IMDRF International Medical Device Regulators Forum

IMDRF Stakeholders Forum

Regulatory Updates
ANVISA

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South Korea

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ANVISA

Construction of the Regulatory Agenda for 2021/2023

ANVISA
Regulatory Agenda

Publication of the Regulatory Agenda 2021 – 2023

- May 2021

Medical Devices

- 21 Regulatory projects

https://www.gov.br/anvisa/pt-br/assuntos/regulamentacao/agenda-regulatoria/agenda-2021-2023/arquivos/portal_lista_final_ar_2021-2023.pdf

SCAN ME

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Software as Medical Device Regulation

Public Consultation No. 1035/2021
Deadline for contributions ended on 06/15/21
Expected approval of the final document: End of 2021

Based on IMDRF documents:

- Software as a Medical Device (SaMD): Key Definitions (IMDRF/SaMD WG/N10FINAL:2013) (IMDRF, 2013)
- Software as a Medical Device (SaMD): Possible Framework for Risk Categorization and Corresponding Considerations (IMDRF/SaMD WG/N12FINAL:2014) (IMDRF, 2014)
- Software as a Medical Device (SaMD): Application of Quality Management System (IMDRF/SaMD WG/N23 FINAL:2015) (IMDRF, 2015)
- Software as a Medical Device (SaMD): Clinical Evaluation (SaMD WG (PD1)/N41R3) (IMDRF, 2017)
- Principles and Practices for Medical Device Cybersecurity (IMDRF/CYBER WG/N60FINAL:2020)

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GMP Certification Requirements

Public Consultation No. 1041/2021
Deadline for contributions ended on 06/15/21
Expected approval of the final document: End of 2021

Main objectives:

- The purpose is to clarify some points of the standard under revision (RDC 183/2017) and simplify the submission process, reducing the number of documents required.
- Allows the use of international data from the IMDRF countries to support Certification.

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Unique Device Identification (UDI)

Public Consultation No. 1051/2021
Deadline for contributions ended on 06/09/21

Key points:
Aligned with IMDRF documents
Phased implementation, starting with high-risk medical devices

- 2 years for risk class IV medical devices;
- 3 years for risk class III medical devices;
- 4 years for risk class II medical devices;
- 6 years for risk class I medical devices.

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THANK YOU!

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