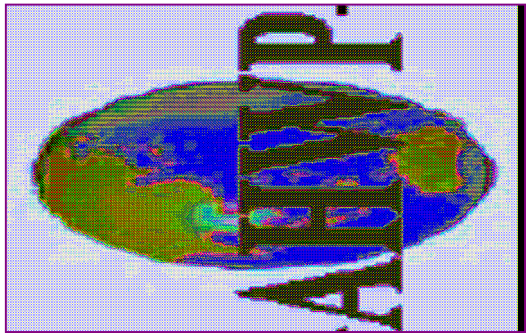
Medical Device Regulatory Requirements: **Classification**

AHWP Meeting - Hong Kong, November 5, 2009

Carolyn Albertson

Sr. Director Global Regulatory and Government Affairs

Abbott Laboratories



Overview

- General principles of classification
- Factors which influence classification
- Risk levels
- Classification and the regulatory process
- Examples of classification schemes
- Re-classification opportunities
- Benefits of harmonization
- GHTF guidance

General Principles

- Regulatory controls should be proportional to the level of risk associated with a medical device
- Risk presented for a medical device depends, on part, on
  - the intended use of the device
  - the intended users of the device
  - the mode of operation and technology of the device
- Classification rules should be intended to accommodate new technologies
- Rules should have the flexibility to adapt, i.e., allow for re-classification opportunities (both “down” and “up” classification)

Factors Which Influence Classification

- Duration of contact with the body
- Degree of invasiveness
- Delivery of medicinal products or energy to the patient
- Intended to have a biological affect on the patient
- Local vs systemic effects
- Use of software
- Historical knowledge
- Post-market experience

Risk Levels

- Level 1 (A): Low Risk
- Level 2 (B): Low- Moderate Risk
- Level 3 (C): Moderate-High Risk
- Level 4 (D): High Risk

Low Risk Devices - Examples

- Tongue depressors
- Eye exam charts
- Surgical retractors
- Medical adhesive tape and bandages
- Ophthalmic eye shield
- Urine collection bottle

Low-Moderate Risk Devices - Examples

- Hypodermic needles
- Suction equipment
- Non-medicated impregnated gauze dressings
- Tubing for blood transfusions
- Organ storage containers
- Administration sets for infusion pumps
- Anesthesia breathing circuits

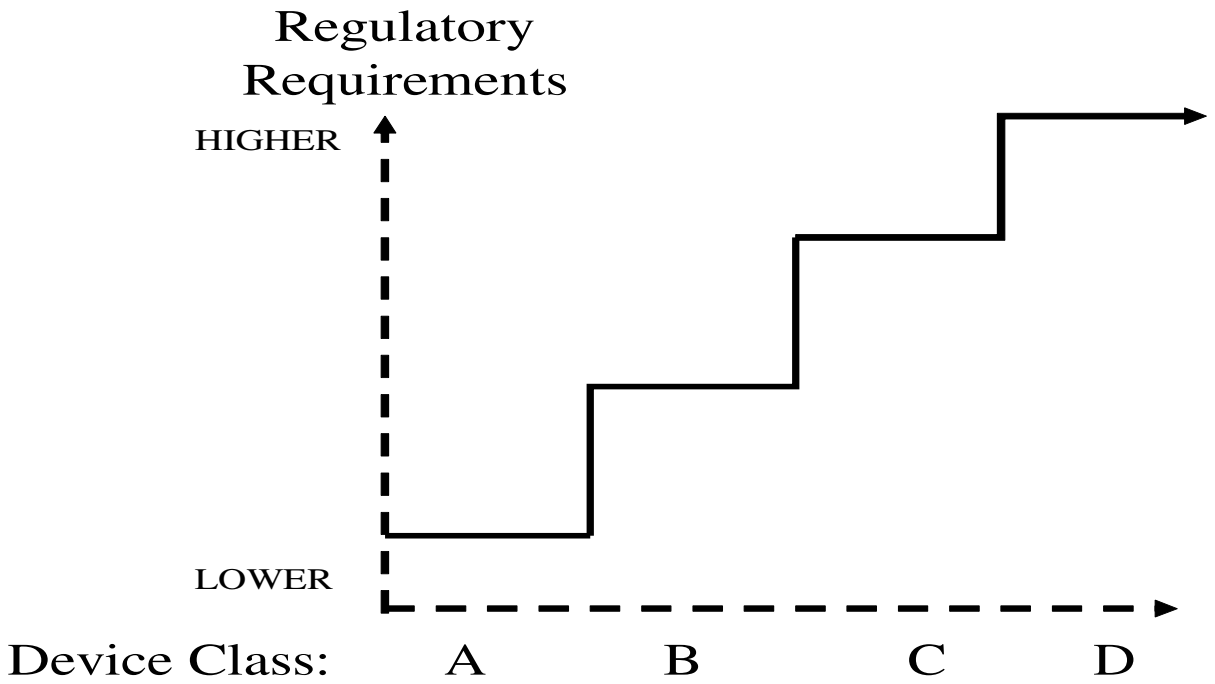
Moderate-High Risk Devices - Examples

- Lung ventilator
- Bone fixation plate
- Dressings for severe burns
- Blood bags
- Hemodialyzers
- Urethral stent
- Insulin pen for self-administration
- Surgical adhesive

High Risk Devices - Examples

- Heart valves
- Implantable defibrillator
- Angioplasty balloon catheters and related guide wires
- Dedicated disposable cardiovascular surgical instruments
- Absorbable suture
- Carotid artery shunts
- Neurological catheter
- Spinal and vascular stents
- Pacemakers

Level of Regulatory Control Based on Risk



GHTF, Principles of Medical Device Classification SG1Final Document
GHTF/SG1/N15:2006, page 11

Classification and the Regulatory Process

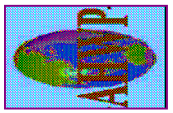
- Classification is fundamental to the regulatory process
- Regulatory requirements are determined and applied based upon how a device is classified
  - Registration requirements (documentation, labeling, performance data, clinical data, etc.)
  - Post market requirements (change management, PMS, adverse event reporting)
- Relationship between device class and conformity assessment is critical to:
  - Establish a consistent approach to pre-market approval requirements
  - Establish consistent post market requirements
  - Provide a consistent approach to the classification of new products

Regulatory Requirements Need to Match Inherent Risk of the Device

- Regulatory Controls Include:
  - Operation of a quality system
  - Technical data
  - Clinical evidence to support claims
    - Literature based
    - Clinical experience
    - Clinical investigations
  - Level of proactive PMS
- Need for external audit of manufacturer's quality system
- Independent external review of manufacturer's technical data

Use of Rules in Risk-Based Classification System

- Rules are derived based upon those features of a device that create risk
- Rules should be sufficiently clear in order to readily identify the class of a given medical device
- Rules should be capable of accommodating future technological developments and advancements
- When two or more rules apply to a particular medical device based upon its intended purpose, the device is allocated to the highest level of classification indicated.



Examples of Medical Device Classification Schemes

	Low Risk	Low-Moderate Risk	Moderate-High Risk	High Risk
Australia	I, I^{s}, I^{m1}	IIa	IIb	III, AIMD
Canada	I	II	III	IV
China	I	II		III
EU	I, I^{s}, I^{m1}	IIa	IIb	III
Hong Kong SAR[2]	I	II	III	IV
India[2]	A	B	C	D
Japan	I	II	III	IV
Singapore[2]	A	B	C	D
US	I	II		III
GHTF	A	B	C	D

[1]class 1 sterile, class 1 measuring

[2]GHTF guidance followed

Examples of IVD Product Classification

	Low Risk	Low-Moderate Risk	Moderate-High Risk	High Risk
Australia	I, I^s, I^{m1}	IIa	IIb	III, AIMD
Canada	I	II	III	IV
China	I	II		III
EU	I, I^s, I^{m1}	IIa	IIb	III
Hong Kong SAR[2]	I	II	III	IV
India[3]	A	B	C	D
Japan	I	II	III	IV
Singapore	A	B	C	D
US	I	II		III
GHTF	A	B	C	D

[1]self-certified

[2]currently not covered under MDACS

[3]currently regulated as drugs but comprehended as devices in draft Schedule M III

Re-classification Opportunities

- Post-market experience
- Historical knowledge

Benefits of Harmonization of Classification Schemes

- Eliminates differences between jurisdictions, ie eliminates “one-off” requirements
- Reduces cost of gaining regulatory compliance (reduction of additional clinical trials, avoidance of duplicative testing, etc due to misaligned classification)
- Establishes a common language and estimation of risk as it relates to product classification
- Provides predictability for manufacturers and regulators, especially for new product classification and assignment of risk
- Ensures alignment of post-marketing requirements
- Allows patients earlier access to new technologies and treatments

GHTF Guidance

- SDG1/N29: Information Concerning the Definition of the Term "Medical Device"
- SG1/N15: Principles of Medical Device Classification
- SG1/N41: Essential Principles of Safety and Performance of Medical Devices
- SG1/N40: Principles of Conformity Assessment for Medical Devices
- SG1/N11: Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)
- SG1/N44: Role of Standards in the Assessment of Medical Devices

GHTF Guidance (continued)

- SG5/N1: Clinical Evidence – Key Definitions and Concepts
- SG2/N54: Medical Device Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices
- SG1/N45: Principles of In Vitro Diagnostic (IVD) medical Device classification
- SG1/N46: Principles of conformity assessment for In Vitro Diagnostic (IVD) Medical Devices

Ideal Approach

- Adopt a scheme that is currently in use and globally recognized such as the GHTF model
- “the link between…classification and conformity assessment is important to ensure a consistent approach across all countries/regions adopting the global regulatory model recommended by the GHTF, so that premarket approval for a particular device many become acceptable globally.”[1]

[1] GHTF, Principles of Medical Device Classification, SG1/N15, page 4


Thank You