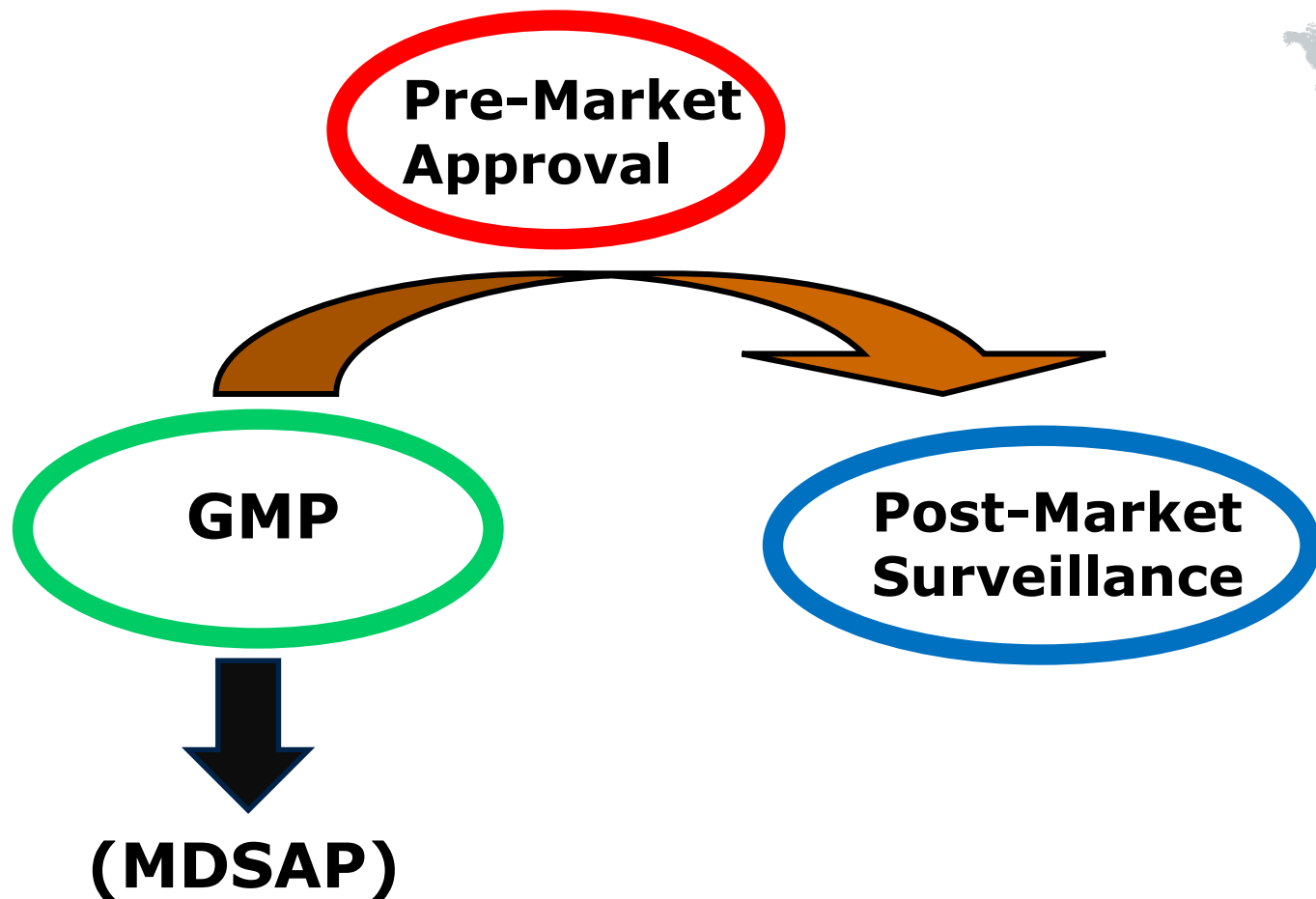


HOW BRAZIL USE MDSAP

Thiago Rezende P. Cunha - ANVISA



Brazilian GMP Certificate



- **RDC nº16, of March 28th, 2013**

Approves the Technical Requirements of Good Manufacturing Practices for Medical Devices and IVD Products.

- **RDC nº 183, of October 17th, 2017**

Administrative procedures for granting the Certification of Good Manufacturing Practices to Medical Devices Manufacturers.

Brazilian GMP Certificate



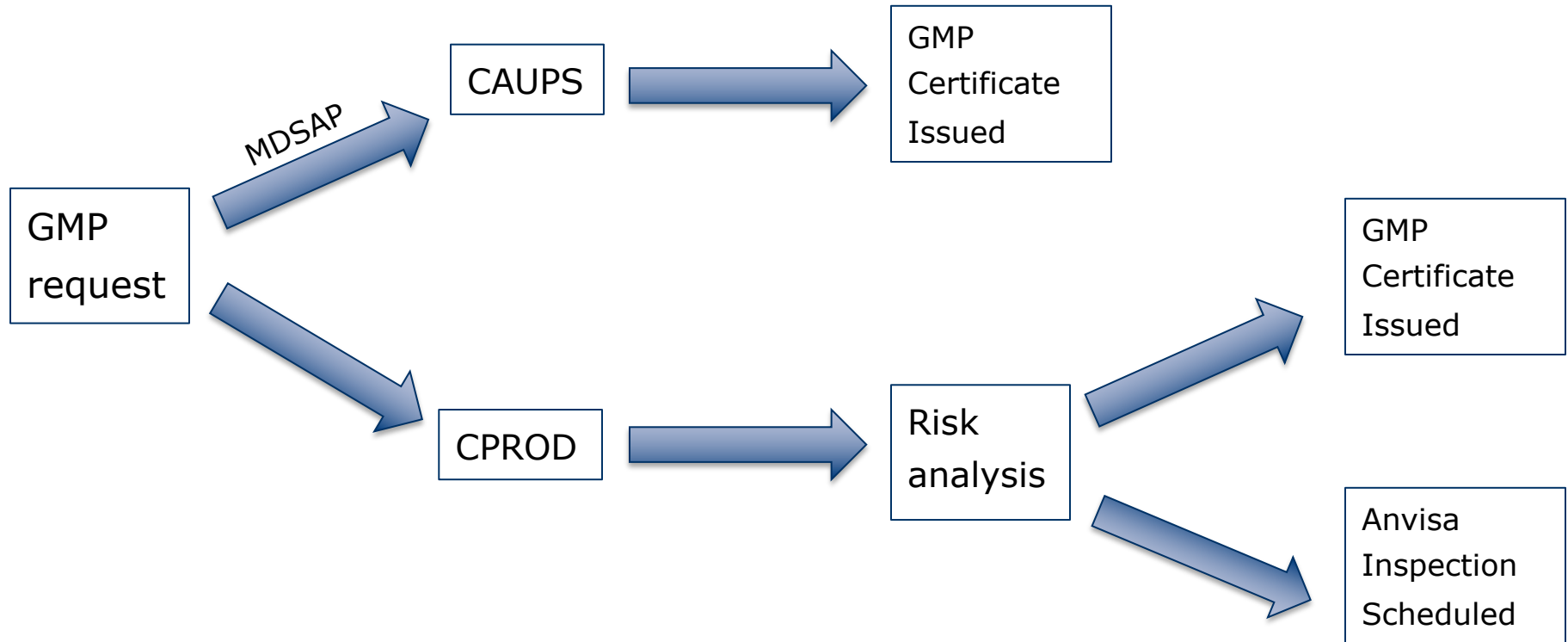
- Final Product
 - Final Release + 1 Production stage
 - SaMD
-
- Compulsory for registration of devices Risk Class III and IV

Brazilian GMP Certificate



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

Brazilian GMP Certificate



Brazilian GMP Certificate



MDSAP Audit Report

- Analyzed by Anvisa Specialist;
- Must cover RDC n°16/2013 requirements;
- Initial or Recertification
- Surveillance reports in special circumstances

NC Grading Exchange Form

- Must be updated in REPs
- NCs grades 4 or 5 must be closed;
- 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.

Advantages of MDSAP for ANVISA



- Resources saving
- Standard Reporting
- RDC nº 16/2013 in the scope
- Authenticity of reports (received directly from the AOs)
- Possibility to request additional information
- Faster GMP Certificates Issuance
- Annual Monitoring (surveillance audits)
- 5-day notice

Use of MDSAP Reports by ANVISA



2017 → 38 Certificates Issued (4.7%)

2018 → 107 Certificates Issued (19,3%)

2019 → 374 Certificates Issued (48,7%)

2020 → 544 Certificates Issued (49,1%)

ANVISA On-Site International Inspections:



2017 → 238 Inspections

2018 → 110 Inspections

2019 → 84 Inspections



MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM