How Brazil use MDSAP?

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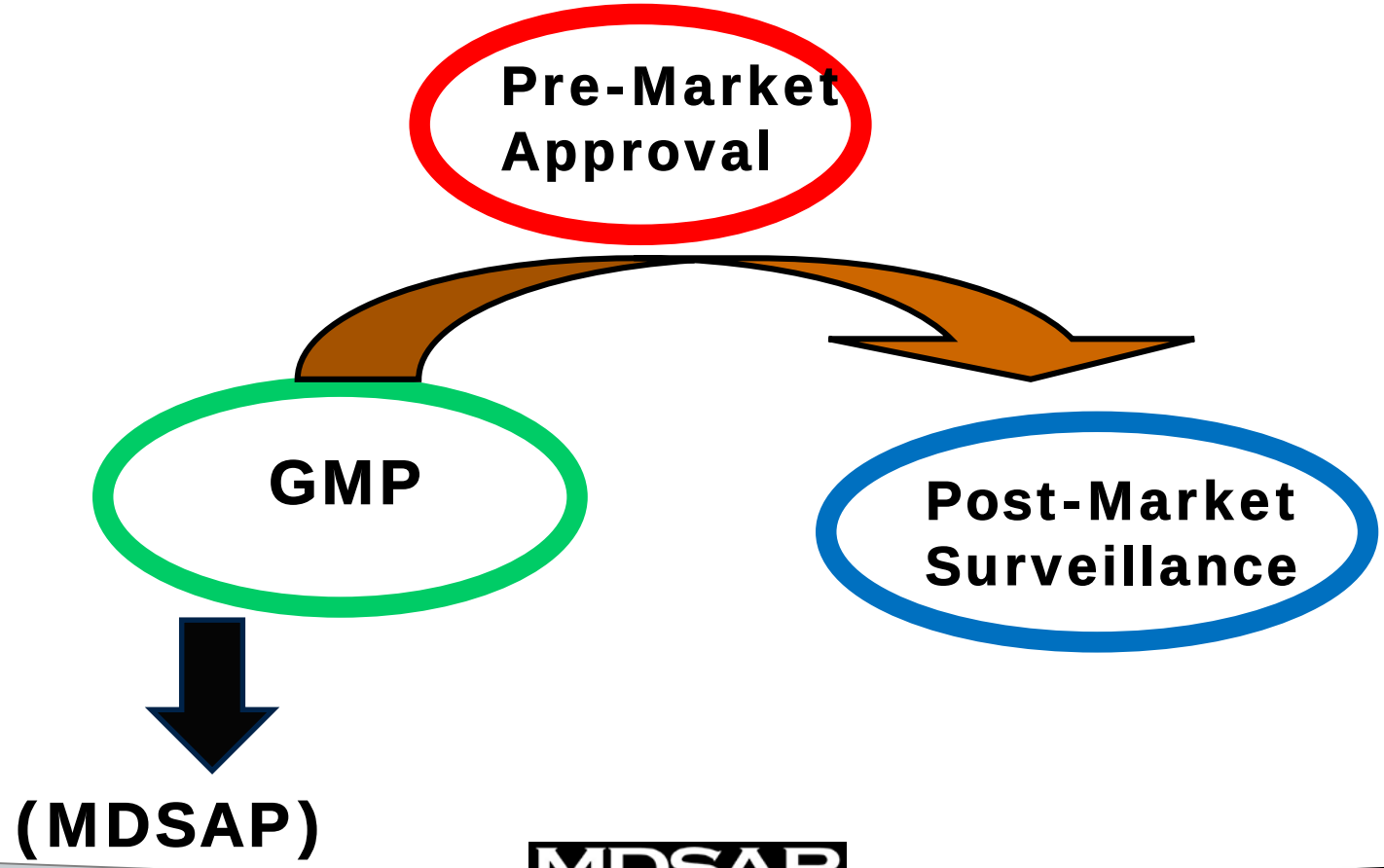
ANVISA - BRAZIL

Medical Devices Regulatory Scheme



Brazilian GMP Certificate

- Final Product
- Final Release + 1 Production stage
- SaMD

- Compulsory for registration of devices Risk Class III and IV

Brazilian GMP Certificate

- MDSAP
- Confidential Information / RAs Agreement
- Audit Report by IMDRF Country / Risk analysis
- Anvisa GMP Inspection

Brazilian GMP Certificate

- Reports analyzed by Anvisa Specialist;
- Reports must cover RDC n°16/2013 requirements;
- No NCs grades 4 or 5 issued;
- NCs grades 1 to 3 with satisfactory action plans.

5-day notice

- Anvisa may also investigate information reported on 5-day notice related with possible risks to patients or public health.

Brazilian GMP Certificate

- NCs raised against other RAs requirements will not impact the Certification or be investigated.

GMP Certificate

- If the company complies with the GMP, the GMP certificate is issued.
- It is published in the Government Official Journal www.in.gov.br
- It is valid for 2 years since its publication.
- Can be cancelled in case of marketing deviations or other significant events.

Use of MDSAP Reports by ANVISA

- 38 Certificates Issued in 2017 (4.7%)
- 107 Certificates Issued in 2018 (19,3%)
- 321 Certificates Issued in 2019 (48,7%)

ANVISA On-Site International Inspections:

- 238 Inspection (2017)
- 110 Inspections(2018)
- 84 Inspections (2019)

Thank you!

Brazilian Health Regulatory Agency

Agência Nacional de Vigilância Sanitária - Anvisa

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