Regulatory and Policy Updates
ANVISA

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Regulatory Updates

- **Resolution RDC n° 270/2019 -** Simplification of the regulatory process for the lowest-risk medical devices.
- Regulatory process for Class I devices (including IVDs) change from cadastro (simplified approval) to a simple notification.
- Effective on 05/02/2019.

Regulatory Updates

- **Public Consultation n° 546/2018** - Regulations for custom-made devices

- Core elements of the Public Consultation:

- Device manufacturers and importers must be fully licensed by ANVISA;
- Manufacturers of Class III and IV devices must have valid Brazilian Good Manufacturing Practice (BGMP) certifications

Regulatory Updates

- **Public Consultation n° 584/2018; 584/2018 and 586/2018** – Updates requirements for Reprocessing & Reuse of Medical Devices.

- Requirements for labeling and for good practices for the processing Medical Devices;

- Anvisa's goal with the proposal of a new RDC is to improve the management of risks associated with the processing of medical devices.

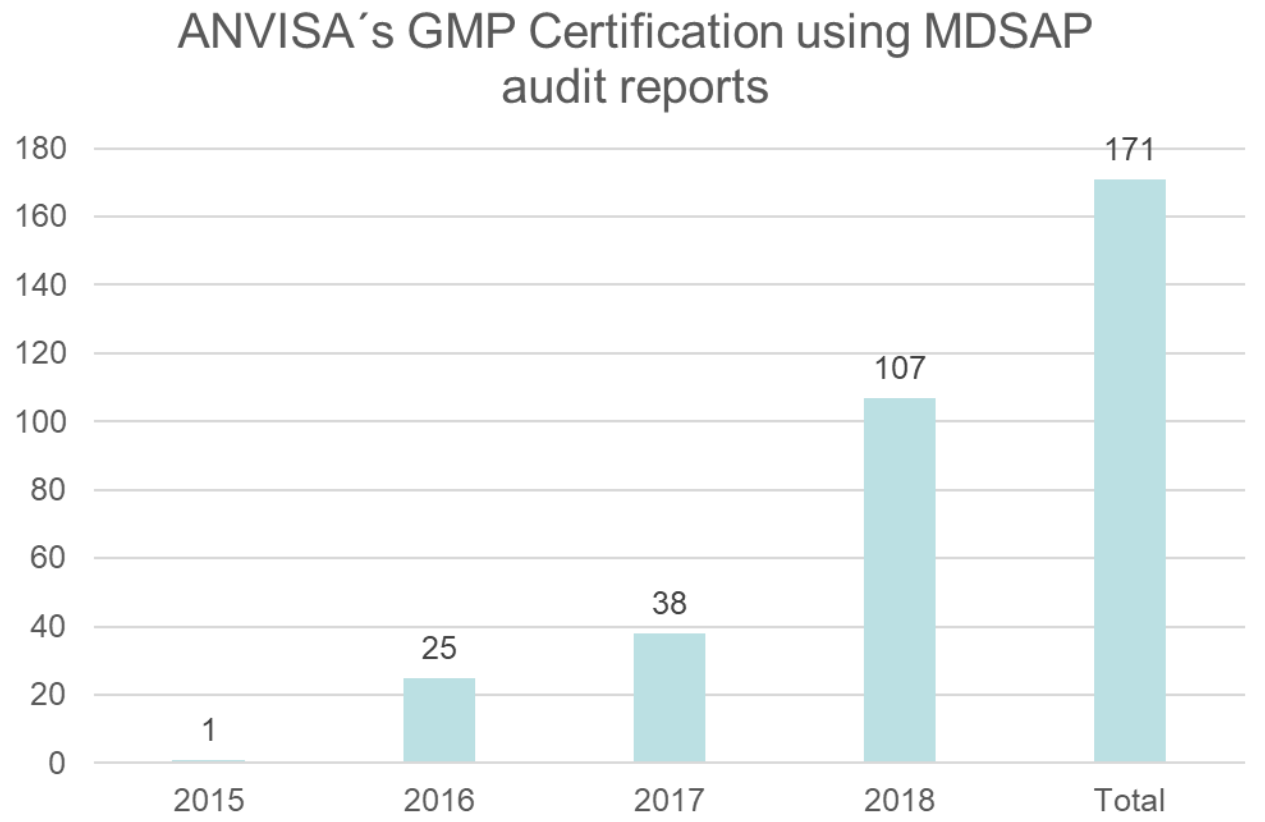
Regulatory Updates

- **Public Consultations**

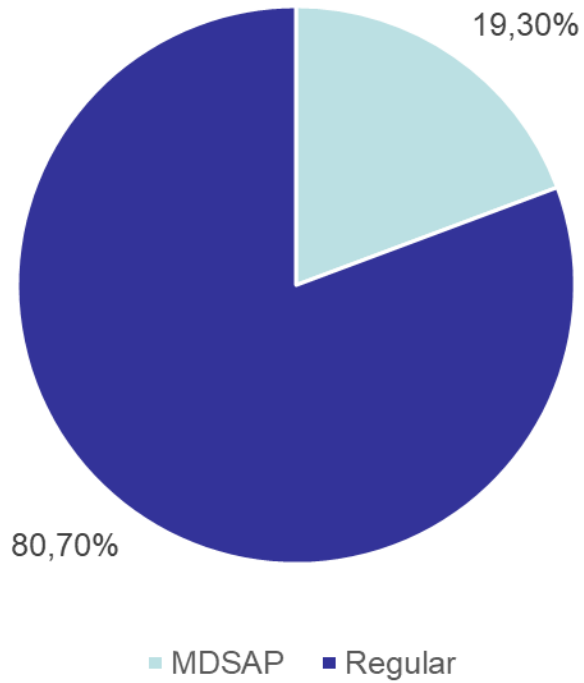
How to submit your contribution?

http://portal.anvisa.gov.br/consultas-publicas#/

You can also upload documents, such as position papers and send it to ANVISA.


ANVISA´s GMP Certification using MDSAP audit reports
180
160
140
120
100
80
60
40
20
0
1
25
38
107
171
2015
2016
2017
2018
Total

Anvisa's GMP Certification 2018



MDSAP Certification 2019

Increasement Projection:
30% to 40%
of the total GMP Certification
to be issued by Anvisa.

Thank you!

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