Good Manufacturing Practices in Brazil: Anvisa RDC Resolution No. 16/2013, similarities and differences compared to ISO 13485:2016

Webinar Series on Medical Devices

Part I - ISO 13485 and the MDSAP Audit Model

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ANVISA
Agência Nacional de Vigilância Sanitária

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Source: https://www.mercosur.int/pt-br/quem-somos/paises-do-mercosul/

Anvisa in Mercosur

Sub-working groups in Brazil

- SGT Nº 3 “Technical Regulations and Conformity Assessment”
- SGT Nº 11 “Health”
- Both linked to the Common Market Group (CMG).

SGT No. 3 is tasked with harmonizing Technical Regulations and Conformity Assessment Procedures, also with coordinating actions related to the industrial and agricultural sectors, and Anvisa's topics are dealt with in the Food Commission and temporary Working Groups with specific mandates. Face-to-face meetings are held twice a semester.

SGT No. 11 has the general task of harmonizing laws and guidelines, promoting technical cooperation and coordinating actions related to health, goods, services, raw materials and health products (all of those regulated by Anvisa, except for food), professional practice, epidemiological surveillance and health control. Anvisa's topics are addressed by the Health Surveillance Commission and its PAF Health Control Subcommittee; at the Health Care Services Commission and its Subcommittee on the Evaluation and Use of Technologies in Health Services; in the Committee on Sanitary Products - its Subcommittees (Psychotropic and Narcotic, Pharmacopoeia, Medical, Cosmetic and Sanitizing Products) and temporary Working Groups. Face-to-face meetings are held once a semester.

There is also an active participation of Anvisa in the field of the Committees of the Meeting of Ministers of Health dealing with the International Health Regulations, Donations and Transplants, Blood and Blood Products, as well as Tobacco Products.

Resolution RDC No. 16 of 28 March 2013

In Brazil, the RESOLUTION OF THE COLLEGIATE COUNCIL OF ANVISA - DRC No. 16 of 28 MARCH 2013 (available in http://antigo.anvisa.gov.br/legislacao#/visualizar/29010) approves the Technical Regulations on Good Manufacturing Practices for Medical Products, In vitro Diagnostics.

Considering the need to internalize the MERCOSUR / GMC / RES Resolution. No. 20/11, which approved the "Technical Regulation for Good Manufacturing Practices of Medical Products and Diagnostic Products for In Vitro Use of MERCOSUR".

Resolution RDC No. 183 of 19 October 2017

Article 4 All Processes for Certification of Good Manufacturing Practices referred to by this Resolution shall be accompanied by the following documents:

...

X - copy of the most recent inspection or audit report issued by the health authority of the country of origin or by a third organization accredited by the latter;

XI - copy of the most recent inspection or audit report issued by the health authority of a member country of the International Medical Device Regulators Forum (IMDRF) or by a third organization accredited by it, when required; and

XII - copy of the most recent audit report issued by an external auditing organization that has been recognized by Anvisa, when required

- Some of the reports are issued with reference to ISO 13485:2016, although Anvisa evaluates the reports considering compliance with DRC 16/2013.

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Resolution RDC No. 16 of 28 March 2013

CHAPTER 1 – GENERAL DISPOSITIONS

CHAPTER 2 – GENERAL REQUIREMENTS OF THE QUALITY SYSTEM

2.1. General Dispositions / 2.2. Management Responsibility / 2.3. Staff / 2.4. Risk Management / 2.5. Purchasing Control

CHAPTER 3 – QUALITY DOCUMENTS AND RECORDS

3.1. General Requirements / 3.2. Historical record of the product / 3.3. Inspections and test records

CHAPTER 4 – DESIGN CONTROL AND PRODUCT MASTER FILE

4.1. Design Control / 4.2. Product Master File

CHAPTER 5 – PROCESS AND PRODUCTION CONTROLS

5.1. General Instructions / 5.2. Packing Controls, labeling and instructions for use / 5.3. Inspections and tests / 5.4. Inspection, measuring and testing equipment / 5.5. Validation / 5.6 Change control

CHAPTER 6 – HANDLING, STORAGE, DISTRIBUTION AND TRACKING

6.1. Handling / 6.2. Storage / 6.3. Distribution / 6.4. Identification and tracking / 6.5. Non-complaint components and products

CHAPTER 7 – CORRECTIVE AND PREVENTIVE ACTIONS

7.1. Corrective and Preventing Actions / 7.2. Complaint Management / 7.3. Quality Audit

CHAPTER 8 – INSTALLATION AND TECHNICAL ASSISTANCE

8.1. Installation / 8.2. Technical Assistance

CHAPTER 9 – STATISTICAL TECHNIQUES

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ABNT NBR ISO 13485:2016 (Brazil)
Sanitary products - Quality management systems - Requirements for regulatory purposes

1. Scope
2. Regulatory reference
3. Terms and definitions
4. Quality Management System

4.1. General Requirements / 4.2. Documenting Requirements / 4.2.1. General / 4.2.2. Quality Manual / 4.2.3. Sanitary Products Records / 4.2.4. Documents Control / 4.2.5. Records Control

5. Management responsibility

5.1. Management Commitment / 5.2. Customer focus / 5.3. Quality Policy / 5.4. Planning / 5.4.1. Quality objectives / 5.4.2. Quality management system plan / 5.5. Responsibility, Authority and Communication / 5.5.1. Responsibility and Authority / 5.5.2. Top Management Representative / 5.5.3. Internal communication / 5.6. Critical analysis by top management / 5.6.1. General / 5.6.2. Critical Analysis Entries / 5.6.3. Critical analysis outputs

6. Resources Management

6.1. Provision of Resources / 6.2. Human resources / 6.3. Infrastructure / 6.4. Working environment and contamination control / 6.4.1. Working environment / 6.4.2. Contamination control

7. Product realization

7.1. Planning the realization of the product

7.2. Customer-related processes

7.2.1. Determination of product-related requirements 7.2.2. Critical analysis of product-related requirements / 7.2.3. Communication

7.3. Design and development

7.3.1. General / 7.3.2. Project Planning & Development / 7.3.3. Inputs for design and development / 7.3.4. Design and Development By-products / 7.3.5. Critical Design and Development Analysis / 7.3.6. Design and Development Verification / 7.3.7. Design and Development Validation / 7.3.8. Project and Development Transfer / 7.3.9. Control of design and development changes / 7.3.10. Design and development

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7.4. Procurement

7.4.1. Procurement process / 7.4.2. Procurement information / 7.4.3. Verification of the purchased product

7.5. Production and provision of services

7.5.1. Production control and provision of services / 7.5.2. Cleaning of the product / 7.5.3. Installation Activities / 7.5.4. Technical assistance activities / 7.5.5. Specific requirements for sterile sanitary products / 7.5.6. Validation of production processes and provision of services / 7.5.7. Specific requirements for validation of sterilization processes and sterile barrier systems / 7.5.8. Identification / 7.5.9. Traceability / 7.5.10. Customer Property / 7.5.11. Product preservation

7.6. Control of monitoring and measurement equipment

8. Measurement, analysis and improvement

8.1. General

8.2. Monitoring and measurement

8.2.1. Feedback / 8.2.2. Complaints Management / 8.2.3. Notification to regulatory authorities / 8.2.4. Internal Audit / 8.2.5. Process monitoring and measurement / 8.2.6. Product tracking and measurement

8.3. Non-compliant product control

8.3.1. General / 8.3.2 Actions in response to the non-compliant product detected prior to delivery / 8.3.3 Actions in response to the non-compliant product detected after delivery / 8.3.4 Rework

8.4. Data analysis

8.5. Improvement

8.5.1. General / 8.5.2. Corrective action / 8.5.3. Preventive Action

Differences:

- Chapter organization;
- Requirements details.

Examples of additional requirements in DRC 16/2013:

- Pest control;
- Formalization of sampling plans;
- Records of training of service providers and consultants.

Pest control

5.1.3.4. Contamination control. Each manufacturer should establish and maintain procedures to prevent contamination of equipment, components, manufacturing materials, intermediate products and finished products with cleaning and disinfection materials, including hazardous substances or contaminants generated by the manufacturing process. A pest control program should be established and whenever chemical agents are used, the company must ensure that they do not affect the quality of the product.

Formalization of sampling plans

9.2. Sampling plans should be formalized in writing and based on valid statistical logic. Each manufacturer should establish and maintain procedures to ensure that sampling methods are suitable for their intended use and that they are periodically revised. The revision of sampling plans should consider the occurrence of product nonconformities, quality audit reports, complaints and other indicators.

Records of training of service providers and consultants

2.3.3. Consultants. Each manufacturer shall ensure that any consultant advising on the methods used or on the controls used for the design, purchase, manufacture, packaging, labelling, storage, installation or technical assistance of products has sufficient qualifications (instruction, training and experience) to advise on the matters for which it was contracted for. The recruitment of consultants shall be carried out in accordance with the purchasing control requirements provided for in this Technical Regulation.

The Medical Device Single Audit Program (MDSAP) is based on: ISO 13485: 2016 (international), TG (MD) R Sch3 (Australia), RDC Resolution ANVISA 16/2013 (Brazil), MHLW Ordinance No. 169 (Japan), 21 CFR Part 820 (United States) and the specific requirements of medical device regulatory authorities participating in the MDSAP program.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Full details of the requirements established by Resolution RDC No. 16/2013, in addition to the requirements of ISO 13485:2016, can be found in MDSAP AUDIT APPROACH, Document No: MDSAP AU P0002.006, Revision Date : 2021-04-01, available at https://www.fda.gov/medical-devices/medical-device-single-audit-program-mdsap/mdsap-audit-procedures-and-forms

AUDIT APPROACH

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Obrigado!

¡Gracias!

Thank you!

Coordination of Sanitary Inspection and Inspection of Health Products(CPROD)

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