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
Anvisa's GMP Certification 2018: 80.70%

MDSAP Certification 2019: 19.30%

Increase Projection: 30% to 40% of the total GMP Certification to be issued by Anvisa.
Thank you!

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