



# How the Regulatory Authorities use MDSAP? #Brazil

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Date: 2018-05-09

# 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.

# Use of MDSAP Reports by ANVISA

- 72 Certificates Issued;
- 07 Certificates Issued with complementary information;
- 02 Reports waiting for complementary information.

# Thank you!

**Brazilian Health Regulatory Agency  
Agência Nacional de Vigilância  
Sanitária - Anvisa**

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