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 (Class I).

• The regulatory process changed from Cadastro (simplified approval) to a simple Notification for class I devices.
New Regulation for Personalized Medical Devices

- Approved on September, 12, 2019

- Establishes new procedure for authorizing custom-made medical device

- Fully aligned with IMDRF/PMD WG/N49 FINAL:2018
New Regulation for Personalized Medical Devices

• Key Points:

• Company Authorization for custom made devices: Manufacturers must demonstrate technology mastery and comply with Brazilian GMP

• Authorized Companies must notify ANVISA of the manufacturing or importing of each individual custom-made device
New regulation for Personalized Medical Devices

• Key Points:
  
  • Labelling must contain patient and physician information
  
  • Implant Card Requirements

Document available on Anvisa's website:
http://portal.anvisa.gov.br/2017-2020/temas
Anvisa's GMP Certification using MDSAP Audit Report per year

- 2015: 1
- 2016: 25
- 2017: 38
- 2018: 107
- 2019 (until Aug.): 265
- Total: 436
ANVISA'S GMP CERTIFICATIONS 2019 until August

MDSAP Audit Report 48%

RDC 183/2017 52%
Software as a Medical Device (SaMD) Forum

• September, 18, 2019 – Brasília – DF

• This is an event that marks the beginning of the regulatory process for internalizing the IMDRF SaMD documents in Brazil.
Thank you!

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