Vision

Develop, manage and oversee a single audit program that will allow a single regulatory audit to satisfy the needs of multiple regulatory jurisdictions.

Policy

To jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers' quality management systems. The single audit of a medical device manufacturer's quality management system will include the assessment of the quality management system processes including management responsibility, resource management, product realization, measurement, analysis and improvement, and adverse event reporting; as well as compliance with Good Manufacturing Practices (GMPs) or other applicable requirements specific to a participating regulatory authority.

Objectives

1. To operate a single audit program that provides confidence in program outcomes.
2. To enable the appropriate regulatory oversight of medical device manufacturers' quality management systems while minimizing regulatory burden on industry.
3. To promote more efficient and flexible use of regulatory resources through work-sharing and mutual acceptance among regulators while respecting the independence of each authority.
4. To promote, in the longer term, greater alignment of regulatory approaches and technical requirements globally based on international standards and best practices.
5. To promote consistency, predictability and transparency of regulatory programs by standardizing:
    a. oversight practices and procedures of participating regulators over third party auditing organizations, and
    b. practices and procedures of participating third party auditing organizations.
6. To leverage, where appropriate, existing conformity assessment structures.

Outcome

An international coalition of countries dedicated to pooling technology, resources, and services to improve the safety and oversight of medical devices in a more efficient manner that is also less burdensome for industry.

Approval:

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Australia, Therapeutic Goods Administration

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Brazil, Agência Nacional de Vigilância Sanitária

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Canada, Health Canada/Santé Canada

Kimberly A. Trautman

United States of America, Food and Drug Administration

DOCUMENT HISTORY				
VERSION NO.	VERSION DATE	REVISION DATE	DESCRIPTION OF CHANGE	PROJECT MANAGER
001	10/18/12		Initial Release	Robert G. Ruff