shall be documented.

Art. 16. Each manufacturer shall ensure that any consultant who provides guidance on methods employed or controls used for design, purchasing, manufacturing, packaging, labeling, storage, installation, or servicing of products have sufficient qualifications - education, training and expertise - to advise on matters for which he was hired.

Art. 17. The hiring of consultants must be conducted in accordance with the requirements of purchase control provided for in this Resolution.

Section IV

Risk Management

Art. 18. Each manufacturer shall establish and maintain an ongoing process of risk management which involves the entire product lifecycle of a medical device or an in vitro diagnostic device, from the conception to discontinuation, to:

I - identify associated hazards;

II - estimate and evaluate the risks involved;

III - control the associated risks; and

IV - evaluate the effectiveness of established controls.

Art. 19. The risk management continuous process must include the following elements:

I - analysis;

II - assessment;

III - control; e

IV – risk monitoring.

Art. 20. The executive management of the company shall designate responsible personnel, establish the policy to determine the risk acceptability criteria, as well as determining a periodic review of risk management activities to ensure its adequacy and effectiveness.

Section V

Purchasing Control

Art. 21. Each manufacturer shall establish and maintain procedures to ensure that the components, manufacturing materials, and finished products manufactured, processed, labeled or packaged by third parties or stored by them under contract, comply with the specifications.

Single paragraph. Each manufacturer shall ensure that the services performed by third parties referred to in the caput of this article comply with the specifications established by it.

Art. 22. Each manufacturer shall establish and maintain, according to the impact on the quality of the final product, criteria for assessing suppliers, specifying the requirements, including quality requirements, which the suppliers shall meet.

Art. 23. Each manufacturer shall evaluate and select potential suppliers according to their ability to meet established requirements, keeping records of approved suppliers.

Single paragraph. Assessment records shall be kept, as well as their results.

Art. 24. An agreement shall be documented in which the suppliers undertake to notify the manufacturer about any change in the product or service, so that the manufacturer can determine if the change affects the quality of the finished product.

Art. 25. Each manufacturer shall maintain records of purchase orders that clearly describe or make reference to specifications, including quality requirements for components, manufacturing materials, finished products or services requested or contracted.

Art. 26. Each manufacturer shall review and approve the purchase documents before their release.

Art. 27. The approval of purchasing orders, including the date and manual or electronic signature of the responsible, shall be documented.

CHAPTER III

QUALITY DOCUMENTS AND RECORDS

Section I

General Requirements

Art. 28. Each manufacturer shall establish and maintain procedures for document control to ensure that all documents indicated in this Resolution are correct and appropriate for the intended use and are understood by everyone who may affect or influence the quality of a product.

Art. 29. Each manufacturer shall designate persons to evaluate and approve all documents established in this Resolution for adequacy before their issuance.

Single paragraph. The approval referred to in the caput of this article, including date and manual or electronic signature of the responsible for approving the documents shall be documented.

Art. 30. Each manufacturer shall ensure that all documents are updated and available at the sites of use and that all unnecessary or obsolete documents are removed from use or protected from unintentional use.

Art. 31. Changes to specifications, methods or procedures related to the quality system shall be evaluated, documented, reviewed, and approved by persons whose function and level of responsibility are equivalent to those who performed the original revision and approval.

Art. 32. Each manufacturer shall maintain records of changes to documents, including:

I - description of the change,;

II - identification of the changed documents;

III - identification of the affected documents;

IV - identification of the person responsible for the

change;

V – date of change approval; and

VI - date on which the change shall enter into force.

Art. 33. A list of valid documents shall be maintained, in order to identify their current status and ensure that only updated and approved documents are in use.

Art. 34. All quality documents and records shall be legible and be stored so as to minimize damage, prevent losses, and promote quick recovery.

Art. 35. All documents and records electronically filed shall have backups.

Art. 36. The documents and records considered as confidential by the manufacturer may be marked to alert the competent health authority.

Art. 37. All the required documents and records related to a product shall be maintained for a period of time equivalent to the life cycle of the product, counted from the date of its distribution, and in no case can it be less than two years.

Section II

Device history record

Art. 38. Each manufacturer shall maintain device history records.

Art. 39. Each manufacturer shall establish and maintain procedures to ensure that the device history records are kept for each batch or series to demonstrate that the products were manufactured according to the device master record and the requirements of this Resolution.

Art. 40. The device history record shall contain or refer to the following information:

I - manufacturing date;

II - components used;

III - quantity manufactured;

IV - results of tests and inspections;

V - special processes parameters;

VI - quantity released for distribution;

VII - labeling;

VIII - Identification of serial number or batch of the device; and

IX - final release of the device.

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

Section III

Inspections and tests records

Art. 41. Each manufacturer shall maintain records of results of established tests and inspections, when directly related to critical quality attributes of the product.

Art. 42. The established inspections and tests records shall include acceptance criteria, results, equipment / instrument used, and date and manual or electronic signature of the responsible.

CHAPTER IV

DESIGN CONTROL AND DEVICE MASTER RECORD (DMR)

Section I

Design control

Art. 43. Each manufacturer shall establish and maintain procedures of control of the product design to ensure that the specified requirements for the design are met.

Art. 44. Each manufacturer shall establish and maintain plans that describe or refer to design and development activities, as well as the responsible for each activity.

§ 1° The plans referred to in the caput of this article must include any interaction between different organizational and technical groups that may have some interface with the design.

§ 2° The plans referred to in the caput of this article shall be evaluated, updated, and approved as the design development progresses.

Art. 45. Each manufacturer shall establish and maintain procedures to ensure that the requirements relating to a product are appropriate and meet its intended use, including the needs of the user and patient and applicable legal and regulatory requirements.

Single paragraph. The procedures referred to in the caput of this article shall include a mechanism that allows incomplete, ambiguous, or conflicting requirements to be identified and addressed.

Art. 46. The design input shall be documented, evaluated, and approved by a designated qualified person.

Art. 47. The approval of design requirements, including the date and manual or electronic signature of the responsible for the approval, shall be documented.

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

Art. 48. Each manufacturer shall establish and maintain procedures for product design verification.

§ 1° The design verification shall be performed by designated personnel and shall ensure that the design output meets the input.

§ 2° The results of design verification, including the identification of the design verified, verification methods, date and name of the person responsible for the verification, shall be documented in the design history file.

Art. 49. Each manufacturer shall establish and document the design output in order to allow the assessment of design's compliance to the requirements established as input.

§ 1° The design output shall meet the requirements of the input, include the acceptance criteria and identify the design features that are fundamental to the intended use of the product.

§ 2° The design output shall be documented, reviewed and approved prior to release.

Art. 50. Each manufacturer shall establish and maintain procedures to ensure that the assessments of design results are planned, conducted and documented in the various stages of design development.

Single paragraph. The procedures referred to in the caput of this article shall ensure that representatives from all functions directly related to the design stage being reviewed, as well as the individuals from related areas and experts needed, are involved.

Art. 51. The results of design review shall be documented in the device history record.

Art. 52. Each manufacturer shall establish and maintain procedures to ensure that the product design is correctly translated into production specifications.

Art. 53. Each manufacturer shall establish and maintain procedure to validate the product design.

Art. 54. The design validation shall be performed under pre-determined operation conditions, in the initial production of a batch or unit.

Art. 55. The design validation shall ensure that the product meets the needs of the user and indication of use and shall include tests of the products under real or simulated conditions of use.

Art. 56. The design validation shall include software validation, when appropriate.

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

Art. 57. The results of design validation, including its identification, methods, data and manual or electronic signature of the responsible shall be documented in the design history file.

Art. 58. In the design validation, stability studies shall be conducted whenever applicable.

Art. 59. Each manufacturer shall ensure that the design is released for production only when it is approved by the persons assigned by the manufacturer.

§ 1° The persons assigned, referred to in the caput of this article, shall review all records required to the design history file in order to ensure it is complete and the final design is compatible with the approved plans, prior to its release.

§ 2° The release referred to in the caput of this article shall be documented, including date and manual or electronic signature of the responsible.

Art. 60. Each manufacturer shall establish and maintain procedures to identify, document, validate, review and approve design changes before its implementation, including an assessment of the risks within the risk management process.

Art. 61. Each manufacturer shall establish and maintain a design history file for each product.

Single paragraph. The design history file shall contain or make reference to all records necessary to demonstrate that the design was developed in accordance to the approved design plan and the requirements of this Resolution.

Section II

Device master record (DMR)

Art. 62. Each manufacturer shall maintain device master records (DMR's).

Art. 63. The DMR for each type of product shall include or make reference to the following information:

I - product specifications, including the corresponding drawings, composition, formulation, components specifications, and software design specifications and its source codes;

II - production process specifications, including infrastructure specifications, equipment, production methods and instructions, and environmental specifications of production;

III - packaging and labeling specifications, including methods and processes used;

IV - procedures for inspecting and testing with the respective acceptance criteria; and

V - methods and procedures for installation, maintenance, and servicing.

CHAPTER V

PROCESS AND PRODUCTION CONTROL

Section I

General Requirements

Art. 64. Each manufacturer shall design, conduct, control and monitor all production processes in order to ensure that the product comply with its specifications.

Art. 65. Each manufacturer shall establish and maintain procedures of process control, which describe any process controls necessary to ensure compliance to the product specification.

Single paragraph. The process controls shall be established at any step where deviation from product specifications may occur, as a result of the manufacturing process.

Art. 66. The process controls shall include:

I - documented instructions, standard operating procedures, and methods that define and control the method of production, installation and maintenance;

II - monitoring and control of process parameters;

III - compliance to technical rules, standards or reference codes; and

IV - instructions for releasing the beginning of the process;

Art. 67. The company facilities shall be properly designed to:

I - ensure proper flow of people;

II - provide the performance of all operations; and

III - prevent exchanges or contamination of components, manufacturing materials, intermediate products, and finished products, and ensure the correct handling of these materials.

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

Art. 68. Each manufacturer shall provide appropriate environmental conditions to production operations, in order to prevent contamination or other adverse effects on the product.

Single paragraph. For the purposes of the provisions in the caput of this article, the correct functioning of established environmental control systems shall be monitored, keeping the corresponding records.

Art. 69. Each manufacturer shall establish and maintain appropriate cleaning and sanitization procedures, as well as a schedule that meets the requirements of manufacturing process specifications.

Single paragraph. Each manufacturer shall ensure that the personnel involved understand the cleaning and sanitization procedures.

Art. 70. Each manufacturer shall ensure that personnel who are in contact with the product or its environment are clean, health and dressed appropriately for the activity to be performed.

Art. 71. Any person who, by medical examination or observation of supervisors, seems to be in a health condition that may affect the product, shall be removed from the operations until the health condition is considered adequate.

Single paragraph. Personnel must be instructed to report to supervisors when they are in a health condition that could affect the product.

Art. 72. Each manufacturer shall limit the consumption of foods and beverages to specific locations in order not to affect the production areas.

Art. 73. Each manufacturer shall establish and maintain procedures to prevent the contamination of equipment, components, manufacturing materials, intermediates and finished products by cleaning and disinfection materials, including hazardous substances or contaminants generated by the manufacturing process.

Art. 74. A pest control program shall be established and shall be ensured that, whenever chemical agents are used, these agents do not affect the product quality.

Art. 75. The treatment and destination of garbage, chemical wastes and by-products shall occur in accordance with the applicable legislation in force.

Art. 76. Biological safety standards shall be observed in the cases where there is biological risk.

Art. 77. Each manufacturer shall ensure the compliance to applicable standards related to the health of workers, including the use of personal protective equipment, which is compatible with the labor processes performed.

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

Art. 78. Each manufacturer shall ensure that all equipment used in the manufacturing process are appropriate for the intended use and properly designed, constructed, and installed to facilitate the maintenance, adjustments, cleaning and use.

Art. 79. Each manufacturer shall establish and maintain a program for maintenance, adjustments, and, when appropriate, cleaning of equipment to ensure that all manufacturing specifications are being achieved.

Single paragraph. The maintenance program shall be in a place of easy access to the personnel responsible for the maintenance and use of the equipment.

Art. 80. The maintenance activities shall be recorded with date of performance and identification of the persons in charge.

Art. 81. Each manufacturer shall ensure that any acceptable tolerances or inherent limitations are attached in a visible place or near the equipment requiring periodic adjustment, or are easily available to the personnel in charge of these adjustments.

Art. 82. Each manufacturer shall establish and maintain procedures for use and removal of manufacturing materials, to ensure that such materials are removed from the product or limited to a specified amount that does not adversely affect the product quality.

Art. 83. Special processes shall be conducted in accordance with established procedures and parameters in order to assure the compliance to the specifications.

Single paragraph. The critical parameters of special processes shall be monitored and recorded in the device history record.

Section II

Controls of packaging, labeling and instructions for use

Art. 84. Each manufacturer shall establish procedures for product packaging in order to protect the product from any change, damage or contamination during the processing, storage, handling, and distribution processes.

Art. 85. Each manufacturer shall establish and maintain procedures to ensure the integrity and prevent accidental mixing of labels, instructions for use, packaging materials or identification tags.

Art. 86. Each manufacturer shall ensure that labels are designed, printed, and, when applicable, applied so as to remain legible and attached to the product during processing, storage, handling and use steps.

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

Art. 87. The labels and instructions for use shall not be released for use until an authorized person has examined their compliance to the information contained therein.

§ 1° The approval of labels and instructions for use shall be documented in the device history record, including date, name and manual or electronic signature of the responsible.

§ 2° In the case of importers, the approval documentation referred to in § 1° of this article may be registered in a specific document in lieu of the device history record.

Section III

Inspection and tests

Art. 88. Each manufacturer shall establish and maintain procedures for inspections, tests or other means of verification, so as to ensure compliance to the specified requirements in the entire production chain.

Art. 89. Conformity to specified requirements must be evaluated upon receipt of components and manufacturing materials, as well as at intermediate stages of production and final acceptance of the finished product.

§ 1° The results of the activities referred to in the caput of this article shall be documented, including its conclusion – accepted or rejected.

§ 2° The authority and responsibility for carrying out the activities referred to in the caput of this article shall be defined by the manufacturer.

Art. 90. The components and manufacturing materials received, as well as components, intermediate products, and returned products shall not be used or processed until the verification of their compliance to the established requirements.

Art. 91. Each manufacturer shall establish and maintain procedures for the retention of components, manufacturing materials, intermediate products, and returned products until the inspections, tests or other verification have been completed and documented.

Art. 92. The finished products shall only be released once activities specified in the DMR have been completed and the documentation and associated data have been reviewed by a person assigned to ensure that all acceptance criteria have been met.

Single paragraph. The release of the products shall be documented, including the date and manual or electronic signature of the responsible.

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

Section IV

Measurement and testing equipment

Art. 93. Each manufacturer shall ensure that all measurement and testing equipment, including mechanical, automated or electronic equipment, are suitable for its intended purposes and are capable of producing valid results.

Art. 94. Each manufacturer shall establish and maintain procedures to ensure that measurement and testing equipment are routinely calibrated, inspected and controlled.

Art. 95. Each manufacturer shall establish and maintain calibration procedures that include specific guidelines and precision and accuracy limits, as well as prescriptions for corrective actions when the precision and accuracy limits are not achieved.

Art. 96. The calibration shall be performed by personnel who have the necessary instruction, training, practice and expertise.

Art. 97. The measurement and testing equipment shall be identified so as the calibration status can be determined.

Art. 98. Each manufacturer shall establish and maintain calibration standards for measurement equipment that are traceable to the official national or international standards.

Single paragraph. When there is no applicable standard available, the manufacturer shall establish and maintain its own standard.

Art. 99. Each manufacturer shall ensure the maintenance of records of calibration dates, measurements obtained, responsible in charge of this task, and the next date for this operation.

§ 1º The records referred to in the caput of this article shall be maintained by the manufacturer.

§ 2º The records referred to in the caput of this article shall be available for the personnel using this equipment and for those responsible for calibrating it.

Art. 100. Each manufacturer shall establish and maintain procedures to ensure that the handling, preservation, and custody of equipment for testing, inspection and measurement are performed in order to preserve its precision and suitability for use.

Art. 101. Each manufacturer shall protect the facilities and equipment for inspection, testing and measurement, including hardware and testing software, from adjustments that may invalidate the calibration.

Art. 102. Each manufacturer shall establish procedures to assess the impact of results from previous measurements when identifying non-conformities in testing and measurement equipment, and the result of the assessment shall be documented.

Section V

Validation

Art. 103. Special processes shall be validated according to previously established protocols and the results of validations, including the date and identification of the responsible for the approval shall be recorded.

Art. 104. Analytical methods, auxiliary systems supporting the processes or environmental control, automated computerized systems and software that may adversely affect the quality of the product or the quality system shall be validated.

Art. 105. Each manufacturer shall establish procedures to periodically verify their processes, analytical methods, auxiliary systems supporting the processes and environment control, automated computerized systems, and validated software, and, when applicable, to establish the frequency for revalidation.

Art. 106. Each manufacturer shall establish procedures for change control in order to control the changes in auxiliary systems, software, equipment, processes, methods or other changes that may influence the quality of the products, including a risk assessment within the risk management process.

§ 1° The procedure referred to in the caput of this article shall describe the actions to be taken, including, when applicable, the need for requalification or revalidation.

§ 2 The changes referred to in the caput of this article shall be formally requested, documented and approved before their implementation.

CHAPTER VI

HANDLING, STORAGE, DISTRIBUTION AND TRACEABILITY

Section I

Handling

Art. 107. Each manufacturer shall establish and maintain procedures to ensure that inversions (exchanges), damages, deterioration or other adverse effects affecting components, manufacturing materials, intermediate products, finished products, and samples for quality control do not occur during any stage of handling.

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

Art. 108. Each manufacturer shall establish and maintain procedures to identify the compliance of components, manufacturing materials, intermediate products and finished products, in order to ensure that only those duly approved are used or distributed.

Art. 109. The procedures mentioned in article 107 and article 108 of this Resolution shall ensure that components, manufacturing materials, intermediate products or finished products:

I - are not used or distributed when the quality or suitability condition for use deteriorates over time;

II - nearest to expiry date are distributed or used firstly; and

III - are not distributed or used, with an expired period of validity.

Section II

Storage and distribution

Art. 110. Each manufacturer shall establish and maintain procedures for identification of components, manufacturing materials, intermediate products, finished products and samples for quality control, in order to prevent inversions (exchanges) during storage.

Art. 111. Components, manufacturing materials, intermediate products, finished products and samples for quality control shall be stored in physical and environmental conditions that prevent damages, deterioration or other adverse effects during the period of storage.

Art. 112. Each manufacturer shall maintain distribution records, including or referring:

I - to the name and address of the consignee;

II - to the identification and amount of products shipped, with shipment date; and

III - to any numerical control used for traceability.

Section III

Identification, traceability and non-conformities

Art. 113. Each manufacturer shall establish and maintain procedures for identification of components, manufacturing materials, intermediate products and finished products during all stages of storage, production, distribution and installation in order to prevent confusion and to ensure the correct fulfillment of order.

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

Art. 114. Each manufacturer shall identify each unit, batch or lot of products with a serial or batch number and this identification shall be recorded in the device history record.

Single paragraph. In the case of distributors, storers and importers, the identification referred to in the caput of this article may be recorded in a specific document in lieu of the device history record.

Art. 115. Each manufacturer shall establish and maintain procedures to ensure that components, manufacturing materials, intermediate products, finished products, and returned products, which do not comply with the established requirements, are not installed or used inadvertently.

Single paragraph. The procedures referred to in the caput of this article shall contain prescriptions to identify, document, evaluate, segregate, and dispose non-conforming components, manufacturing materials, intermediate products, and finished products.

Art. 116. The assessment of non-conforming components, manufacturing materials, intermediate products, and finished products shall include the need for investigation and notification of those people and/or organizations involved in such non-conformity.

Single paragraph. The results of assessments and eventual investigations referred to in the caput of this article shall be recorded.

Art. 117. The responsibility for the review and the authority to dispose of non-conforming components, manufacturing materials, intermediate products, finished products and returned products shall be defined.

Art. 118. The review and disposition process of non-conforming components, manufacturing materials, intermediate products, finished products, and returned products shall be described in an established procedure.

§ 1° The disposition of the products mentioned in the caput of this article shall be documented and the record of the rationale and manual or electronic signature(s) of the responsible(s) shall be kept.

§ 2° In case of authorization of use of the products mentioned in the caput of this article, the decision shall be based on risk assessment technically justifiable.

Art. 119. Each manufacturer shall establish and maintain procedures for re-work, re-inspection, and re-assessment of intermediate or finished products after re-work, to ensure that they meet the original specifications.

Single paragraph. The activities related to re-work and re-assessment of the products referred to in the caput of this article, including problems resulting from re-work, shall be documented in the device history record.

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

CHAPTER VII

CORRECTIVE AND PREVENTICE ACTIONS

Section I

General Requirements

Art. 120. Each manufacturer shall establish and maintain procedures to:

I - analyze processes, work operations, quality audit reports, quality records, servicing records, complaints, returned products and other sources of quality data, in order to identify existing and potential causes of non-conformities related to the product, process or quality system;

II - investigate the cause of non-conformities related to the product, process or quality system;

III - identify and carry out the necessary actions to prevent the occurrence, to correct the event, and to prevent the recurrence of non-conformities;

IV - verify or validate the effectiveness of the corrective action to ensure that it does not adversely affect the product;

V - record activities related to corrective and preventive actions;

VI - ensure that information concerning quality issues or non-conforming products are properly disseminated to those directly involved in the maintenance of product quality or in preventing the occurrence of such problems;

VII - submit relevant information on quality issues identified and preventive and corrective actions to the executive management for information and monitoring, as well as the competent health authority, when applicable; and

VIII - determine product recalls and other field actions that are relevant for products already distributed.

§ ° The analysis referred to in item I of this article shall be based on valid statistical technique to detect recurrent quality problems, when applicable.

§ 2° In order to comply with the provisions in item IV of this article, any changes made, when applicable, shall observe change control procedures and validation protocols established.

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

Section II

Complaints management

Art. 121. Each manufacturer shall establish and maintain procedures to receive, examine, evaluate, investigate, and file complaints, ensuring that:

I - complaints are received, documented, examined, evaluated, investigated, and filed by a formally designated unit;

II - complaints are notified to the competent health authority, when applicable;

III - complaints are examined to evaluate whether an investigation is necessary;

IV - all complaints involving possible product non-conformity are examined, evaluated and investigated;

V - records are maintained, when an investigation is conducted, containing the following information:

a) product name;

b) date of receipt of the complaint;

c) any control number used;

d) name, address and telephone number of the claimant;

e) nature of the complaint; and

f) date and investigation results, including the actions taken.

§ 1 When the investigation mentioned in item III of this article is not conducted, the unit shall record the reason why the investigation has not been performed and the name of the responsible for the decision to not investigate.

§ 2 When any complaint referred to in item IV of this article is related to death, injury or threaten to public health, it shall be immediately reviewed, evaluated and investigated.

Section III

Quality audit

Art. 122. Each manufacturer shall conduct and document quality audits to assess the quality system compliance to the requirements established.

Art. 123. Quality audits shall be conducted by demonstrably trained persons, according to audit procedures established, but who do not have direct responsibility for the matters being audited.

Single paragraph. Those responsible for conducting the quality audit cannot have direct responsibility for the subject matters being audit.

Art. 124. Those responsible for the audited areas shall be notified on non-conformities identified.

CHAPTER VIII

INSTALATION AND SERVICING

Art. 125. Each manufacturer shall establish and maintain appropriate instructions and procedures to correctly installation of the products.

Art. 126. At the time of installation of the product, by the manufacturer or its authorized representative, it shall be verified if the product works according to established criteria.

Single paragraph. The results of the verification referred to in the caput of this article shall be recorded.

Art. 127. Each manufacturer shall ensure that the installation instructions and procedures are distributed along with the product or otherwise available to the responsible for installing the product.

Art. 128. Each manufacturer shall establish and maintain procedures to ensure that finished products undergoing servicing by the manufacturer or its representative meet the specifications.

Art. 129. Each manufacturer shall establish and maintain procedures to ensure that the servicing records are maintained and that include:

I - product subject of service;

II - control number used;

III - date of service;

IV - identification of service provider;

V - description of service performed; and

VI - results of tests and inspections for approving the service.

Art. 130. Each manufacturer shall periodically review the servicing records.

Single paragraph. In cases where the analysis referred to in the caput of this article identifies failure trends, which represent hazards, or records involving death or severe injury, the corrective / preventive action shall be initiated according to the requirements of this Resolution.

CHAPTER IX

STATISTICAL TECHNIQUES

Art. 131. Each manufacturer shall establish and maintain procedures for identifying valid statistical techniques to assess the performance of the quality system and capability of the process to meet the established specifications.

Art. 132. Sampling plans shall be formalized in writing and based on valid statistical logic.

Art. 133. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and are regularly reviewed.

Art. 134. The revision of sampling plans shall consider the occurrence of non-conformities of products, quality audit reports, complaints and other indicators.

CHAPTER X

FINAL DISPOSITIONS

Art. 135. The documentation that proves compliance with the requirements set out in this Resolution must be available whenever requested by the health surveillance bodies.

Art. 136. Failure to comply with the provisions contained in this Resolution constitutes a sanitary infraction, under the terms of Law No. 6,437, of August 20, 1977, without prejudice to the civil, administrative and criminal liabilities applicable.

Art. 137. Are revoked:

I - the Collegiate Board Resolution – RDC No. 16, of March 28, 2013, published in the Federal Official Gazette No. 61, of April 1, 2013, p. 75; and

II - the Normative Instruction – IN No. 8, of December 26, 2013, published in the Federal Official Gazette, of December 30, 2013, Section 1, p. 758.

Art. 138. This Resolution enter into force on May 2, 2022.

ANTONIO BARRA TORRES