

## COLLEGIATE BOARD RESOLUTION No. 982 of 28 July 2025

Provides for the use of health risk management criteria and compliance monitoring for companies for the initial granting or renewal of the Good Manufacturing Practices Certificate or the Good Distribution and/or Storage Practices Certificate.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 7, items III and IV, and Article 15, items III and IV of Law no. 9,782 of 26 January 1999, and Article 187, item VI, Paragraph 1 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 28 July 2025, and I, Acting Director-President, determine its publication.

### CHAPTER I

#### INITIAL PROVISIONS

Article 1. This Resolution provides for the use of health risk management criteria and compliance monitoring for companies for the initial granting or renewal of the Good Manufacturing Practices Certificate (CBPF, in Portuguese) and the Good Distribution and/or Storage Practices Certificate (CBPDA, in Portuguese) for establishments that manufacture, distribute, and store active pharmaceutical ingredients (APIs), medicinal products, cannabis products for medicinal purposes, biological products, and medical devices.

Article 2. For the purposes of this Resolution, the following definitions are adopted:

I – storage: a set of operations that includes the safe storage, handling, and preservation of products and related controls;

II – Equivalent Foreign Regulatory Authority (EFRA): a foreign regulatory authority or international entity that has regulatory practices aligned with those of Anvisa, responsible for ensuring that products authorized for distribution have been adequately evaluated and meet recognized standards of quality, safety, and efficacy, and which will be considered by Anvisa as a practice of regulatory reliance;

III – Good Distribution and/or Storage Practices Certificate (CBPDA, in Portuguese): a document issued by Anvisa certifying that a given establishment complies with the technical requirements of Good Distribution and Storage Practices or Good Storage Practices, as set forth in current legislation, necessary for the commercialization of the product;

IV – Good Manufacturing Practices Certificate (CBPF, in Portuguese): a document issued by Anvisa certifying that a given establishment complies with the technical requirements of Good Manufacturing Practices, as set forth in current legislation, necessary for the commercialization of the product;

V – distribution: a set of activities related to the movement of cargo, including the supply, storage, and shipment of products, excluding direct supply to the public;

VI – establishment: a unit responsible for performing one or more activities eligible for certification;

VII – manufacturing: all operations involved in the preparation of a given product, including acquisition of material, production, quality control, release, storage, shipment of products, and related controls;

VIII – pharmaceutical form: the final presentation of a pharmaceutical preparation after one or more operations, with or without the addition of excipients, to facilitate its use in a specific route of administration;

IX – risk management: a systematic process consisting of several steps for identifying, evaluating, controlling, monitoring, and communicating associated risks, with the aim of ensuring safety, quality, and efficacy throughout the life cycle of products subject to health surveillance;

X – health inspection: a set of technical and administrative procedures aimed at protecting individual and public health, through on-site or, in specific cases, remote verification of compliance with the legal and regulatory health frameworks related to the activities carried out and the sanitary conditions of establishments, processes, and products, allowing the adoption of guidance and corrective measures for situations that may cause harm to the health of the population;

XI – active pharmaceutical ingredient: any substance introduced into the formulation of a pharmaceutical form that, when administered to a patient, acts as an active ingredient and may exert pharmacological activity or another direct effect in the diagnosis, cure, treatment, or prevention of a disease, and may also affect the structure and functioning of the human body;

XII – biological active pharmaceutical ingredient: an active pharmaceutical ingredient obtained from starting materials of biological origin;

XIII – Medical Device Single Audit Program (MDSAP): an international program that allows healthcare product manufacturers to be audited by a recognized certification organization;

XIV – inspection report: a report describing the company's status regarding compliance with good manufacturing and/or distribution and storage practices, in accordance with the standards referenced in the scope of the report;

XV – inspection report from an Equivalent Foreign Regulatory Authority (EFRA): a report issued by a foreign regulatory authority or international entity with regulatory practices aligned with those of Anvisa, considered to be in a regulatory reliance practice, the content of which describes the company's compliance with good manufacturing practices in accordance with the standards referenced in the report; and

XVI – equivalent inspection report: a report issued by a health authority or auditing body recognized by Anvisa, describing the company's compliance with good manufacturing and/or distribution and storage practices, in accordance with the standards referenced in the scope of the report.

## CHAPTER II

### CRITERIA

Article 3. The following are criteria for health risk management applied to the granting or renewal of the CBPF or CBPD/A for establishments that carry out activities related to active pharmaceutical ingredients (APIs), medicinal products, cannabis products for medicinal purposes, biological products, and medical devices:

I – product risk class and classification;

II – complexity and criticality of the establishment;

III – storage and transportation conditions of the input(s) and finished product(s);

IV – history of compliance and regularity of companies and products;

V – history of compliance with Good Manufacturing and Distribution and/or Storage Practices by the establishment to be certified;

VI – line, manufacturing stage, and dosage form to be certified;

VII – post-market monitoring of products;

VIII – time elapsed since the last inspection;

IX – inspection reports or CBPFs issued by an Equivalent Foreign Regulatory Authority (EFRA);

X – inspection reports or CBPFs issued by regulatory authorities or member entities of the Pharmaceutical Inspection Cooperation Scheme (PIC/s);

XI – inspection report issued by a health authority of a member country of the International Medical Device Regulators Forum (IMDRF);

XII – audit reports issued under the Medical Device Single Audit Program (MDSAP);

XIII – results of laboratory, inspection, or control analyses;

XIV – national and international epidemiological and health context;

XV – control through random inspection;

XVI – risk of discontinuation of products subject to health surveillance in the Brazilian market; and

XVII – inspection report issued by Anvisa or by State, District, or Municipal Health Surveillance bodies, according to the organization of health surveillance actions and powers exercised by the Union, States, Federal District, and Municipalities.

Paragraph 1. The criteria listed in items I to XVII of this article are not arranged in order of application or relevance and will be used in combination, considering the health risk involved and the applicability of the criterion to the manufacturing unit subject to certification.

Paragraph 2. Anvisa will analyze the risk management criteria based on the information provided by the applicant, along with the information available in Anvisa's systems and external databases.

Paragraph 3. The result based on Artificial Intelligence models may be used as a risk management criterion, provided it meets Anvisa's technical standards of consistency, data protection, traceability, and technical validation.

## **CHAPTER III**

### **APPLICATION**

Article 4. The initial granting or renewal of the CBPF or CBPDA referred to in Article 1 of this Resolution must occur through:

- I – analysis of the inspection report from an Equivalent Foreign Regulatory Authority (EFRA);
- II – risk analysis, according to the criteria established in Article 3 of this Resolution; and
- III – inspection, motivated by the results of the risk analysis.

Paragraph 1. The adoption of one or more of the mechanisms listed in items I to III of this article does not exempt the preparation of a technical opinion.

Paragraph 2. The mechanisms listed in items I to III of this article may be used in combination, observing the principles of Public Administration.

Article 5. The health requirements and technical-administrative guidelines for all initial granting or renewal processes of the CBPF and CBPDA referred to in Article 1 of this Resolution shall remain in effect, regardless of the adoption of the mechanisms referred to in Article 4 of this Resolution.

## **CHAPTER IV**

### **COMPLIANCE MONITORING**

Article 6. The granting or renewal processes of the CBPF and CBPDA referred to in Article 1 of this Resolution will be subject to continuous compliance monitoring, based on the criteria established in Article 3 of this Resolution.

Paragraph 1. The information obtained through the monitoring referred to in the caption of this article may indicate the need for an inspection, regardless of the validity of the CBPF or CBPDA.

Paragraph 2. Based on the monitoring data referred to in the caption of this article, Anvisa may, at any time, determine the initiation of an investigation or the cancellation of the Certificate.

Paragraph 3. The cancellation referred to in Paragraph 2 of this article must be supported by justifications related to the identification of irregularities or risks related to the establishment or the products supplied by it.

Article 7. Anvisa's actions to verify compliance with Good Manufacturing or Distribution and Storage Practices may be supplemented by specific inspection programs.

Sole paragraph. The programs referred to in the caption of this article will be defined based on the health risk management provided for in Article 3 of this Resolution, considering the complexity of the related activities, technologies involved, and historical inspection, monitoring, and product registration data.

**CHAPTER V**

**TRANSITIONAL AND FINAL PROVISIONS**

Article 8. The requirements of this Resolution are hereby established for the granting or renewal of CBPF or CPBDA processes for which no decision has been published in the Federal Official Gazette.

Sole paragraph. The provisions of the caption of this article include petitions filed with Anvisa prior to the entry into force of this Resolution.

Article 9. The application of the health risk management mechanisms established in Article 4 of this Resolution to the initial granting or renewal of CBPF or CBPDA processes referred to in Article 1 of this Resolution is subject to approval by the Collegiate Board of Directors.

Article 10. Resolution – RDC No. 497 of 20 May 2021, published in the Federal Official Gazette No. 98 of 26 May 2021, Section 1, pages 205-207, shall come into effect with the following alterations:

"Article 4. The granting of Certification provided for in this Resolution is subject to analysis through risk management and the issuance of a technical opinion attesting that the establishment meets the technical requirements of Good Manufacturing Practices or Good Distribution and/or Storage Practices necessary for the commercialization of the product.

....." (new wording)

"Article 10. The Good Manufacturing Practices Certification and the Good Distribution and/or Storage Practices Certification must be canceled at any time, whenever there is an analysis through risk management and a technical opinion attesting that the establishment does not meet the technical requirements of Good Manufacturing Practices or Good Distribution and/or Storage Practices necessary for the commercialization of the product.

....." (new wording)

"Article 35. For the decision regarding the Good Practices Certification provided for in this chapter, in the case of establishments located in MERCOSUR countries, except Brazil, Anvisa is responsible for analyzing them through risk management and issuing a technical opinion, based on the guidelines established by existing MERCOSUR legislation. (new wording)

"Article 36. In the case of establishments located in Brazil or in other countries outside MERCOSUR, the Certification referred to in this chapter must be granted after analyzing them through risk management and issuing a technical opinion, which must consider the following items:

.....

Sole paragraph. The technical opinion provided for in the caption of this article may consider other factors defined through risk management." (new wording)

**RÔMISON RODRIGUES MOTA**

**Acting Director-President**