IMDRF International Medical Device Regulators Forum

Update on the Brazilian regulatory aspects on medical devices

IMDRF Stakeholders Meeting
Washington D.C., USA, 17 September 2014

ANVISA

Brazil

Regulatory updates

- Draft Resolution n. 50/2013 was published as a Technical Regulation – Resolution RDC 15, of March 2014.
- This Resolution establishes requirements to prove compliance with Good Manufacturing Practices (GMP) for marketing authorization of medical devices in Brazil.
- It details documents and certifications required for the pre-market approval of medical devices and IVD in Brazil, including the possibility of accepting reports from Auditing Organizations that participate in iniciatives recognized by ANVISA.

Regulatory Updates

- Resolution RDC nº 15/2014 – request of GMP Certification for marketing authorization (MA) submissions.
  - Exclusion of GMP Certification as a requirement for MA of devices class I and II.
  - It keeps GMP Certification as a requirement for MA of devices class III and IV.
  - It allows MA submission review to be initiated prior to GMP certification. However the MA will only be approved after the GMP certificate has been issued.
  - It provides legal mechanism to use reports from GMP audits conducted by third parties (MDSAP reports) to issue Anvisa GMP Certification.

Regulatory Updates

- Resolution RDC nº 27/14 – amendment on Resolution RDC nº 03/11
  - Technical requirements for hypodermic syringes.

- Resolution RDC nº 28/14 – amendment on Resolution RDC nº 05/11
  - Technical requirements for needles.
  - → Update of technical standards (new standard version) mentioned on the resolutions.

Regulatory Updates

- Resolution RDC nº 29/14 – amendment on Resolution RDC nº 04/11
  - Technical requirements for infusion sets.

  → Update of technical standards (new standard version) mentioned on the resolutions.

- Resolution RDC nº 35/2014 – Technical requirements for Blood Bags.

  - Updates the test methodology required for blood bags.

Regulatory Updates
Public Consultation

- Draft Resolution CP nº 24/2014 – new technical regulation that will revoke Resolution RDC nº 24/2009 (medical devices pre-market notification).
  - Defines that all Classes I and II devices are subject of pre-market notification;
  - Excludes revalidation process for pre-market notification;
  - Simplification of process;
  - Adoption of ToC/RPS for nIVD pre-market notification submission.
  - The contributions are currently being reviewed by Anvisa.

Regulatory Updates
Public Consultation

- Draft Resolution CP nº 23/2014 – new technical regulation that will revoke Resolution RDC nº 206/2006 (IVD registration and notification).
  - Exempts Classes I IVD from pre-marketing authorization process;
  - Defines that Class II IVD are subject of notification;
  - Excludes revalidation process for notification;
  - Adoption of ToC/RPS for IVD notification and registration submission.
  - The contributions are currently being reviewed by Anvisa.

Regulatory Updates
Public Consultation

- Draft Resolution CP nº 14/2014 – Teeth Whitening: requirements for marketing.
  - Teeth Whitening with composition upper to 03% of hydrogen peroxide or carbamide peroxide, shall be marketed only under professional prescription (dentist).
  - Advertising shall be restricted to promotional material intended to professionals.
  - The contributions are currently being reviewed by Anvisa.

Regulatory Updates
Public Consultation

- Draft Resolution CP nº 64/2014 – Requirements for Clinical Trials with medical devices.
  - Defines requirements to approve clinical trails with medical devices in Brazil.
  - The contributions are currently being reviewed by Anvisa.

Regulatory Updates
– Under Development

- Proposal of technical regulation for HIV Self-testing: draft text for public consultation under development.
  - Defines marketing requirements.
  - Defines special technical requirements for self-testing devices (eg. usability testing).
- Revision of Resolution RDC nº 185/2001 – Non-IVD Marketing Authorization (registration).
  - Adoption of the ToC/RPS.

Thank you!

Obrigado!