RESOLUTION - RDC No. 15, MARCH 28th, 2014

Makes provisions on the requirements related to the proof of compliance with Good Manufacturing Practices for *registro* registration of healthcare products and makes other provisions.

The Collegiate Board of Directors of the Brazilian National Health Surveillance Agency (ANVISA), in the exercise of the powers vested by Article 15, subsections III and IV, of Law no. 9,782, of January 26th, 1999; Article 54, subsection II, Paragraphs 1 and 3, of the Internal Statute approved under the terms of Annex I of Anvisa Ordinance no. 354, of August 11th, 2006, republished on the Brazilian Official Gazette of August 21st, 2006, and its updates, in view of the provisions of Article 2, subsection III, of Article 7, subsections III and IV, of Law no. 9,782/1999, and the Program for Improvement of the Agency's Regulatory Process, created by Ordinance no. 422, April 16th, 2008, in meeting held on March 25th, 2014, hereby adopts the following Resolution and I, Director-President, determine its publication:

Article 1. This Resolution hereby establishes the requirements related to the proof of compliance with Good Manufacturing Practices (GMP) for registro registration of healthcare products.

Article 2. The protocol of request for Good Manufacturing Practice Certification shall be accepted for application purposes and for the beginning of application reviews to grant registrations, registration revalidations, and alterations/inclusion of manufacturer, all related to healthcare products classified as risk class III and IV.

Sole Paragraph. Granting of registro registrations and change/inclusion of manufacturers, according to the caput hereof, shall be subject to the publication of a valid Certificate of Good Manufacturing Practices, issued by Anvisa, as well as to the compliance with other requirements for the registro of healthcare products.

Article 3. Article 4 of RDC no. 39, of August 14th, 2013, is hereafter in force with the following phrasing:

"Article 4. .....

Sole Paragraph. The certification addressed in the caput hereof may be granted after the submission of a valid audit report, issued by a third-party auditing body, according to specific programs, both acknowledged by Anvisa".(New Phrasing)

Article 4. Article 24 of RDC no. 39, 2013, is hereafter in force with the following phrasing:

"Article 24. .....

Paragraph 1. The Certificate shall describe, for each production line, the respective risk classes of the products whose requirements set forth in the Good Practice standards in force are fulfilled by the establishment.

Paragraph 2. Anvisa shall not issue GMP Certificates for healthcare products classified as classes I and II." (New Phrasing)

Article 5. The provisions hereof shall not exempt manufacturers and importers from the obligation to ensure that the healthcare products they commercialize, regardless of their risk classes, have been manufactured and distributed in compliance with the applicable Good Manufacturing Practices established by Anvisa.

Article 6. RDC no. 25, of May 21st, 2009, published on the Brazilian Official Gazette no. 96 on May 22nd, 2009, Section 1, page 48, subsection VIII of Article 5, Paragraph 2 of Article 8 and subsection IV of Article 9, of Normative Instruction no. 13, of October 22nd, 2009, published on the Brazilian Official Gazette no. 203 on October 23rd, 2009, Section 1, page 62, are hereby revoked.

Article 7. This Resolution comes into force on the date of its publication.

DIRCEU BRÁS APARECIDO BARBANO
Director-President