



MDSAP at ANVISA

Current context, practices and perspectives

Jorge Taveira Samaha, MD, MBA
ANVISA MDSAP SME Representative
Health Regulation Specialist
CPROD/GIPRO/GGFIS/ANVISA



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



MDSAP at ANVISA 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)



MDSAP at ANVISA New IFU



- 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



MDSAP at ANVISA New IFU



- 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)



MDSAP at ANVISA New IFU

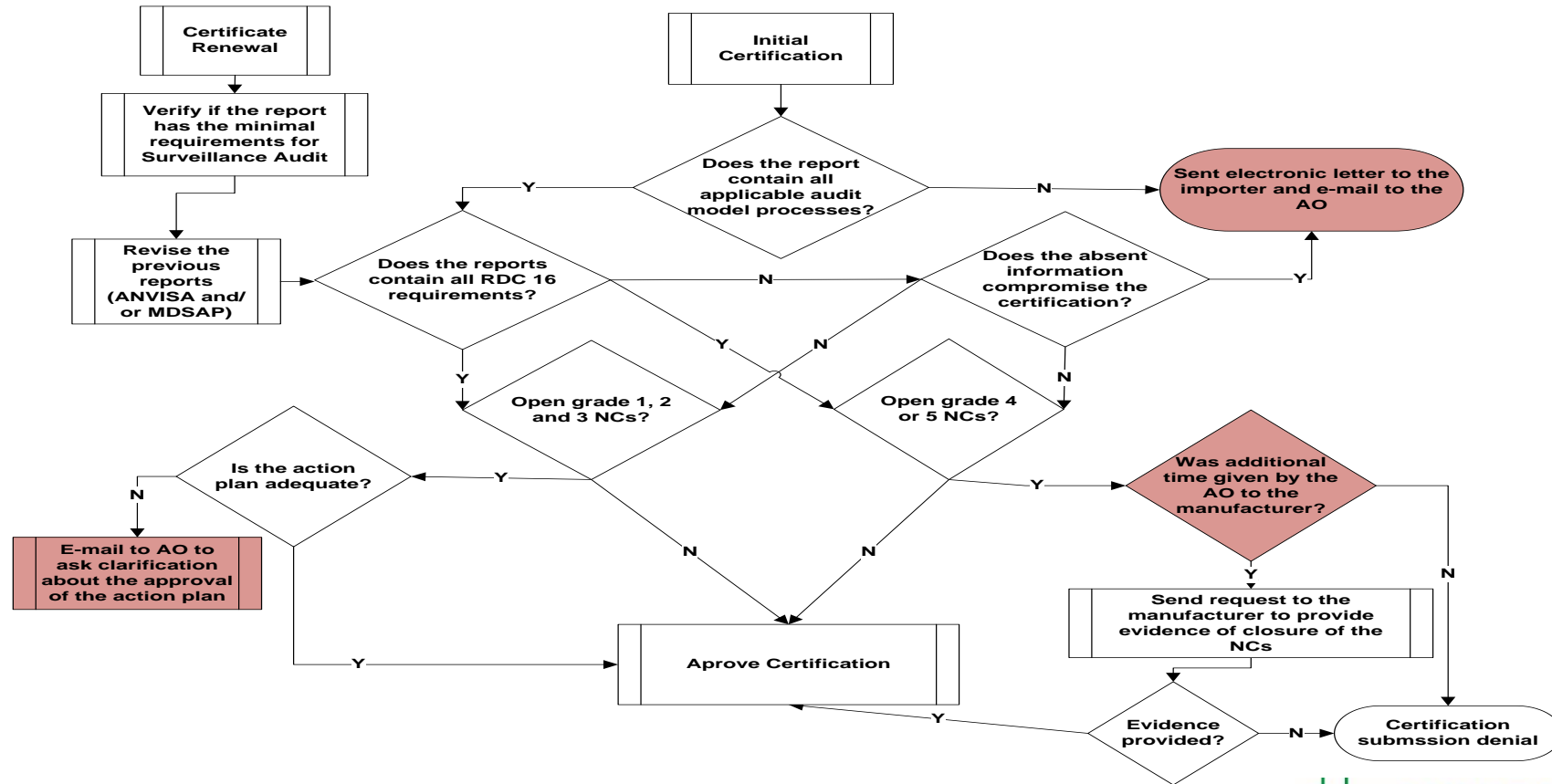


- What we are looking at the report?
 - 5-Days Notice
 - Grade 4 NCs and correspond action & implementation plan
 - Scope of certification
 - Applicable jurisdiction
 - Any potential discrepancies from the program requirements
- Communication with the AO, if needed



MDSAP at ANVISA

Previous IFU





MDSAP at ANVISA Figures



- 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



MDSAP at ANVISA 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!!!

Jorge.Samaha@anvisa.gov.br

mdsap@anvisa.gov.br

mdsap.atendimento@anvisa.gov.br

Agência Nacional de Vigilância Sanitária - Anvisa

SIA Trecho 5 - Área especial 57 - Lote 200

CEP: 71205-050 - Brasília - DF

www.anvisa.gov.br

www.twitter.com/anvisa_oficial

Anvisa Atende: 0800-642-9782

ouvidoria@anvisa.gov.br



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