



Medical Industry
Association of Australia

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GHTF Conference Workshop 1:
Barriers



Regulatory model for development of device regulatory systems: needs, barriers and constraints

Barriers to national implementation:

- Historical legacies
- Differences in legislative philosophies
- Differences in burden of proof
- Allocation of responsibilities
- Differences in scope and classification



Historical legacies

- Individual country's desires to retain sovereignty over decisions impacting that country
- Mistrust of decisions/approvals by third country agencies
- Confidence in own market size to dictate approach



Differences in legislative philosophies

- Four basic models plus hybrids:
 - US FDA model
 - EU model
 - Internal approval plus auto acceptance of US and/or EU approvals
 - Auto acceptance of US and/or EU approvals
- US FDA model - reliance on regulator assessing and approving high risk technology while allowing simplified approval mechanism for evolving technology



Differences in legislative philosophies

- EU model – spreads pre-market assessment burden between manufacturers and third party assessment bodies; post-market review of notified bodies and products
- Canadian system – hybrid EU system with limited use of third party assessment agencies audited by regulator



Differences in legislative philosophies

- Australian system – hybrid EU system with differences in:
 - Medical device classification criteria
 - Conformity assessment requirements for domestic industry
 - Limited application of third party conformity assessment certification
 - Mandatory audits of specified approval applications



Differences in burden of proof

- Different levels of proof are required by different countries
- Degree of mistrust of competency in some countries to assess all devices at all levels of risk
- Lack of consistency in auditing techniques
- No acceptable universal independent approval/certification authority to set audit/certification standards



Allocation of responsibilities between states and manufacturers

- EU system spreads responsibility between manufacturers, state authorities and third party conformity assessors
- US FDA system maintains almost full control of auditing, approval and post-market functions
- Slow progress towards global standards acceptable to all regulators
- Progress in manufacturer standards with acceptance of ISO 13485



Differences in scope and classification

- General acceptance of proposition that medical devices be regulated according to risk presented to users
- Differences remain in approach of two major regulators, EU and FDA, on how best to validate and verify products with similar risk
- Differences in classification methodologies used by EU and FDA
- Tensions between approaches:
 - Cost-effectiveness v. health system outcomes
 - Supporting national health priorities v. industry support



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