IMDRF International Medical Device Regulators Forum

REGULATORY UPDATES

IMDRF Stakeholders Meeting
Vancouver, Canada
March, 2017

ANVISA
Brazil

- **Normative Instruction, ANVISA nº 13 - November 8th, 2016**

  - ✓ This document establishes specific criteria for medical devices grouping in the regulatory review process at ANVISA.

- **Public Consultation, ANVISA nº 257 - September 28th, 2016**

  - ✓ This draft technical regulation establishes requirements for the registration of medical devices which re-use is prohibited, its labeling, instructions for use and gives other provisions.

- **Public Consultation, ANVISA nº 282 - December 9th, 2016**

  - ✓ This draft technical regulation establishes Good Clinical Practices (GCP) inspection procedures for clinical trials of medical devices.

➢ ANVISA recognition of MDSAP Auditing Organizations

Auditing Organization	Resolution
Laboratoire National de Métrologie et d'Essais (GMED Certification Division)	Resolution RE n. 31, published on January 1st, 2017
BSI Group America Inc.	Resolution RE n. 23, published on January 5th, 2017
DQS Medizinprodukte GmbH	Resolution RE n. 194, published on January 24th, 2017
DEKRA Certification B.V.	Resolution RE n. 193, published on January 24th, 2017
TUV SUD America Inc.	Resolution RE n. 324, published on February 8th, 2017
Intertek Testing Services NA Inc.	Resolution RE n. 323, published on February 8th, 2017

THANK YOU!