IMDRF International Medical Device Regulators Forum

IMDRF Stakerolders Forum

Regulatory and Policy Update ANVISA

March 2021

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Construction of the Regulatory Agenda for 2021/2023

ANVISA
Regulatory Agenda

Draft Regulatory Agenda proposal
→ 106 project proposals identified

Public Consultation
→ Directed Consultation, including the medical device sector, held between November and January 2021

Publication of the Regulatory Agenda 2021 – 2023
→ Forecast: April 2021

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New Medical Device Cybersecurity Guide

ANVISA published Guide No. 38/2020 (link in Portuguese), *Principles and Practices of Cybersecurity in Medical Devices*, which is based on the IMDRF/CYBER WG/N60 guidance issued by the International Medical Device Regulators Forum (IMDRF).

The 45-page document includes a comprehensive treatment of general cybersecurity principles as well as guidance on documentation for regulatory submissions. Discussion of major points is divided into sections on pre- and post-market considerations.

Guide No. 38/2020 went into force upon publication in late September/20, and ANVISA is soliciting public comments on it until March 23, 2021.

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UDI Working Group

Anvisa published Ordinance 631/20 which created a working group to establish guidelines for implementation of a UDI system in Brazil. It is expected to be aligned to the UDI Guidance Document (IMDRF/WG UDI/N7Final:2013)

Participants:
Anvisa
Medical Device Manufacturers and Importers
Hospitals
Issuing Bodies

Scope:
Responsibilities for establishing and maintaining a UDI
General UDI rules
UDI-Database design

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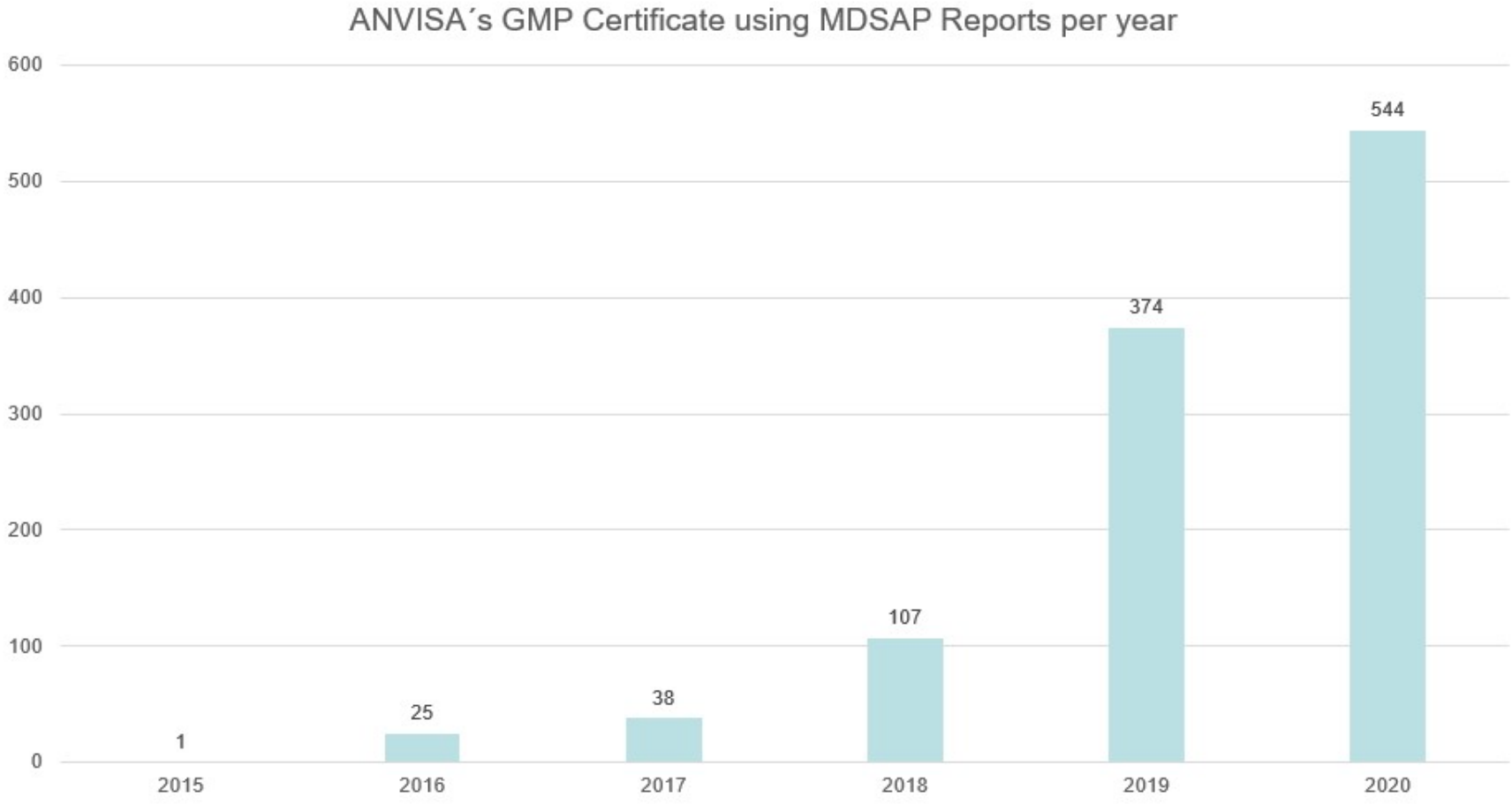

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THANK YOU

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