Regulatory Update from Anvisa – Brazil

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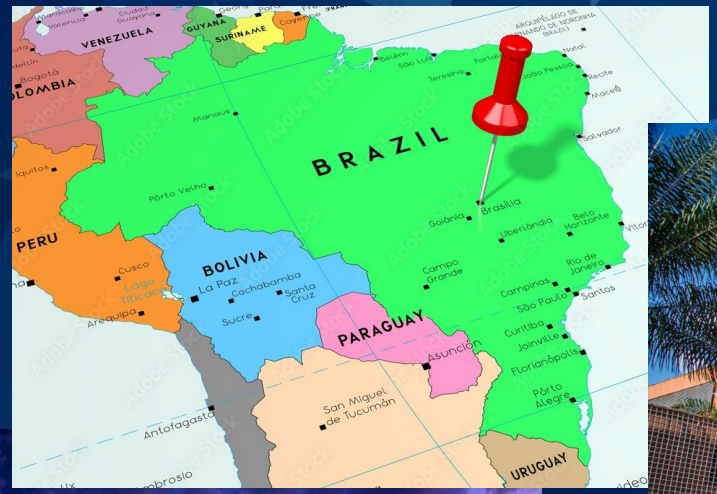
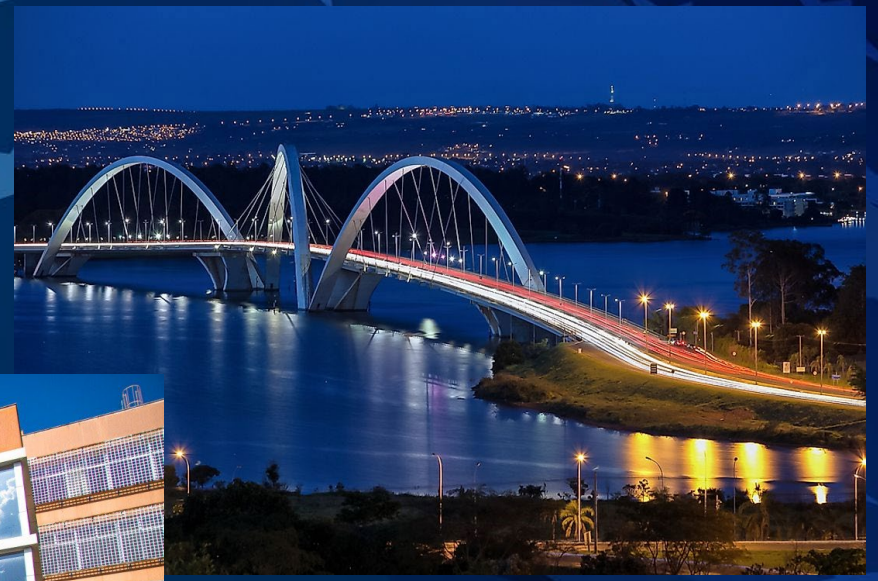
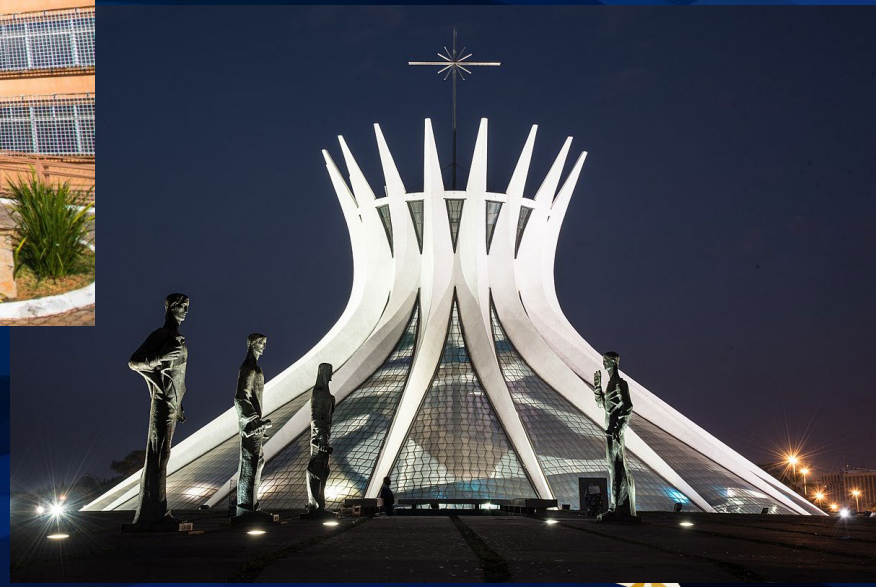
Anvisa – Brazilian Heath Regulatory Agency
March 12, 2024

IMDRF International Medical Device Regulators Forum

Headquarter in Brasília







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IMDRF 2024 Chair

IMDRF
International Medical Device Regulators Forum

Requirements for Market Authorization of In Vitro Diagnostic Medical Devices

- **Final text approved by Anvisa Collegiate Board on 6 December 2023**
  - Harmonized within Mercosur
  - RDC 830/2023
  - Effective on 1st June 2024
  - Update of the documentation required for submission
  - Electronic Instructions for Use requirements
  - Updated definitions and classification rules
  - IMDRF/IVD WG/N64 FINAL:2021 – Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

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Clinical Investigations Requirements

- **Final text approved by Anvisa Collegiate Board on 13 December 2023**
  - RDC 837/2023
  - Effective since 15 December 2023
  - Alignment of the Brazilian regulatory scenario with international practices
  - Simplification of the process of submitting documentation
  - Adoption of a convergent terminology in relation to the development of medical devices

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EP of Safety and Performance

- **Final text approved by Anvisa Collegiate Board on 6 March 2024**
  - Harmonized within Mercosur
  - RDC XYZ/2024
  - Effective 180 days after its publication
  - Based on IMDRF document – Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47FINAL:2018)

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Medical Device Licenses in Brazil

Number of MD Market Authorizations per Year

		2021	2022	2023
Notification	Class I	3102	2718	2711
	Class II	3443	3751	4162
Registration	Class III	938	1014	718
	Class IV	254	328	300
Total		**7737**	**7811**	**7891**

Active Licenses
of Medical Devices
87.758
(31 December 2023)

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Reliance Mechanisms for Market Authorizations

- **Pathway for abridged review of initial submissions**
  - Public Consultation 1200/2023 closed on 25 October 2023
  - Normative Instruction proposal submitted to the Reporting Director
- **Main objectives**
  - Market authorization certificates from Equivalent Foreign Regulatory Authorities will be accepted for expedited review for the grant of Market Authorization in Brazil (registration)
  - Initially from the founding members authorities of MDSAP
- **Expectation to be published and made effective by the second quarter of 2024**

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Use of MDSAP by Anvisa

- **MDSAP Audit Reports are accepted for granting Anvisa GMP Certificates**
  - The Audit Reports are reviewed and they need to cover all requirements in RDC 665/2022
- **MDSAP Certificates started to be accepted for the renewal of Anvisa GMP Certificates (pilot programme started late 2023)**
  - Simple review of the Certificate to optimizes the renewal process
- **Increase in the GMP Certificate validity from 2 to 4 years if based on MDSAP documents**
  - Revision in process after Public Consultation 1208/2023 – expectation to publish the RDC in the first quarter of 2024

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Use of MDSAP by Anvisa

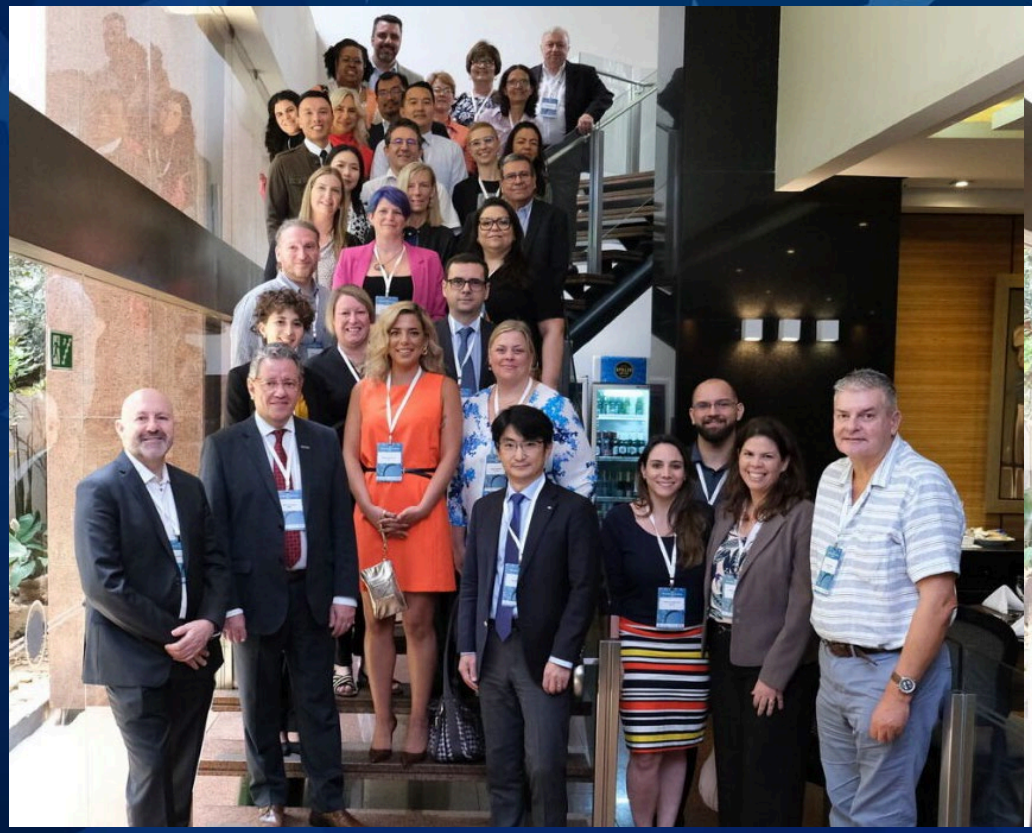
Anvisa GMP Certificates Issued using MDSAP

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	659 (59,1%)

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

ANVISA

MDSAP Forum hosted by Anvisa
Brasília, 23 – 27 October 2023



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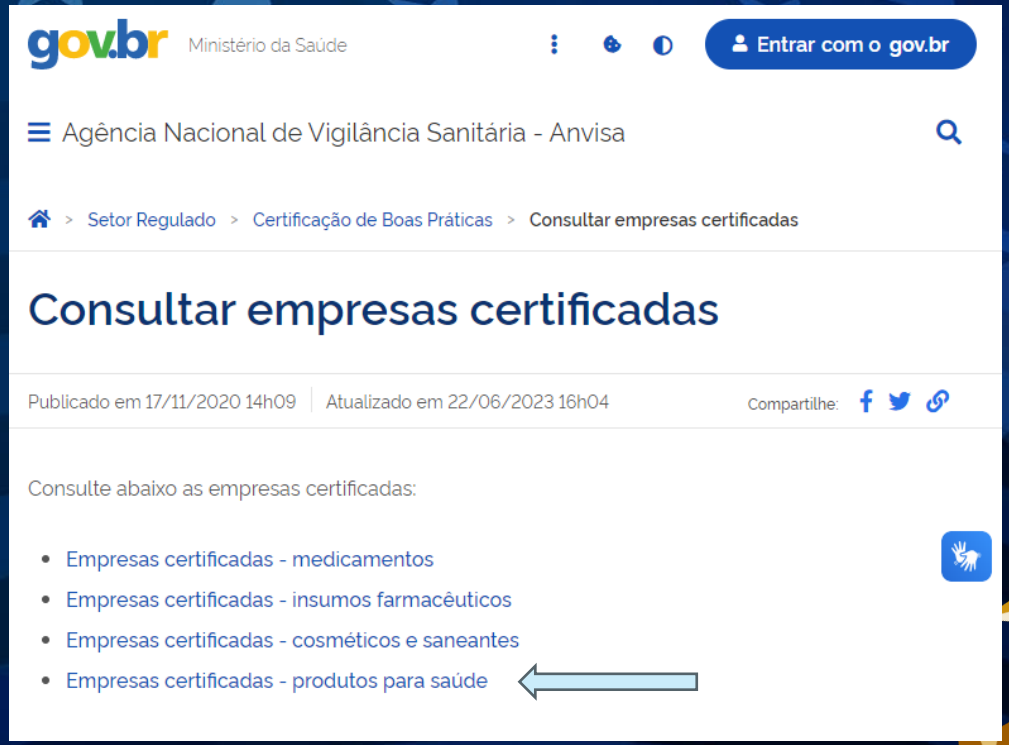
Data Transparency

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

Dashboard link:

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



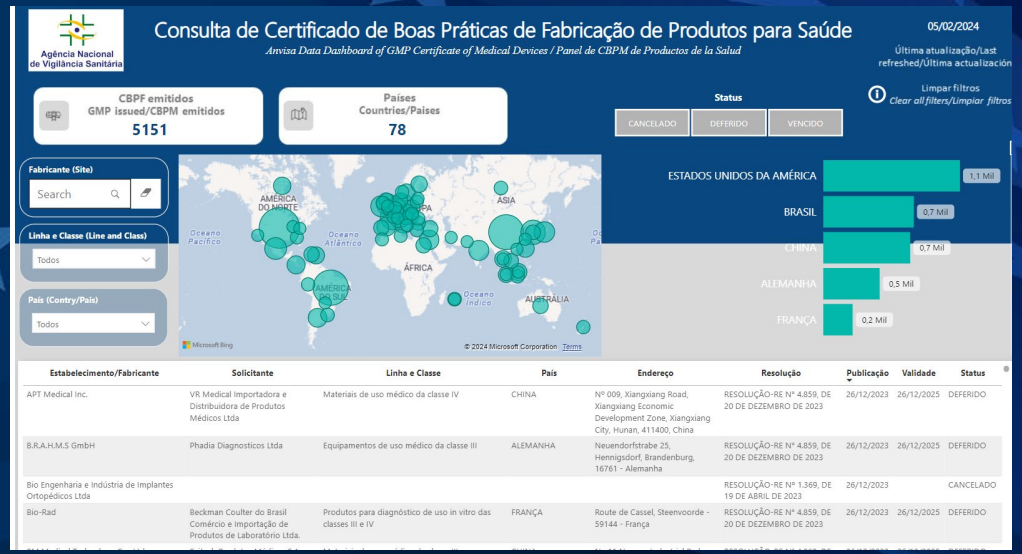
Data Transparency

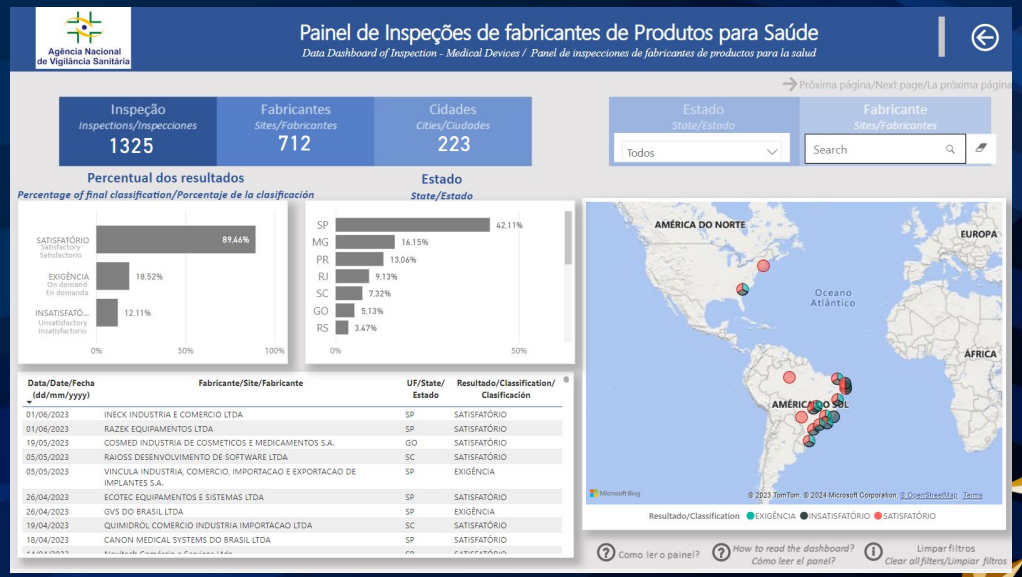
- **Data Dashboard of issued GMP Certificates**

https://app.powerbi.com/view?r=eyJrIjoiYTYzNDM0ZDEtNzkxNC00ODNlLTkwNDAtMjZjMTFjOWVjMTkwIiwidCI6ImI2N2FmMjNmLWMzZjMtNGQzNS04MGM3LWI3MDg1ZjVlZGQ4MSJ9

- **Data Dashboard of Anvisa Inspections – Medical Devices**

Microsoft Power BI





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Anvisa's 25th Anniversary Celebration

The Agency celebrates 25 years of contributions to public health and to the quality of life of Brazilian citizens

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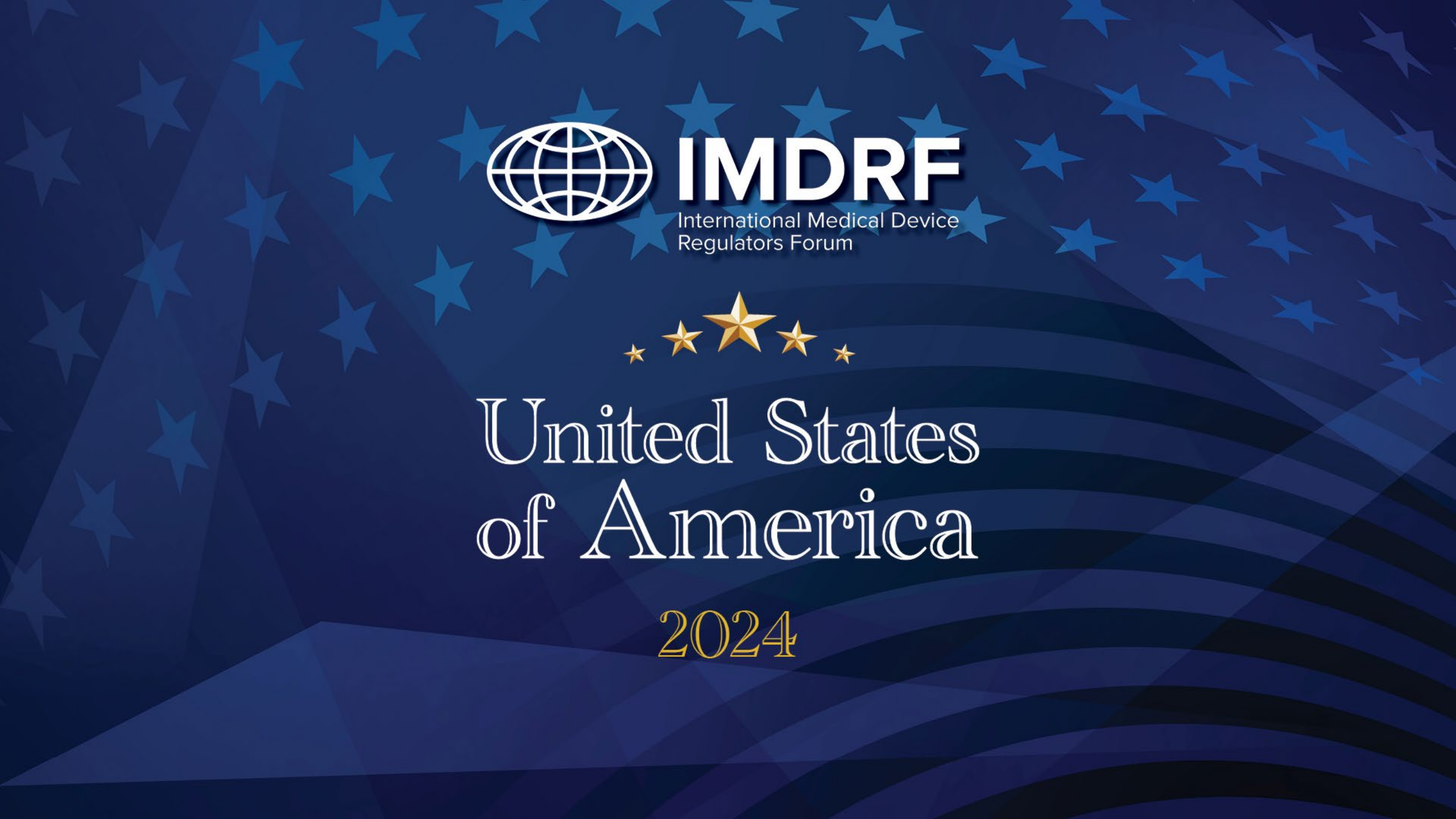
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