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 design and development (where appropriate), Good Manufacturing Practices (GMPs), adverse event reporting, and other applicable requirements of the participating regulatory authorities.

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 sovereignty 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:

Signature on File
Australia, Therapeutic Goods Administration

Signature on File
Brazil, Agencia Nacional de Vigilancia Sanitaria

Signature on File
Canada, Health Canada/Santé Canada

Signature on File
Japan's Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency

Signature on File
United States of America, Food and Drug Administration

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2012-10-18	Initial Release. Signatures date 2012-10-18	Robert G. Ruff
002	2015-07-07	Revised to add signature for Japan's Ministry of Health, Labour and Weltfare, and the Japanese Pharmaceuticals and Medical Devices Agency was added. Japan signature date: 2015-07-24.	Liliane Brown