IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

08:55 – 09:10

Brazil

Augusto Bencke Geyer

General Manager, General Management of Health Product Technology, Brazilian Health Regulatory Agency (ANVISA)

European Commission

European Union

IMDRF International Medical Device Regulators Forum

Regulatory Updates – Brazil

Augusto Bencke Geyer, Office of Medical Devices

ANVISA – Brazilian Health Regulatory Agency

28 March 2023 – Brussels

Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

- Public Consultation took place between 15 September and 14 November 2022
- Anvisa received 29 contributions with 631 comments/suggestions
- All comments will be shared with NRAs from Mercosur jurisdictions for consolidation in April 2023
- Based on IMDRF documents:
  - Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47FINAL:2018)

Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

- Main objectives:
  - The purpose is to update safety and performance requirements of MD and IVDMD and to restructure the previous regulation in line with the Good Regulatory Practices
  - Inclusion of specific requirements for new technologies
  - Harmonization of requirements for all Mercosur jurisdictions

Clinical Investigations Requirements Revision

- Public Consultation took place between 27 October and 27 December 2022
- Anvisa received 8 contributions with 124 comments/suggestions
- Expected to be published until June 2023
- Main objectives:
  - Decrease regulatory cost
  - Adoption of definitions converging with ISO 14155:2020
  - Clarification about clinical investigations that must be submitted to Anvisa for approval before the start of study activities

Requirements for Pre-Market Authorization of Medical Devices

- Resolution RDC 751/2022
- Definitions and classification rules updated considering new technologies
  - Software as Medical Device (IMDRF/SaMD WG/N12FINAL:2014)
  - Nanomaterials
  - Manufacturers (legal manufacturer and manufacturing sites)
  - Notification (low risk products)
  - Regulatory assessment revision

Requirements for Pre-Market Authorization of Medical Devices

- Consolidation with other regulations – MD changes; e-IFU
- Simplification of required administrative documents
- Adoption of the Table of Contents Structure
- Good Regulatory Practices and Regulatory Convergence
- Effective since 1st of March 2023

Requirements for Pre-Market Authorization of In Vitro Diagnostic Medical Devices

- Completion of the consolidation of contributions from the public consultation
- Submission of the final text for deliberation by the collegiate board of Anvisa
- Definitions and classification rules updated according to IMDRF/IVD WG/N64 FINAL:2021 – Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

Requirements for Pre-Market Authorization of In Vitro Diagnostic Medical Devices

- Consolidation with other regulations – MD changes; e-IFU
- Simplification of required administrative documents
- Adoption of the Table of Contents Structure
- Good Regulatory Practices and Regulatory Convergence
- Expect to publish the RDC in the 1st semester 2023
- Effective date will be 180 days after publication

Use of MDSAP Reports by ANVISA

Number of GMP Certificates Issued Based on MDSAP Reports by ANVISA per Year

Year	# GMP Certificates Issued Based on MDSAP Reports (% of total)
2017	38 (4.7%)
2018	107 (19,3%)
2019	374 (48,7%)
2020	544 (49,1%)
2021	529 (51,4%)
2022	621 (59,7%)
2023	103 (69,1%) – Until 28 February

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Thank you/Questions

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