IMDRF International Medical Device Regulators Forum

REGULATORY UPDATE

IMDRF Stakeholders Meeting
Kyoto, Japan, September 2015

ANVISA
Brazil

Regulatory Updates
Public Consultation

- **Draft Resolution - CP # 52/2015** – a new technical regulation which sets criteria for the registration of HIV autotest products to be used in Public Policies established by the Ministry of Health.

Contributions are currently being reviewed by Anvisa.

Regulatory Updates
Public Consultation

➢ **Draft Resolution - CP nº 61/2015** – a new technical regulation to propose an amendment to RDC ANVISA 55/2008 - regarding the assessment of safety and effectiveness of artificial skin pigmentation products on the pre-market stage. It will accept the use of ISO 10993-1 and the submission of reports based on ISO 14971.

The deadline to send contributions is opened until Oct/17/2015.

Link: www.anvisa.gov.br; Consultas Públicas; Consulta Pública nº 61, de Aug/17/2015.

Regulatory Updates Resolutions

- **RDC ANVISA nº 36/2015** (Draft Technical Regulation nº 23/2014)
- Establishes that Class I and II IVD products are subject to notification;
- Sets requirements for labeling and instructions of use;
- Extinguishes the revalidation process for notifications.

This RDC will enter into force in Oct/2015. Companies should fully comply with the new regulation up to Oct/2016.

Regulatory Updates Instructions

- **IN ANVISA nº 03/2015**

This Normative Instruction establishes criteria for pre-market submissions of products in IVD families.

Regulatory Updates
Resolutions

- **RDC ANVISA nº 37/2015** (Draft Technical Regulation nº 70/2014)

This Resolution establishes requirements regarding the labeling of products made of latex or that may contain it. All medical products in this cathegory must display a notice.

Companies should fully comply with the new regulation up to Aug/2016.

Regulatory Updates
Resolutions

- **RDC ANVISA nº 40/2015** (Draft Consultation nº 24/2014)

- Defines that all Classes I and II devices are subject to pre-market notification;
- –Excludes the revalidation process for pre-market notification;
- –Simplifies process.

To be effective in Oct/2015. Companies should fully comply with the new regulation up to Oct/2016

Regulatory Updates Resolution

- **Resolution RE nº 2.347/2015**, effective since Aug/2015.

Internalization of MDSAP in the legal framework of ANVISA.

New Agreement

Agreement between GMDN and ANVISA

The Agreement allows ANVISA to access GMDN's database in order to use appropriate GMDN terms in submissions for the pre-market approval of medical devices.

This Agreement shall be published in the Brazilian Official Gazzette.

THANK YOU!