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A Guide for the Development of Medical Device Regulations



Draft Global Edition

Key contents and presentation methods

Needs for this Guide



- The safety, performance and consistent quality of medical devices have become international public health concerns
- Increasingly, Member States look to the World Health Organization for guidance on medical device issues
- This guide can be used for information and training purposes

Objectives of this Guide



- To provide basic information about medical device safety issues and regulatory philosophy
- To avoid a proliferation of different regulations by promoting GHTF recommendations
- To reduce regulatory burden by simplification

Difficulties in Developing this Guide



- A vast field of rapidly evolving knowledge
- Terms often complicated by legal technicalities
- An attempt to provide a combined general description of five major regulatory systems is like walking through a legal mine field!

Presentation Methods



- Uses common non-legal binding language, graphics, tables and memory anchors
- Layout a basic framework to integrate the information from the five founding members of the GHTF
- Relies on experts to supply specialized information and correct inaccuracies

Sources of this Guide



- Uses the same concepts and approach from the 1999 PAHO/Health Canada document under the same title by the same author
- Adds references to all current systems of the five founding members of the GHTF
- Promotes GHTF recommendations
- Includes a chapter on the use of standards

Some Special Features



- Uses “big picture” approach to incorporate the needs and responsibilities of each stakeholder
- Includes special regards to users in developing countries
- Introduces non-conventional terms such as “placing on market”

Key Contents



- 1 THE NATURE OF MEDICAL DEVICE SAFETY
- 2 GOVERNMENT REGULATIONS ON MEDICAL DEVICES
- 3 THE GLOBAL HARMONIZATION TASK FORCE
- 4 THE USE OF VOLUNTARY STANDARDS
- 5 OPTIMIZING THE USE OF REGULATORY RESOURCES

1 The Nature Of Medical Device Safety



- Absolute safety cannot be guaranteed
- Risk management issue: to maximize benefit and minimize risk
- Safety must be considered throughout the life span of a medical device
- Requires shared responsibility and cooperation among all stakeholders for optimum safety and performance

2 Gov't Regulations On Medical Devices



- Critical elements for regulatory attention
 - Product
 - Use
 - Representation of Product
- Common regulatory stages
 - Pre-market
 - Placing on-market
 - Post-market

3 Global Harmonization Task Force (GHTF)



- Introduces the objectives and study groups of the GHTF
- Describes some benefits from the GHTF
- Integrates the final recommendations of the GHTF into the common regulatory framework
- Encourages Member States to participate in GHTF activities and to adopt GHTF recommendations

4 The Use of Voluntary Standards



- The understanding of standards and their conformity assessment systems has become essential in establishing medical device regulations
- Conformity with international standards provides an excellent means to harmonize regulatory requirements
- Urges Member States to ensure mechanisms for recognition and conformity assessment with national/international standards

5 Optimizing Use Of Regulatory Resources

Key recommendations



- Draft a clear and comprehensive national policy
- Adopt GHTF recommendations
- Take advantage of established pre-market approval systems and international standards
- Ensure applicable quality system standards for local manufacturing of medical devices
- Give priorities to, device and vendor registrations, post-market surveillance/ vigilance, user education and training
- Promote co-operation among stakeholders

Some Potential Benefits of this Guide



- Readers can easily grasp basic elements in medical device regulations
- It proposes a common framework to describe medical device regulatory systems
- It facilitates understanding and adoption of GHTF recommendations

Future Development



- Specific examples and tools for device and establishment registration
- Detailed methods for post-market surveillance/vigilance
- Quality systems
- Keep pace with GHTF developments

