IMDRF International Medical Device Regulators Forum

REGULATORY UPDATES

IMDRF Stakeholders Meeting
Brasília, Brazil, March 2016

ANVISA

Brazil

Regulatory Updates Resolution

- **ANVISA Normative Instruction nº 04 (24/09/2015)**

- Update of technical standards (ISO/IEC) regarding mandatory certification of electromedical equipments.

- Aim: to improve marketing control, intending reduction of risks to user / patient.

Regulatory Updates Resolution

- **RDC ANVISA nº 52 (27/11/2015)**

  - Sets registration requirements for HIV self-testing products with screening purposes.

Regulatory Updates
Law

- **Law nº13.202 (09/12/2015)**

  - Updates fees for regulatory activities.

Regulatory Updates Resolution

- **Resolution RE n. 3454, published on December 16th 2015**
  - ✓ Allows ANVISA to use MDSAP regulatory audit outcomes from BSI Group America Inc. to issue the Anvisa´s GMP certificate.

- **Resolution RE n. 80, published on January 11th 2016**
  - ✓ Allows ANVISA to use MDSAP regulatory audit outcomes from TUV SUD America Inc. to issue the Anvisa's GMP certificate.

Regulatory Updates Resolution

- **Portaria INMETRO nº 54 (01/02/2016)**

  - Approves the improvement of Conformity Assessment Requirements for equipments under Health Surveillance System.

Regulatory Updates Resolution

- **RDC ANVISA nº 64 (02/24/2016)**

  - Aligns biological safety requirements for tattoo inks to the ISO 10993 requirements.

THANK YOU!

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