IMDRF International Medical Device Regulators Forum

Regulatory Updates – Brazil

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ANVISA – Brazilian Health Regulatory Agency

26 September 2023 – Berlin

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

- Consolidation of comments/suggestions carried out between the jurisdictions that are part of Mercosur - Argentina, Brazil, Paraguay and Uruguay
- Final text approved by Mercosur in September 2023 – Ready to be incorporated to the MD Brazilian regulatory framework
- Based on IMDRF documents:
  - Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47FINAL:2018)

Clinical Investigations Requirements Revision

- Public Consultation took place between 27 October and 27 December 2022 – 8 contributions with 124 comments/suggestions
- 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
- One of Anvisa's directors requested a review of the regulatory process for greater alignment with regulations applicable to medicines

Requirements for Pre-Market Authorization of Medical Devices

- Resolution RDC 751/2022 effective since March 2023
- Definitions and classification rules updated considering new technologies
- 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
- Anvisa has facilitated a series of virtual and in-person seminars focusing on manufacturers and importers

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 already harmonized in Mercosur 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
- Expect to publish in November 2023
- Effective date will be 180 days after publication

Good Manufacturing Practices of Medical Devices Certifications Dashboard

- GMP Certification Database
- Relevant search criteria
- Geographic distribution views available
- Certification status filters
- Constantly updated (weekly)
- Widely helpful to management
- Dashboard link:

https://www.gov.br/anvisa/pt-br/setorregulado/certificados-de-boas-praticas/consultar-empresas-certificadas

Good Manufacturing Practices of Medical Devices Certifications Dashboard

Estabelecimento/Fabricante	Solicitante	Linha e Classe	País	Endereço	Resolução	Publicação	Validade	Status
Acrostak (Schweiz) AG	VR Medical Importadora e Distribuidora de Produtos Médicos Ltda	>Materiais de uso médico das classes III e IV.	SUÍÇA	Stegackerstrasse 14, Winterthur, 8409 - Suiça	RESOLUÇÃO-RE Nº 3.280, DE 30 DE AGOSTO DE 2023	04/09/2023	04/09/2025	DEFERIDO
Allergan Sales, LLC	Allergan Produtos Farmacêuticos Ltda	Materiais de uso médico da classe III.	ESTADOS UNIDOS DA AMÉRICA	8301 Mars Drive, Waco, Texas, 76712, Estados Unidos da América	RESOLUÇÃO-RE Nº 3.268, DE 28 DE AGOSTO DE 2023	04/09/2023	04/09/2025	DEFERIDO
Arrow Internacional de Chihuahua S.A de C.V.	Emergo Brazil Import Importação e Distribuição de Produtos Médicos Hospitalares Ltda.	Materiais de uso médico das classes III e IV.	MÉXICO	Av. Washington nº 3701, Interior Circuito Industrial Alta Tecnologia, Edifício 40, Col. Panamericana, Chihuahua, 31200, México	RESOLUÇÃO-RE Nº 3.268, DE 28 DE AGOSTO DE 2023	04/09/2023	04/09/2025	DEFERIDO
Aurolab	Vision Line Importação e Comércio de Materiais e Equipamentos Médicos Ltda- ME.	Materiais de uso médico das classes III e IV.	ÍNDIA	N.º 1 Sivagangai Main Road, Veerapanjan - Madurai , 625020 - Índia	RESOLUÇÃO-RE Nº 3.277, DE 30 DE AGOSTO DE 2023	04/09/2023	04/09/2025	DEFERIDO

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	412 (62,6%)

Until 31 August

Reliance Mechanisms for Pre-Market Authorizations

- Pathway for abridged review of initial submissions
- Normative Instruction for MD and IVD MD under public consultation
  - Public Consultation 1200/2023
  - Open for contributions until 25 October 2023
    - http://antigo.anvisa.gov.br/consultas-publicas#/visualizar/509352
- Main objective – Product registration certificates from Equivalent Foreign Regulatory Authorities will be used as a trigger for expedited review
- Initially from the same founding members authorities of MDSAP

2023 Medical Device Single Audit Program Forum

- Brasília, Brazil – 23rd to 27th October 2023
- Representatives from:
  - Regulatory Authorities
  - MDSAP Auditing Organizations
  - Trade organizations and device manufacturers

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Thank you/Questions

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