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ANVISA QUALITY CERTIFICATION FOR MEDICAL DEVICES AND PHARMACEUTICAL PRODUCTS

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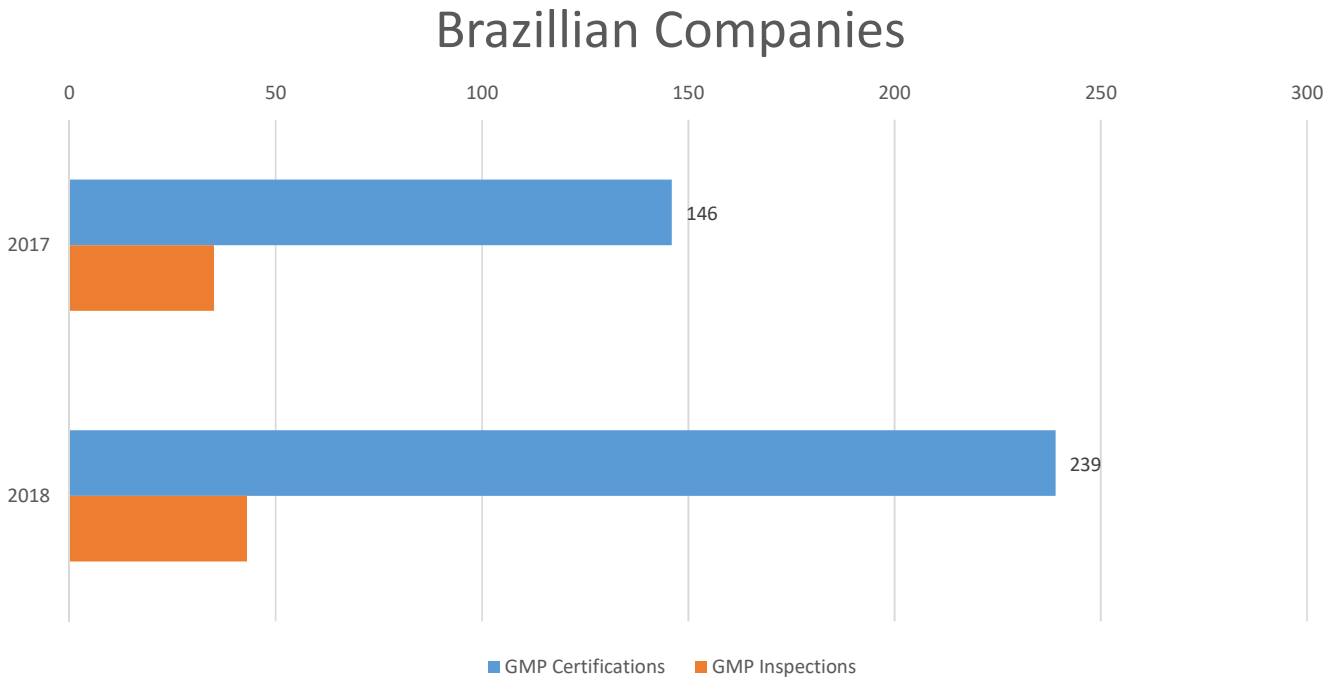
GMP CERTIFICATES AND INSPECTIONS

- In Brazil, a GMP inspection is a prerequisite for an initial GMP certificate to be granted;
- Meaning that if the company complies with GMP, the GMP certificate will be granted and published on the Official Gazette: www.in.gov.br;
- GMP certificates are **valid for 2 years** from the date of publication;
- **GMP certification renewal:** may Anvisa request additional information or schedule a new GMP inspection;
- GMP Certificates can be cancelled in case of market deviations or other significant events.

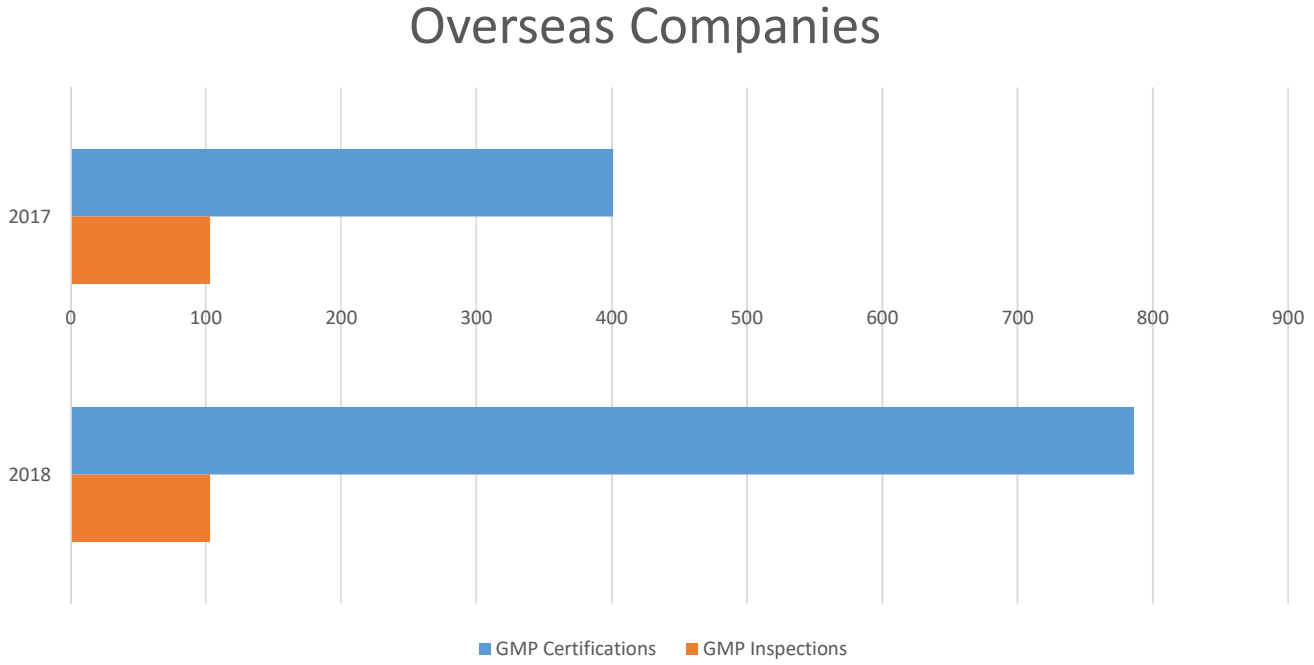
GMP GUIDELINE FOR PHARMACEUTICAL PRODUCTS (RDC 17/2010)

RDC 17/2010 Content	INTERNATIONAL REFERENCE
GMP Principles and Guidance – article 6 to 318	Annex 4, 37th Report – WHO Technical Report Series 908, 2003.
Sterile Products – article 319 to 427	Annex 6, 36th Report – WHO Technical Report Series 902, 2002.
Biological Products –article 360 to 460	Annex 3, WHO Technical Report Series 822, 1992.
Validation – article 461 to 526	Annex 4, 40th Report – WHO Technical Report Series 937, 2006.
Water for Pharmaceutical Purposes – article 527 to 569	Annex 3, 39th Report – WHO Technical Report Series 929, 2005.
Computerized Systems – article 570 to 590	Annex 11, EMA GMP Guide and PIC's GMP Guide.
Herbal Medicines – article 591 to 607	Annex 3, 40th Report – WHO Technical Report Series 937, 2006.

GMP INSPECTIONS x GMP CERTIFICATES ISSUED



GMP INSPECTIONS x GMP CERTIFICATES ISSUED



GMP CERTIFICATES FOR PHARMACEUTICAL PRODUCTS, A TREND

Increasing percentage of GMP certificates issued based on risk assessment, with no inspection required by Anvisa:

Brazillian Companies:

2017	76%
2018	82%

Overseas Companies:

2017	74%
2018	87%

MEDICAL DEVICE CERTIFICATION

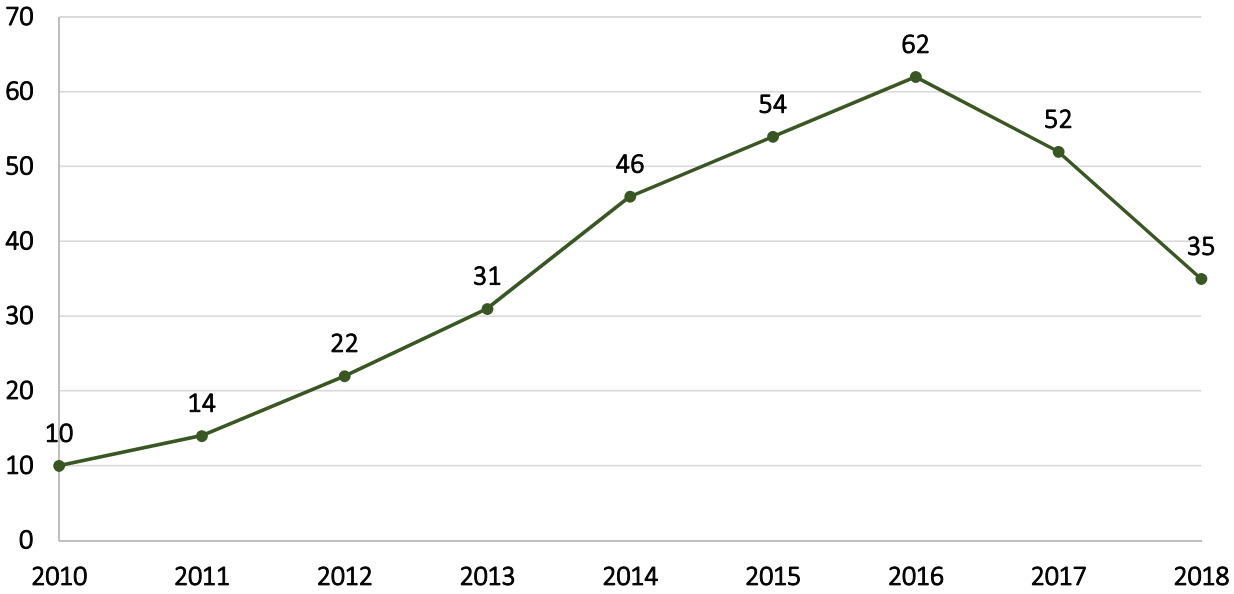
2011

- Inspections performed by Anvisa (based on RDC nº 39/2013 and RDC 16/2013)
- Inspections performed by Anvisa Mercosul Authorities (based on RDC nº 39/2013)

2015

- Inspections performed by Anvisa ; or
- MDSAP inspections (RE nº 2.347/2015)

WAITING LIST FOR INSPECTION



YEAR	MONTHS
2010	10
2011	14
2012	22
2013	31
2014	46
2015	54
2016	62
2017	52

MEDICAL DEVICE CERTIFICATION

2011

- Inspections performed by Anvisa (based on RDC nº 39/2013 and RDC 16/2013)
- Inspections performed by Mercosul Authorities (based on RDC nº 39/2013)

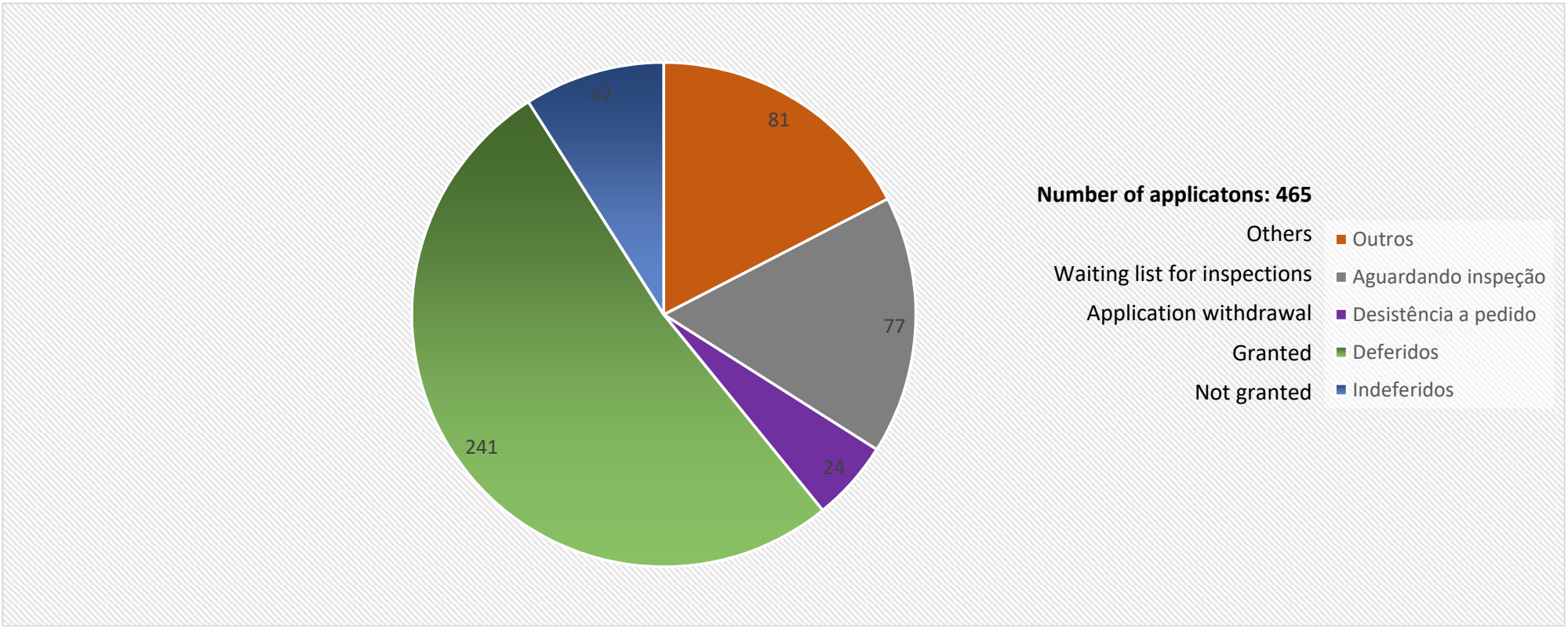
2015

- Inspections performed by Anvisa; or
- MDSAP inspections (RE nº 2.347/2015)

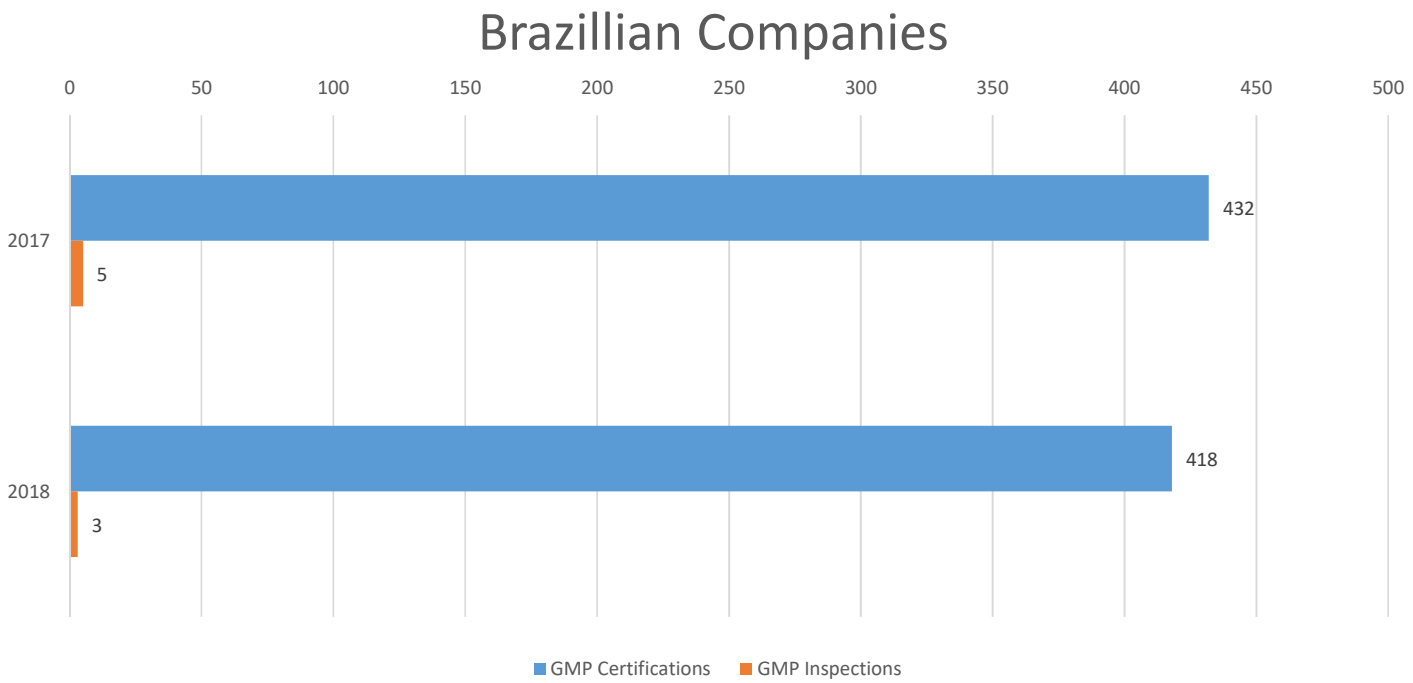
October 2017

- Inspections performed by Anvisa; or
- MDSAP inspections; or
- Inspections performed by Auditing Bodies recognized by Anvisa (RDC nº 183/2017); or
- Inspections based on risk analysis matrix (RDC nº 183/2017)

Impacts arising from the adoption of RDC 183/2017 on the waiting list (from 2013 to october 2017) for GMP inspections for medical devices:



GMP INSPECTIONS x GMP CERTIFICATES ISSUED



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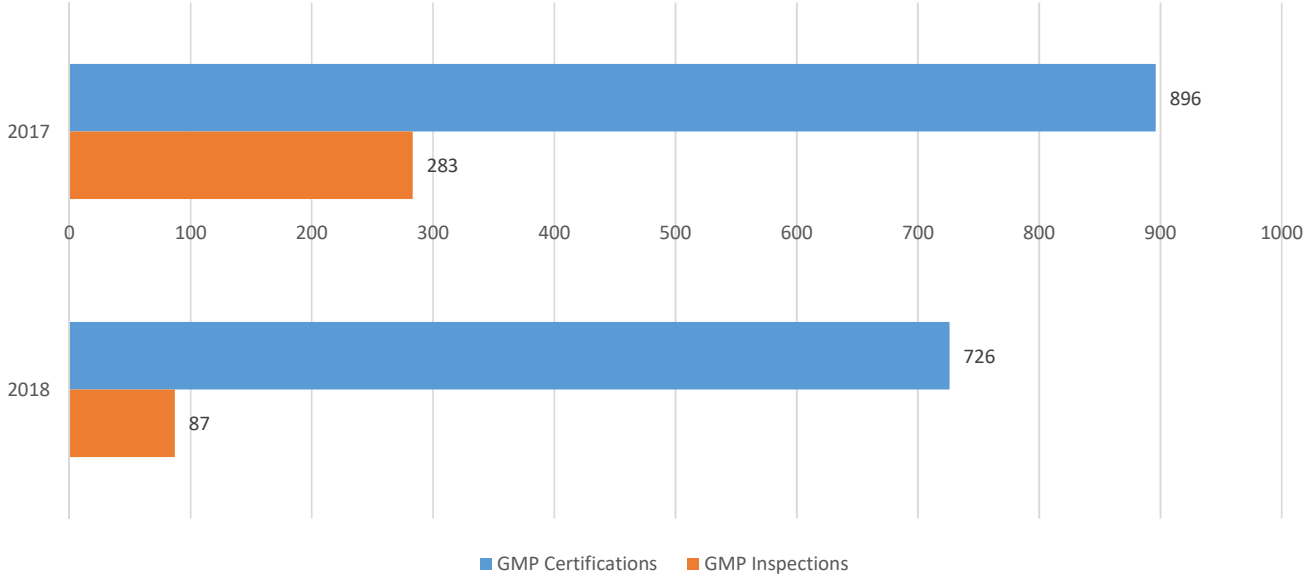
GMP INSPECTIONS x GMP CERTIFICATES ISSUED

Overseas Companies



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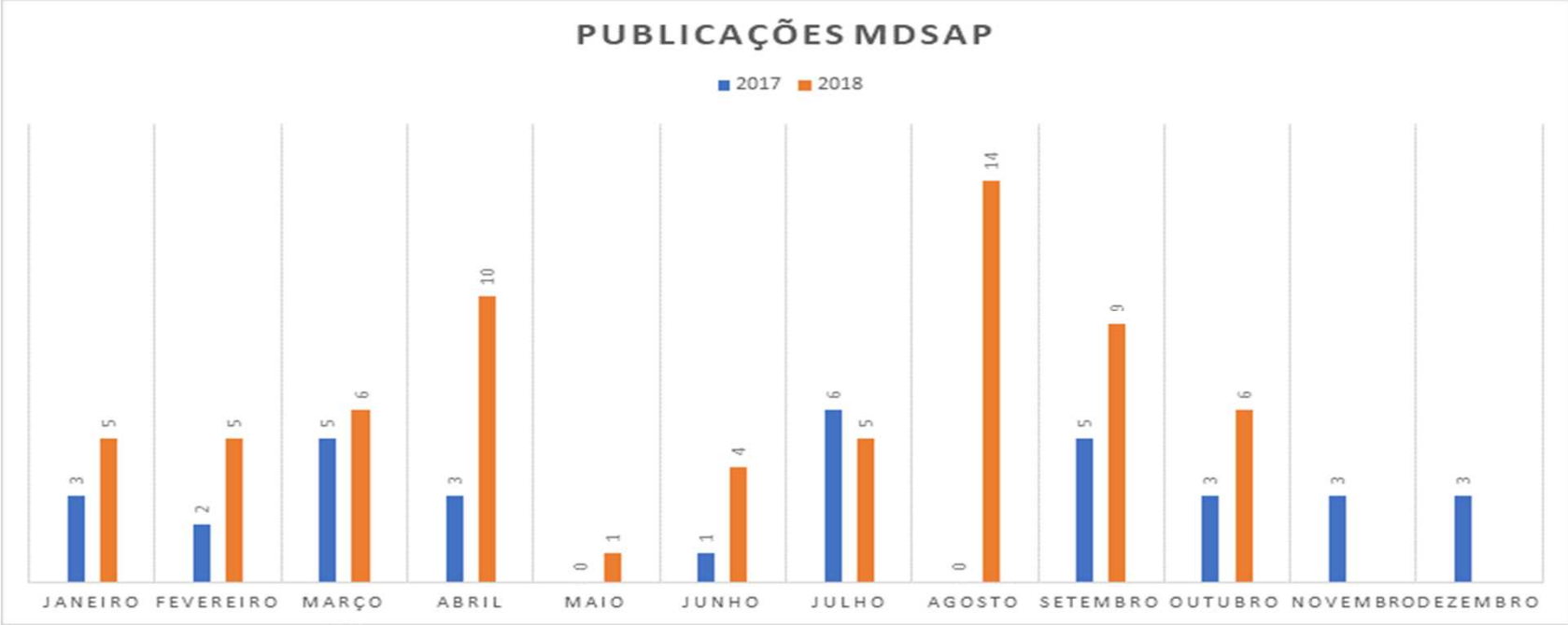

GMP CERTIFICATION FOR MEDICAL DEVICES, CURRENT CHALLENGES

•Improve the risk analysis tools adopted in GMP certification so inspections are not required, and quality and safety criteria are still assured; and

•Adopt inspection programs that take into account the risk profile of manufacturing sites and products, as well as the necessity of proviging access to specific product (for example, new technologies).

THANK YOU!
OBRIGADA!

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