Quality System Requirements for Medical Devices

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An overview of quality requirements for manufacturers of medical devices for sale in Canada, US and Europe

REGULATORY REQUIREMENTS

Canada

- *Medical Devices Regulations* (July 1998)

FDA

- *Title 21 Code of Federal Regulations*

REGULATORY REQUIREMENTS (con't)

Europe

- *Medical Devices Directives*
  - 93/42/EEC (June 14, 1993), Concerning Medical Devices (MDD)
  - *90/385/EEC, (Jan. 1, 1993) Concerning Active Implantable Medical Devices (AIMD)*
  - 98/79/EC (October 1998) Concerning In Vitro Devices
  - 2000/70/EC (Nov. 16, 2000) Concerning Human Blood or Plasma
- Requires CE MARK (QS + Product Certification)

PARTICULAR EMPHASIS FOR MEDICAL DEVICES

- Safety & Effectiveness of Product (Design)
- Quality Records
- Identification & Traceability
- Process Control
- Environmental Control of Manufacturing
- Packaging & Labelling
- Postmarket Surveillance
- Problem Reporting
- Recall & Advisory

HEALTH CANADA'S Medical Devices Regulations

- Product Classification
- Safety & Effectiveness
- Device Licensing (Inc'l QS Requirements)
- Labelling
- Distribution Records
- Complaint Handling
- Mandatory Problem Reporting
- Recall
- Custom-made & Special Access Devices
- Devices for Investigational Testing

STEPS TO A SUCCESSFUL REGISTRATRION

- Determine if a Medical Device
- Determine Market Jurisdiction
- Classify Your Device
- Select the Registrar/Notified Body
- Determine QS Requirements
- Ensure Compliance With Relevant Regulatory Requirements
- Complete Technical Documentation

CLASSIFYING YOUR PRODUCT

- HC Schedule 1, Parts 1 & 2
- FDA Classification by Regulation
  - Premarket notification (510K), or
  - Premarket Approval
- European MDD, Annex IX
- Higher the Classification,Greater the Risk
- Highest Classification Applies

CLASSIFICATION COMPARISONS

Canada	US	Europe
IV	III	III
III	III	IIb
II	II	IIa
I	I	I

SELECTING THE REGISTRAR/NOTIFIED BODY

- Is the Registrar Accredited under CAMCAS
- Need Notified Body if Selling in Europe
- Ensure Scope of QS Registration Covers Your Products
- Registrars/Notified Bodies Provide Useful Guidance Early in Process

DETERMINING QS REQUIREMENTS

- HC's *Medical Devices Regulations* (32 (1))
  - CAN/CAS ISO 13485:1998 & CAN/CAS ISO 13488:1998
- US FDA's *Quality System Regulation*, Part 820 of Title 21 CFR
  - Embodies Principles of ISO 13485:1996
- Europe's MDD
  - Uses EN 46001:1996 & EN 46002:1996 Model

DETERMINING QS REQUIREMENTS (con't)

- ISO 13485:1996 (core standard)
- Same as CAN/CAS ISO 13485
- Virtually Same as EN 46001
- FDA's QSR Embodies Principles of ISO 13485:1996

ABOUT ISO 13485:1996

- ISO 9001:1994 + particular requirements for medical devices
- Elements Most Affected
  - 4.4 Design
  - 4.8 Product Identification & Traceability
  - 4.9 Process Control
  - 4.14 Corrective & Preventive Action
  - 4.15 Storage, Handling, Packaging & Labelling

ISO 9001:2000 & ISO 13485:1996

- ISO 9001:2000 Introduced in Dec. 2000
- ISO/CD 13485 Draft Available 2001-06-05 & Final Expected in 2003
- ISO/CD 13485 Stand-Alone Standard, In Line With ISO 9001:2000
- ISO/CD 13485 Excludes “Continuous Improvement” & “Customer Satisfaction”
- Recommend Drafting QM to ISO/CD 13485

ENSURE ALL REGULATORY REQUIREMENTS MET

- Labelling
- Distribution
- Complaint Handling
- Mandatory Reporting
- Product Recall Provisions
- Etc.

TECHNICAL DOCUMENTATION

- Varies With Product Class
- Must Demonstrate Product Safety (not just how made)-- Including References to Harmonized Standards Where Appropriate
- Show How Product Classified
- Describe Product & Intended Use
- Identify File Location(s)
- Responsibility for Technical Documentation

HARMONIZED STANDARDS

- International or National Standards Recognized by a Regulatory Body for use in Demonstrating Compliance With a Regulatory Requirement
- Official Publications
- Example:
  - ISO 10993 Biocompatibility
  - ISO 14971 Risk Analysis
  - EN 1441 Risk Analysis
  - EN 60601 Medical Device Electrical Equipment
  - EN 980 Labelling
  - ANSI Z80.20 Oxygen Permeability

GUIDANCE DOCUMENTS

- HC, the FDA and the EU all Publish Guidance Documents Related to the Application of Regulations
- Examples Include:
  - Mandatory Problem Reporting
  - Device Classification
  - Complaint Handling & Recalls
  - Applying for a Device License

MEDICAL DEVICES REFERENCE GUIDE

- Prepared by Orion Canada for Industry Canada's Life Science Branch
- *Reference Guide for Manufacturers Selling Medical Devices in Europe, Canada and the United States – 2001 Version*
- Log into *strategis.gc.ca/meddev*

INFORMATION SOURCES

- HC:
  - www.hc-sc.gc.ca/hpd-dgps/therapeut/
- FDA
  - www.fda.gov/cdrh/dsma/cgmphome.html
- EU
  - www.europa.int
- Orion Canada
  - www.orioncanada.com

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