MDSAP at ANVISA

Current context, practices and perspectives

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MDSAP at ANVISA
Brief History & Hallmarks

- Nov./ 2012: inks the SoC
- 2013: development of the structure
- From jan./2014 to jul./2017: pilot phase
- Oct./2017: RDC 183/2017 – modes of GMP Certification
- Oct./2018: REPs launch
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Peculiarities

- Legal bind for issuing GMP certification by Law nr. 9.782/1999 which requires a specific fee – TFVS, from the Portuguese acronym
- ANVISA uses MDSAP audit reports for Brazilian GMP certification purposes
- The report shall cover Brazilian specific requirements
- Due to this legal frame, there is no double taxation on MDSAP manufacture sites, but the process is somewhat more expensive than those in Agencies that “automatic” accepts MDSAP Certs., i.e., uses the certificate
- Dual process – QMS vs. PMA (licencing)
- End of pilot phase
- Considerably increase in participation of manufactures sites (Brazil included)
- Advent of RDC 183/2017 and REPs
- Changes in ANVISA’s organizational
- **Need of internal adjustments**
  - Revision of the internal procedures for use MDSAP Audit Report in the GMP certification process

- Simplifies and straightforward the certification on BGMP

- Multi-site certification approach (under evaluation)
What we are looking at the report?
- 5-Days Notice
- Grade 4 NCs and correspond action & implementation plan
- Scope of certification
- Applicable jurisdiction
- Any potential discrepancies from the program requirements

- Communication with the AO, if needed
Y
N
Y
N
Does the report contain all applicable audit model processes?

Does the report contain all RDC 16 requirements?

Does the absent information compromise the certification?

Y
N
Y
N
Is the action plan adequate?

E-mail to AO to ask clarification about the approval of the action plan

Open grade 4 or 5 NCs?

Open grade 1, 2 and 3 NCs?

Was additional time given by the AO to the manufacturer?

Send request to the manufacturer to provide evidence of closure of the NCs

Evidence provided?

Y
Y
N
N
Aprove Certification

Y
N
Certificate Renewal

Sent electronic letter to the importer and e-mail to the AO

Initial Certification

Does the absent information compromise the certification?
- Participants sites: 210
- Increase of around 900% from the end of pilot phase
- 87 BGMP Certs issued based on MDSAP Audit Reports (from the end of pilot phase – positive opinion at RAC level, i.e., July/2017)
- Most of participants are waiting expiration of the previous certification, according RDC 39/2013 (administrative proceedings for BGMP certification)
- A dozen and half of participants still waiting MDSAP Audit Reports from their AOs
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Challenges

- IT tools and resources
- RDC 183/2017 integration
- Human Resources and competencies requirements
- Brazil’s and ANVISA’s new administration
We would be glad to answer any questions you may have!

Thank you!!!

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