IMDRF International Medical Device Regulators Forum

REGULATORY UPDATE

IMDRF Stakeholders Meeting
Tokyo, Japan, March 2015

ANVISA

Brazil

REGULATORY UPDATE

➢ ANVISA Normative Instruction nº11/2014

- Update of technical standards (ISO) regarding mandatory certification of electromedical equipments.
- Aim: to improve marketing control with impact in reduction of the risks to the user / patient.

➢Law nº13.097/2015 (19/1/2015)

- Use of confidential information of audits received under the scope of agreements with foreign authorities for GMP certification
- Authorizes inspections and audits by national or international organizations recognized by ANVISA
- Exclude revalidation for the Operating Company Authorization for importers and companies installed in Brazil
- Allows the marketing authorization of products to be valid up to 10 years (current situation: marketing authorization valid for 5 years) - to be regulated

➢RDC ANVISA nº 6/2015

- Packaging, labeling and marketing of whitening teeth products classified as medical devices
- Teeth whitening with composition higher than 3% of hydrogen peroxide shall be marketed only under professional prescription (dentist)

➢Clinical Trials

- Defines requirements to approve Clinical Trials with medical devices.
- Publication at the National Gazette (DOU) .

TASK FORCE

➢Medical Devices Reprocessing (Ordinance ANVISA nº 1.910/2014)

- To evaluate the current situation of products and services related to medical devices reprocessing
- To propose directives for the review of RDC 156/2006 (requirements for marketing authorization, labelling and reprocessing of MD), R.E. 2.605/2006 and R.E. 2.606/2006 (list of single use MD unsuitable for reprocessing).

TASK FORCE

- **Medical Devices Working Group (Interministries Ordinance nº 38/2015 Ministries of Health, Finance and Justice)**

- Restructuring and improvement of transparency of production, import, purchase, distribution, use, taxation, technology assessment and incorporation and price regulation procedures
- Improvement of clinical regulation and access to medical devices (prosthesis, orthosis, special materials)

RISK COMUNICATION

- **Meeting with Glucose meter Importers (September 2014)**

- Present a study developed by INMETRO and Federal University of Viçosa – UFV on evaluation of Glucose meter's instructions for use .

- Conduct Adjustment Agreement signed to solve the problems detected and improve control (focus on accuracy)

Thank you

[Conclusion]