How Brazil use MDSAP?

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ANVISA - BRAZIL
Medical Devices Regulatory Scheme

- Pre-Market Approval
- GMP
- Post-Market Surveillance

(MDSAP)
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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