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

- To evaluate the current situation of products and services related to medical devices reprocessing
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 COMMUNICATION

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]