IMDRF International Medical Device Regulators Forum

Update on the Brazilian regulatory aspects on medical devices

ANVISA

Brazil

Basis for the regulation on medical devices - Law N. 6.360/1976

- basis for regulation of all products under health surveillance in Brazil, including medical devices.
- identify the need for pre and post market control of products, as well as the shared responsibility of the Federal, State and Municipality levels in the different aspects of health surveillance.
- organize the role of ANVISA in promoting the access by the consumers to products that proved to have quality, safety and efficacy.

Basis for the regulation on medical devices - Decree N. 8.077/2013

- allows more efficient regulatory management and better use of ANVISA's human and technical resources.
- promotes enhanced communication channels for regulatory information among stakeholders (including society, foreign authorities, industry and Government at the national, state and municipality levels).
- implements legal basis for more dynamic regulatory processes with further effectiveness.

Regulatory updates - Brazil

Normative Instruction N. 8 of December, 2013 - Establishes rules related to the application of the requisites described in GMP Resolution (RDC 16/2013) specifically to companies that import, store and distribute medical devices.

Regulatory updates - Brazil

Normative Instruction N. 9 of December, 2013 - Establishes a list of Technical Norms that must be considered within the Brazilian Conformity Assessment System (SBAC) applicable to equipment regulated by ANVISA (such as electro-medical equipment, diagnostic kits, mechanical wheelchairs).

Other updates - Brazil

Public Consultation N. 50, of November 2013 - Proposed Resolution detailing the documents and certifications required for the pre-market approval of medical devices and IVD in Brazil, including the possibility of accepting reports from Auditing Organizations that participate in initiatives recognized by ANVISA. The contributions are currently being reviewed by ANVISA.

Other updates - Brazil

Ongoing review of Normative Instruction N. 1 of April, 2012 - This norm establishes model forms to report Field Actions, used by the companies that have registered medical devices with ANVISA. The forms are to be updated.

Thank you!
Obrigado!