Update on the Brazilian regulatory aspects on medical devices

ANVISA

IMDRF-4 Stakeholders Meeting
November 13, 2013

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Basis for the regulation on medical devices

Law N. 6.360/1976

- basis for regulation of all products under health surveillance in Brazil, including medical devices.

- identify the need for pre and post market control of products, as well as the shared responsibility of the Federal, State and Municipality levels in the different aspects of health surveillance.

- organize the role of ANVISA in promoting the access by the consumers to products that proved to have quality, safety and efficacy.

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Basis for the regulation on medical devices

Decree N. 8.077/2013

- allows more efficient regulatory management and better use of ANVISA's human and technical resources.

- promotes enhanced communication channels for regulatory information among stakeholders (including society, foreign authorities, industry and Government at the national, state and municipality levels)

- implements legal basis for more dynamic regulatory processes with further effectiveness.

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Regulatory updates - Brazil

Approval of new regulation on GMP - Good Manufacturing Practices inspections for medical devices - Resolution RDC 16, of March 2013.

- unification of requirements for both medical devices and IVD
- all companies (Brazilian and foreign) had to comply with the new requirements before the 6-month "adjustment period"
- English version soon to be available for online consultation.

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Regulatory updates – Brazil

Approval of harmonized procedures within Mercosur on GMP inspections for medical devices - Resolution RDC 22, of April 2013.

Approval of standard documents and procedures within the National Health Surveillance System related to GMP inspections for medicines, API and medical devices (reports to be sent electronically to ANVISA) - Resolution RDC 34, of July 2013.

Continuation of Mercosur discussions for an updated norm for the pre-market approval of medical devices.

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Regulatory updates – Brazil

Approval of new procedures for granting Certificates of Good Manufacturing, Distribution and / or Storage Practices for products under health surveillance in Brazil - Resolution RDC 39, of August 2013.

Public Consultation (Nov 2013): proposed Resolution detailing the documents and certifications required for the pre-market approval of medical devices and IVD in Brazil (requirements vary with the product's risk class), including the possibility of accepting reports from Auditing Organizations that participate in iniciatives recognized by ANVISA.

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Regulatory updates – Brazil

Sanitary regulations in Brazil are being restructured with a focus on:

- The modernization of the national regulatory environment;
- Further guaranteeing safety and efficacy of products, in order to enhance and promote patient's wellbeing;
- Supporting and strengthening Public Health Policies and the decentralized National Health Surveillance System;
- Rationalization of processes and norms.

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Thank you!
Merci!
Obrigado!

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