

ASQ- Portland Chapter (PDX) Global Regulatory Overview



**US regulations (21 CFR Section 820)
and Europe, Canada, Japan, Australia
and Brazil**





Global Harmonization Task Force (GHTF) members

	US	Australia	Japan	EU	Canada
Regulatory Body	Food & Drug Administration (FDA)	Therapeutic Goods Administration (TGA)	Ministry of Health and Welfare (MHW) via PMDA	Competent Authority (CA) (27 Member states)	Health Canada (HC)
QS standard & Regulations	QSR: 21 CFR 820 & 510(k), PMA, IDE Requirements	ISO 13485:2003 & TGA Directorate	MO. 73 (MO. 02) MO. 169	EN ISO 13485:2003 & Directives (MDD, IVDD, AIMDD)	CSA ISO 13485:2003 & CMDR SOR/98-282
Quality Systems auditor	FDA	TGA	PMDA and/or Registrar for CMD devices	Notified Body (NB) (3rd party)	Registrar (3rd party) (CMDCAS)
Pre-market reviewer	FDA	TGA	PMDA	(NB) (3rd party)	HC
Post-market compliance & enforcement	FDA (+ AP)	TGA	PMDA & Registrar	(NB) (3rd party) + CA	HC (6 Regions)

BRAZIL REGULATORY PROCESS





- As of May 22, 2010, ANVISA, the Brazilian Health Surveillance Agency, requires manufacturers of high risk equipment and materials (classes III and IV); as well as high risk IVD products (classes II, III and IIIa) to comply with Brazilian Good Manufacturing Practices (GMP).
- Additionally, certain Class I and II medical devices, identified in Instrução Normativa 07/2009, must also meet this requirement.



BRAZILIAN REGULATIONS

- The main resolutions are:
 - ❖ RDC 59/2000 - Good Manufacturing Practices (requisitos de Boas Práticas de Fabricação para estabelecimentos que fabriquem ou comercializem produtos médicos) B-GMP.
 - ❖ RDC 25/2009 - Defines the need for inspections and certification under RDC 59/2000
 - ❖ RDC 185/2001 - Registration and classification of devices, technical file requirements
 - ❖ RDC 32/2007 - Certification of electro medical devices
 - ❖ RDC 56/2001 - Essential requirements for medical devices as part of the Technical File Requirements



RDC 59-QMS INSPECTIONS BY ANVISA

- RDC 59 - quality management system document is similar to 21 CFR Section 820 but with some specific requirements.
- For Class III and IV device, the manufacturer must provide proof of compliance RDC 59/00 and RDC 25/2009.
- Inspections conducted by ANVISA every 2 years.
- Domestic and foreign manufacturers of electro medical devices require an INMETRO certificate which includes an annual inspection at the manufacturing site and routine testing



RDC 185/01

- Brazilian Resolution RDC 185/01 is similar to the European Medical Devices Directive (93/42/EEC) and classification is very similar. Based on Annexes.
- Annex II - 18 rules found for classification of devices
- Annex III – Part A/B/C defines Tech file requirements
- RDC 25 defines some exemptions for Class I and II devices
- Technical documentation for the safety and performance of the device is required showing compliance with RDC 56/2001 – Essential Requirements.



RDC 185/01 : Annex II

Scope and Classification of Devices

- RDC 185/01 for medical devices classification is fairly aligned with both the GHTF classification scheme and the EU under the MDD.

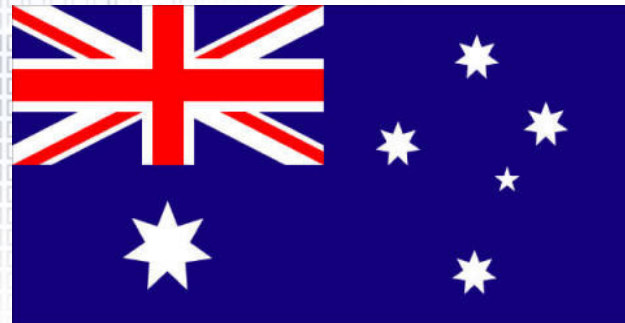
Brazil
I, II, III, IV

GHTF
A, B, C, D

EU MDD
I, IIa, IIb, III



Australia -TGA





TGA

The revised medical devices regulatory framework for Australia, introduced in October 2004, has been implemented in response to the initiatives of the Global Harmonization Task Force (GHTF) to harmonize medical device regulatory requirements.

The resulting regulatory framework has many similarities with that adopted by the European Union (EU). However while similar, the two systems do have some differences.



TGA – Requires a In Country Sponsor

- The Therapeutic Goods Administration (TGA) regulates the medical equipment market in Australia.
- Australia's regulatory framework is harmonized with international accepted best practice, and is based on the guidelines of the Global Harmonization Task Force (GHTF) and the European Community (EC) requirements.
- If a product does not have a CE Mark and/or country of origin is not within the EU, a Conformity Assessment of the manufacturing facility will have to be undertaken by the TGA.



TGA – Requires a In Country Sponsor

- Medical devices are classified according to the degree of risk associated with their application.
- Approval for sale in Australia can only be obtained by an Australian Sponsor of the product,
- U.S. exporters need to appoint an Australian partner before their products can be approved by the TGA.



TGA

- The European Union's Medical Device Directives (EU MDD):
 - The EU Directive 93/42/EEC (Medical Device Directive),
 - The EU Directive 90/385/EEC (Active Implantable Medical Device Directive), and
- The Australian legislation for medical devices implemented in October 2002:
 - The *Therapeutic Goods Act 1989* (the Act); and
 - *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations).



TGA Audit

ATTACHMENT 1. APPLICATIONS FOR INCLUSION TO BE SELECTED FOR AUDIT BY THE TGA

Kinds of Medical Devices	Applications to be Audited	Level of Audit
Any kind of medical device not specified below	May be selected	To be determined on a case by case basis
Medical devices manufactured in Australia	No	Not Applicable
Medical devices previously registered on the ARTG after 4 October 2000, that underwent "full" evaluation by the TGA	Yes	1
Posterior Chamber PMMA monofocal intra-ocular lens	Yes	1
Barrier contraceptives or devices intended to prevent transmission of disease in the course of penile penetration during sexual intercourse, other than condoms	Yes	2
Class AIMD medical devices	Yes	2
Class III medical devices not assessed under the EC MRA of the EFTA MRA	Yes	2
Implantable breast prostheses containing material of fluid consistency other than water only or a saline solution only	Yes	2
Implantable contraceptive devices	Yes	2
Implantable intra-ocular lens	Yes	2
Intra-ocular visco-elastic fluids	Yes	2
Medical devices intended by the manufacturer specifically to be used for disinfecting another medical device	Yes	2
Prosthetic heart valves	Yes	2



Australia-EU Classification

Australia

- Class I
- Class IIa
- Class IIb
- Class III
- AIMD

EU

- Class I
- Class IIa
- Class IIb
- Class III
- AIMD (covered by AIMDD)



TGA PROCESSING TIME

- TGA processing time for a Class III approval is typically 4-5 months. It is a 3 stage process and requires a CE audit file that must be carefully reviewed



Australia Strategy

- Use an independent organizations vs. a distributor to act as a TGA sponsor for procurement of TGA approval
- Benefits: It enables flexibility in appointing distributors and enables transfer of the approvals to another entity by transferring the company ownership, if desired.
- Holding of a TGA approval by a distributor locks us into that distributor as they own the approval.
- Start the process every time we change distributors
- Huge burden on us both financial and regulatory!



EUROPEAN UNION





CE Marking and European Directives

CE marking is:

- a legal requirement to place products on the market in the European Union
- mandated by European New Approach Directives
- the manufacturer's claim that the product meets the essential requirements of all relevant European Directives





CE Marking and European Directives

CE marking is **NOT**:

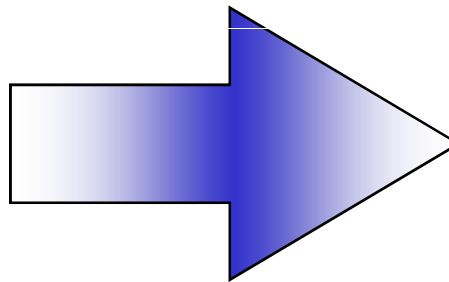
- awarded by certification body
- a product certification mark
- a mark signifying quality
- a symbol owned by a notified body





The EEA and CE Marking

CE marking combines local regulations in directives that are believed consistent with a unified European approach





Member states of the EU- 27

-
1. Austria
 2. Belgium
 3. Bulgaria
 4. Cyprus
 5. Czech Republic
 6. Denmark
 7. Estonia
 8. Finland
 9. France
 10. Germany
 11. Greece
 12. Hungary
 13. Ireland
 14. Italy
 15. Latvia
 16. Lithuania
 17. Luxembourg
 18. Malta
 19. Netherlands
 20. Poland
 21. Portugal
 22. Romania
 23. Slovakia
 24. Slovenia
 25. Spain
 26. Sweden
 27. United Kingdom



23 official EU languages

1. Bulgarian
2. Czech
3. Danish
4. Dutch
5. English
6. Estonian
7. Finnish
8. French
9. German
10. Greek
11. Hungarian
12. Irish
13. Italian
14. Latvian
15. Lithuanian
16. Maltese
17. Polish
18. Portuguese
19. Romanian
20. Slovak
21. Slovenian
22. Spanish
23. Swedish





MDD 93/42/EEC

Article 1	Definitions, scope
Article 2	Placing on the market and putting into service
Article 3	Essential requirements
Article 4	Free movement, devices intended for special purposes
Article 5	Reference to standards
Article 6	Committee on standards and technical regulations
Article 7	Committee on Medical Devices
Article 8	Safeguard clause
Article 9	Classification
Article 10	Information on incidents occurring following placing of devices on the market
Article 11	Conformity assessment procedures
Article 12	Particular procedure for systems and procedure packs
Article 13	Decisions with regard to classification, derogation clause





MDD 93/42/EEC



Article 14	Registration of persons responsible for placing devices on the market
Article 15	Clinical
Article 16	Notified bodies
Article 17	CE marking
Article 18	Wrongly affixed CE marking
Article 19	Decision in respect of refusal or restriction
Article 20	Confidentiality
Article 21	Repeal and amendment of directives
Article 22	Implementation, transitional provisions
Article 23	Directive addressed to the Member States



MDD 93/42/EEC



Annex I	Essential requirements
Annex II	EC declaration of conformity (Full quality assurance system)
Annex III	EC type-examination
Annex IV	EC verification
Annex V	EC declaration of conformity (Production quality assurance)
Annex VI	EC declaration of conformity (Product quality assurance)
Annex VII	EC declaration of conformity
Annex VIII	Statement concerning devices for special purposes
Annex IX	Classification criteria
Annex X	Clinical evaluation
Annex XI	Criteria to be met for the designation of notified bodies
Annex XII	CE marking of conformity



Route to CE Marking

1. Classify devices
2. *Select conformity assessment procedure*
3. Choose notified body
4. Prepare technical documentation
5. Obtain assessment by notified body
6. Write declaration of conformity
7. Affix CE Marking





Hierarchy of EU Documents

Directive

MEDDEV
Guidelines

NB-MED Recommendations

Consensus Statements



Essential Requirements

Essential Requirements:

- Are set in Annex I of the MDD
- Require the manufacturer to:
 - Define fitness for purpose
 - Perform risk / benefit analysis
 - Determine their product's safety
 - Choose voluntary standards to use as a tool



Essential Requirements - HS

Not all ISO, EN standards are harmonized, for a standard to be harmonized it must be published

Where no harmonized standard is available, the following are options:

- European (EN's not harmonized)
- EU national (BS/DIN etc)
- International (ISO/IEC)
- Non-EU national (ANSI/CSA/ASTM)
- New or emerging standards
- Manufacturer's specifications



Technical Documentation

- Technical documentation can include:
 - Technical file (Product Description, manufacturing controls, DHR, etc.)
 - Design dossier
- Provides evidence of compliance with the directive and the essential requirements
- May need to be reviewed by the NB
- Must be available to CA



Declaration of Conformity

A declaration of conformity is:

- A manufacturer's claim that:
 - Product satisfies essential requirements
 - Conformity assessment completed, if required
 - Products are designed, manufactured, and tested in accordance with technical documentation
- Issued on the manufacturer's own authority
- A legal document



Four Classes

1. Class III - Highest Risk
 2. Class IIb - Medium to High Risk
 3. Class IIa - Medium Risk
 4.
 - Class I Sterile*
 - Class I Measuring*
- Class I - Lowest risk

Always reference the rules in Annex IX Reference MEDDEV 2.4/1
Rev 8-Check with Notified Body:

- NB Confirms with Competent Authority



Classification Rules

18 Rules listed in Annex IX of the MDD:

1 - 4 Non invasive devices

5 - 8 Invasive devices

9 -12 Active devices

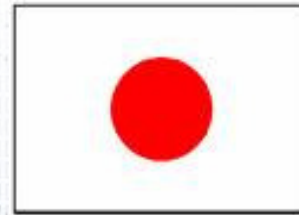
13 -18 Special rules

Very important to look at definitions and 'implementing rules'
as well



Amending Directives to MDD

- 2000/70/EC - Amendment concerning Medical Devices containing substances derived from human blood or human plasma
- 2001/104/EC - Corrigendum concerning Medical Devices containing substances derived from human blood or human plasma
- 2003/12/EC - Directive on the re-classification of breast implants
- 2003/32/EC - Directive introducing detailed specifications regarding requirements with respect to medical devices manufactured utilizing tissues of animal origin
- 2000/50/EC - Reclassification of hip, knee and shoulder joint replacements



Overview of the Japanese Regulatory Structure

Pharmaceutical Affairs Law 2002 (PAL)



Terms and Acronyms

PAL	Pharmaceutical Affairs Law of Japan
MAH	Market Authorization Holder (in Japan, the organization who imports the Medical Device) The Customer
CB	Certification Body. <i>(For example, BSI Japan is a Certification Body registered by MHLW)</i>
PMDA	Pharmaceutical Medical Device Agency
MHLW	Minister of Health, Labor and Welfare in Japan
Customer	in the PAL system, the customer receives the product. <i>(For export to Japan, the customer is the MAH, and MO No.169 should be interpreted in this light)</i>



Terms and Acronyms

Peripheral Governments	Local government at Tokyo, Hokkaido and the prefectures in Japan (these provide license services for the MAH)
GQP	Good Quality Practice. Requirements apply to the MAH
GVP	Good Vigilance Practice. Requirements apply to the MAH
Seihin-Hyojunsho	Device Master Record defining what the product is and how it is manufactured, and if applicable, installed and/or serviced (MHLW Ordinance No.169, Article 6.2 and 6.3).
STED	Summary Technical Documentation to prove safety and efficacy of device, reviewed by 3 rd party or PMDA for Certification of Product
Foreign Manufacturer	Manufacturers located outside of Japanese territory who sterilize, package, distribute or manufacture medical devices.



Terms and Acronyms

Certification	Product certification means that the Manufacturer of DCMD has; a) licensed MAH, b) accredited manufacturer site (s), c) completed STED and d) certificate from CB before exporting to Japan. (note: certification and product certification are used interchangeably)
MD	Medical Device
SDMD	Specially Designated MD which require Design Controls

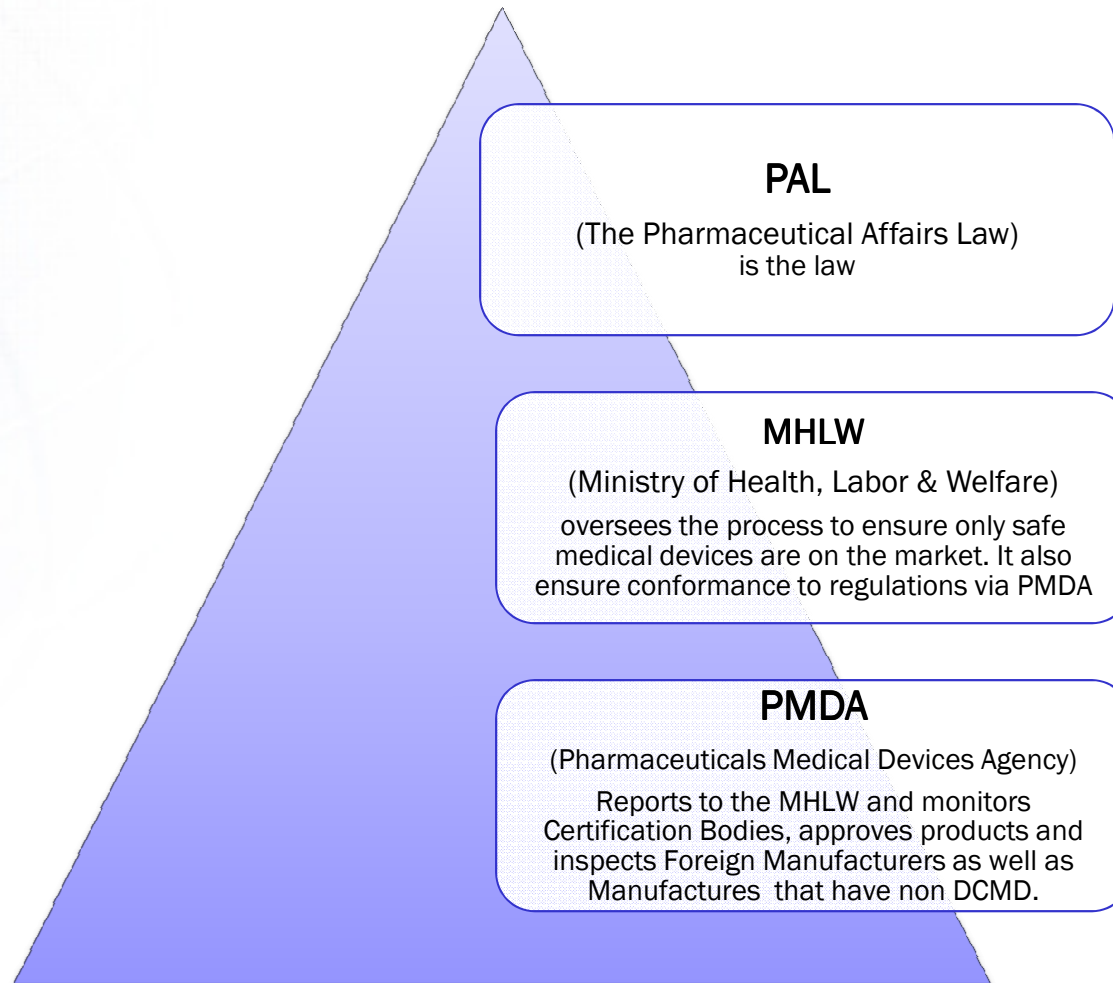


Terms and Acronyms

GMD	A General MD whose potential risk is almost insignificant to the human body in case of malfunction or side effect
CMD	A Controlled MD having potential risk to the human body in case of malfunction or side effect (1785 types currently)
DCMD	A Designated Controlled MD which can be subject to 3rd party certification by a CB (designation is done by MHLW)
SCMD	A Specially Controlled MD whose potential risk is significant to the human body in case of malfunction or side effect



Current Regulatory Structure in Japan:





PMDA is Responsible for:

- Issuing accreditation via an inspection of foreign medical device manufacturers for all classes of MD MO 73 (MO.02)
- Providing license to Japanese medical device manufacturers via an inspection [locations within Japan] (MO. 02), these manufacturers may also choose to be MAH's and therefore they would also be assessed to MO. 136 (GQP) and required to comply to MO 135 for QVP,
- Provide license to MAH's in Japan via an assessment (MO. 136 GQP). This is also done via the prefectural governments.
- Provide evaluation and approval of SCMD, CMD [which are not DCMD], and certain General MD
- May be involved with MHLW for Highest risk [class IV devices] approvals.



Ministerial Ordinances:

MO. No. 169, 2004(QMS)

- Standards for Manufacturing Control and Quality Control for Medical Devices and In-Vitro Diagnostic Reagents.
- This document states the quality system requirements similar to ISO 13485:2003
- Inspection is carried out by PMDA or CB for DCMD
- Available in English

MO. No 180 (MO No. 2 revised via MO No. 73, 2005)

- Regulations for Buildings and Facilities of Pharmacies, etc.
- This document is used to carry out the accreditation inspection of the manufacturing and sterilization locations-domestic or foreign manufacturers
- Inspection is carried out by PMDA
- Available in English

MO. No. 136, 2004: (GQP)

- Standards for Quality Assurance for Drugs, Quasi-drugs, Cosmetics and Medical Devices (this document is used to carry out inspections for licensing the MAH, packaging and distribution center.
- Inspection carried out by PMDA or peripheral government
- Available in English

MO. No. 135 (GVP)

- This document is not available in English, as it is required that the manufacturer will do reporting through the MAH
- Standards for Safety Assurance for Drugs, Quasi-Drugs, Cosmetic Medical Devices
- Good Vigilance Practices

English Version can be obtained via <http://www.pmda.go.jp/english/operations/pal.html>

Announcement No. 122 - Essential Requirements for Medical Devices -STED



Ministerial Ordinance No. 169

- For all Class IV and Class III devices, and those designated Class I devices a QMS assessment, according to Ordinance No. 169,, **CAN ONLY BE** conducted by PMDA.
- Other Class I devices are exempt from QMS certification.



Other Assessment Types

- Assessments of manufacturers for their facilities, according to Ordinance No. 180 (02), are conducted by PMDA.
- Inspection is based on building and facilities standards – MHLW Ministerial Ordinance 180 (No.2, 1961, revised by MHLW Ministerial Ordinance No.73, 2005)
- Assessments of MAH, according to Ordinance No. 136 (GQP), are conducted by the Japan Prefectural Government.



Accreditation also requires that foreign manufacturer have a MAH

- Manufacturers much choose a Market Authorization Holder (MAH), and have a contract that describes their relationship prior to submitting their Accreditation Application
- Since the MAH is the customer in Japan, the MAH reports under GVP (MO No.135) when there is a need
- Ministerial Ordinance No.169, Article 3, sections 1 and 2, describes the requirements of this ordinance which the MAH needs to impose on the manufacturer
- The MAH is an important link with MHLW as they have the responsibility to ensure that only quality (read as safe) medical devices are on the market



Example

License or Accreditation

Applies to the
company itself

Examples:

Tokyo Medical (located in
Japan) is **licensed** by
Prefecture (Japan)

US Medical based in USA is
accredited by PMDA

Via MO. 180 (02)

Approval or Certification

Applies to the
product only

Example:

US Medical cannula (a
DCMD) are **certified** by TUV for
sale in Japan

US Medical stents (a SCMD)
have been **approved** by PMDA
& MHLW for sale in Japan



Accreditation of Foreign Manufacturer

- Manufacturer must comply with relevant Building and facilities standards (i.e., ordinances) MO. 180 (MO 02)
- Inspections are also done when a person intends to change (e.g. relocate, merger) or add category (sterile product, higher class device)
- The person has to obtain the accreditation of the change (requiring an onsite inspection or documentation review prior to initiating change) and must obtain new Accreditation certificate listing new change or category



After package is file with PMDA

- Inspections are carried out, then
- Applicant receives a unique site number to reference in product submissions
- Only applicable to products within the scope of the filed submitted
- Currently taking about 7 months to complete process with PMDA

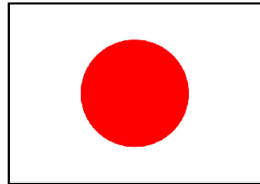


Product Classification – Requirements are based on product classification

Classification	Description	Site Requirements	Product Approval
Class III, IV	Specially Controlled Medical Devices	Accreditation & QMS audit	PMDA
Class II	Controlled Medical Devices	Accreditation & QMS audit	PMDA
Class II - with Japan standard (JIS)	Controlled Medical Devices	Accreditation & QMS audit	PMDA or Qualified Third Party
Class I	General Medical Device	Accreditation (Possible QMS audit)	PMDA (notification only)



Japanese Regulatory System



Summary:

- Ministerial Ordinance No.169 is a lot like ISO 13485:2003, but there are some distinct differences. When exporting to Japan, Japan expects that the Manufacturer understands the PAL process, and has written the proper regulations into the QMS
- Japan is a very large market for medical devices, and so the extra efforts will pay off with increased product sales, and more importantly, safer products!



Canada





Canadian Medical Devices Regulations

Consolidated Statutes and Regulations



Food and Drugs Act

SOR/98-282 Medical Devices Regulations



Canadian Medical Devices Regulation



Part 1	General
Section 1	Interpretation
Section 2-5	Application
Section 6-8	Classification of Medical Devices
Section 9	Manufacturer's Obligations
Section 10-20	Safety and Effectiveness Requirements
Section 21-23	Labeling Requirements
Section 24	Contraceptive Devices - Advertising
Section 25	Class I Medical Devices
Section 26-43	Class II, III, and IV Medical Devices
Section 44-51	Establishment License
Section 52-56	Distribution Records
Section 57-58	Complaint Handling
Section 59-62	Mandatory Problem Reporting
Section 63-65	Recall
Section 66-68	Implant Registration



Canadian Medical Devices Regulation



Part 2	Custom-made Devices and Medical Devices to be Imported or Sold for Special Access
Section 69	Application
Section 70	General
Section 71-72	Authorization
Section 73-74	Additional Information
Section 75	Labeling
Section 76	Distribution Records
Section 77	Reporting an Incident
Section 78	Implant Registration
Section 86	Labeling



Canadian Medical Devices Regulation

Part 3	Medical Devices for Investigational Testing Involving Human Subjects
Section 79	Application
Section 80	General
Section 81	Records
Section 82-83	Authorization
Section 84-85	Additional Information
Section 86	Labeling
Section 87	Advertising
Section 88	Other Requirements
Part 4	Export Certificates
Section 89-92	Export Certificates
Part 5	Transitional Provisions, Repeal, and Coming into Force
Section 93-95	Transitional Provisions
Section 96	Repeal
Section 97	Coming into Force





CMDR Applicability of Quality System Requirements

- Class I Medical Devices (Sec. 25)
 - No quality system (QS) requirement
- Class II Medical Devices (Sec. 26 - 32)
 - the QS under which the device is manufactured must satisfy ISO 13485:2003 with possible exclusion of Clause 7.3





Introduction to the “Medical Devices Regulations”

Regulation begins with introductions to three Major Areas

- Item 1 Interpretation (Definitions)
- Items 2-5 Application – (Regulation applies to....., applicability, non applicability)
- Items 6-7 Classification of Medical Devices – (General information that there are 4 classifications and to apply Schedule 1 for classification rationale)

Following the introduction, the regulations proceeds to:

Part 1-General



Classification-Schedule 1: Part 1 & 2

- **Schedule 1: Classification Rules for Medical Devices**
 - **Part 1- Medical Devices other than In Vitro Diagnostic Devices**
 - Invasive devices -Rules 1 to 3
 - Non invasive devices – Rules 4 to 7
 - Active devices Rules 8-12
 - Special Rules 13-16
 - **Part 2 – In Vitro Diagnostic Devices**
 - Use with respect to Transmissible Agents Rules 1-3
 - Other uses Rules 4-5
 - Special rules 6-9



Classification

The EU has four classes of medical devices which generally correspond to Canada's four classes, as illustrated in the following table.

Canadian Medical Devices Regulations		European Council Directive 93/42/EEC (MDD)
Class IV	generally corresponds to	Class III
Class III	generally corresponds to	Class IIb
Class II	generally corresponds to	Class IIa
Class I	generally corresponds to	Class I



Part 1- General Requirements

Sections 8-9

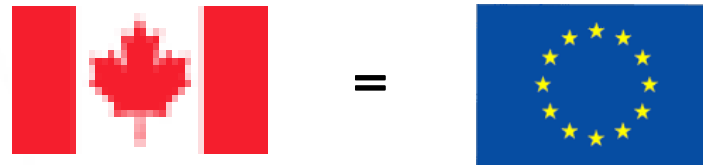
Manufacturer's Obligation (9)

- The manufacturer **will ensure** that the medical device meets safety and effectiveness requirements AND
- **Shall** keep objective evidence to establish that the medical device meets those requirements
- This includes up keeping with all pertinent device data including current standards and device modifications



Part 1- General Safety & Effectiveness Requirements

Sections 10-20



- Canada uses a similar approach to the European approach and the references in the MDD to the use of Recognized Standards for complying with the essential requirements
- Compliance to these requirements is the core requirement of the regulation
- Compliance must be met for all classifications.
- However, the MDD spells out the essential requirements in much greater detail.



Part 1- General

Application for a Medical Device

License Section 32-43

Attestations of a senior official of the manufacturer that:

- Objective evidence has been established to show conformance to Safety and Effectiveness requirements
- The device label meets labeling requirements as set out in CMDR.

For IVD:

- That investigational testing has been conducted on the device using human subjects representative of the intended users and under similar conditions of use



Part 1- General

Application for a Medical Device License Section 32-43

Requirements for Class III:

- Description of materials used
- Description of packaging
- Description of features
- List of countries where sold
- List of standards complied with in the design/manuf.
- If sterile: a summary of studies
- Device label
- Bibliography of all published reports

Requirements for Class IV:

- Description of materials used
- Description of packaging
- Description of features
- List of countries where sold
- List of standards complied with in the design/manuf.
- Risk assessment summary
- Quality plan, processes
- Clinical data,
- Other additional req.



Part 1- General Distribution Records

Section 52-56

- Records must be retained for the projected life of the device, as defined by the manufacturer, but not less than two years after the device was dispatched from the manufacturer.
- Record retention times are the same as those for the EU and US.

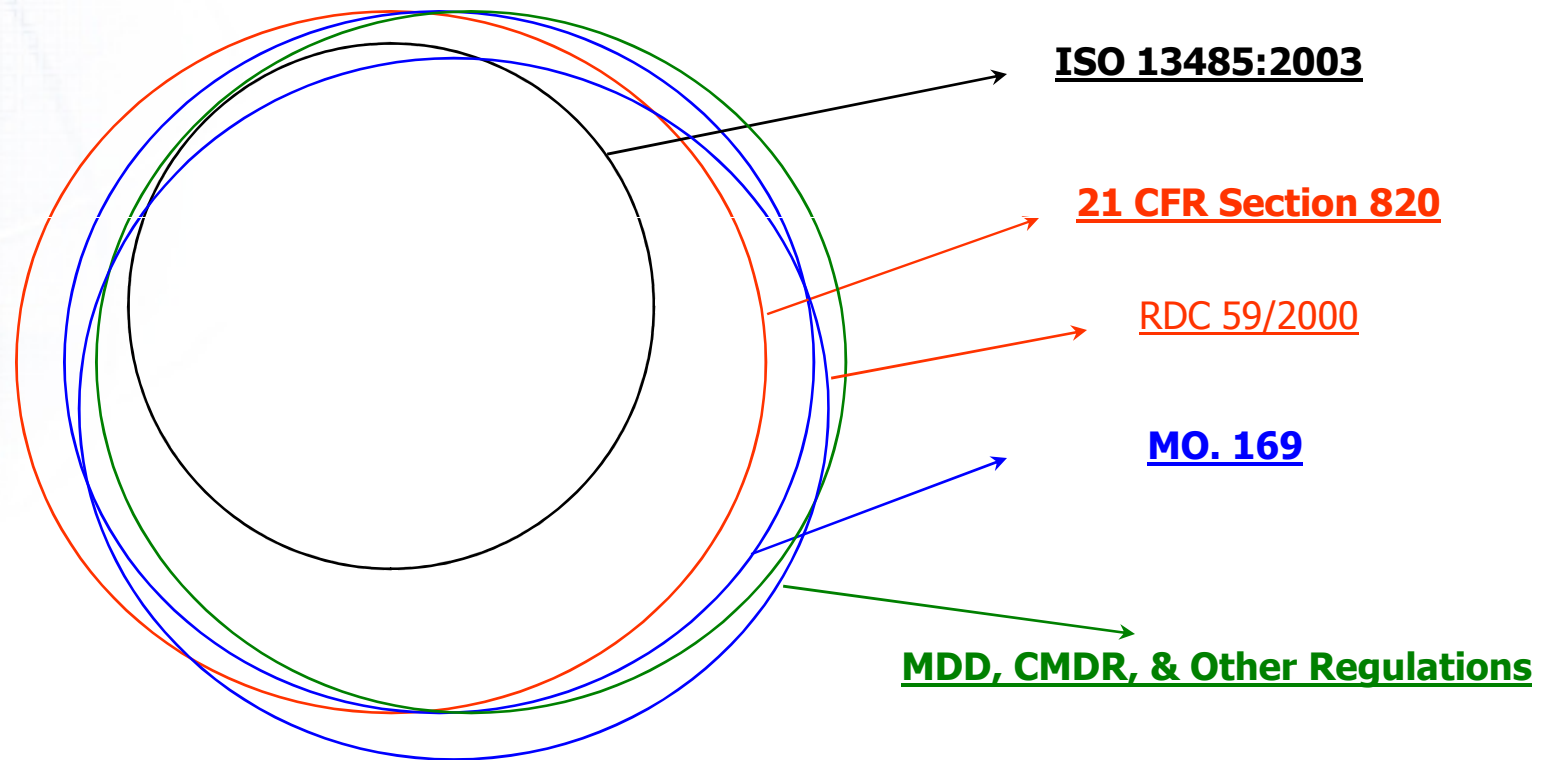


**Comparison Tables:
RDC 59/2000
ISO 13485:2003
21 CFR Section 820
MO. 169**



Medical Device Quality Systems

The structural context of a QMS:





RDC 59/2000 – ANNEX I GOOD MANUFACTURING PRACTICES FOR MEDICAL DEVICES

Part A -General Provisions

1. Scope
2. Definitions
3. Quality System

Part B -- Quality System Requirements

1. Management Responsibility
2. Quality audit
3. Personnel

Part C - -Design Control

Part D -- Control of Documents and Records

Part E -- Purchase Control

Part F - Identification and Traceability

1. Identification and Traceability

2. Products with high risk (class III or IV) - traceability

Part G -- Controls of Process and Production

1. Controls of Process and Production
2. Special processes

Part H - -Inspection and Testing

1. Inspection and Testing
2. Inspection, measurement and test equipment
3. Inspection and Testing Results

Part I -- Non-Conforming Components and Products



RDC 59/2000 – ANNEX I GOOD MANUFACTURING PRACTICES FOR MEDICAL DEVICES

Part J – Corrective Action

Part K – Handling, Storage,
Distribution and Installation

1. Handling
2. Storage
3. Distribution
4. Installation

Part L - -Packaging and
Labeling Controls

1. Product packaging
2. Product labeling

3. Critical product labeling

Part M – Records

1. General requirements
2. Product master record (PMR)
3. Product history record
4. Complaint file

Part N – Servicing

Part O - -Statistic Techniques



Cross-Reference of Requirements

Section	Description – ISO 13485:2003	FDA-QSR
4.0	Quality Management System	
4.1	General	820.5 + 820.20
4.2	Quality System Documentation	820.5 + 820.20 + 820.40 + 820.180
5.0	Management Responsibility	
5.1	Management Team commitments	820.20
5.2	Customer focus	820.160(a)
5.3	Quality policy	820.20
5.4	Planning	820.20 + 820.5 + 820.20
5.5	Responsibility, Authority, Communication	820.20
5.6	Management review	820.20
6.0	Resource Management	
6.1	Provision of resources	820.20
6.2	Human resources	820.20 + 820.25/75



Cross-Reference of Requirements

Section	Description – ISO 13485 2003	FDA-QSR
6.3	Infrastructure	820.70
6.4	Work environment	820.70
7.0	Product Realization	
7.1	Planning of product realization	820.5 + 820.20 + 820.80
7.2	Customer related processes	820.160(a) + 820.30
7.3	Design and development	820.30
7.4	Purchasing	820.50 + 820.80
7.5	Production and service operations	820.80(a) + 820.60/65/120(e)/160(b) + 820.70 + 820.80 + 820.86 + 820.120/130/140/150/160 + 820.200



Cross-Reference of Requirements

Section	Description – ISO 13485 2003	FDA-QSR
7.6	Control of monitoring and measuring devices	820.72
8.0	Measurement, Analysis and Improvement	
8.1	General	820.80 +820.250
8.2	Monitoring and measurement	820.80 +820.22 + 820.250
8.3	Control of non-conformity	820.70(h)/90(a)b1 + 820.90(b) 1 & 2
8.4	Analysis of data	820.250
8.5	Improvement	820.20 + 820.100/198



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Section 2	Quality Management System
Article 5	General requirements for QMS
Article 6	Documentation of QMS
Article 7	Quality manual
Article 8	Control of documents
Article 9	Control of records
Section 3	Management Responsibility
Article 10	Management commitment
Article 11	Customer focus
Article 12	Quality policy
Article 13	Quality objectives
Article 14	Quality management system planning
Article 15	Responsibility and authority
Article 16	Responsible engineering manager
Article 17	Internal communication
Article 18	Management review
Article 19	Review input



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Article 20	Review output
Section 4	Resource Management
Article 21	Provision of resources
Article 22	Personnel
Article 23	Competence, awareness and training
Article 24	Infrastructure
Article 25	Work environment
Section 5	Product Realization
Article 26	Planning of product realization
Article 27	Determination of requirements related to the products
Article 28	Determination of requirements related to products
Article 29	Customer communication
Article 30	Design and development planning
Article 31	Design and development inputs
Article 32	Design and development outputs
Article 33	Design and development review
Article 34	Design and development verification



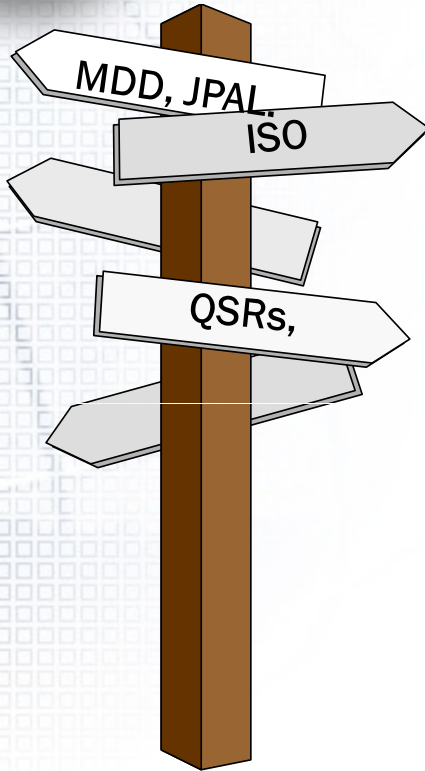
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Article 35	Design & Development Validation
Article 36	Control of Design & Development Changes
Article 37	Purchasing Process
Article 38	Purchasing Information
Article 39	Verification of Purchased Products
Article 40	Control of Production and Service Provision
Article 41	Cleanliness of Products and Contamination Controls
Article 42	Installation Activities
Article 43	Servicing Activities
Article 44	Manufacturing Control of Sterile Medical Devices
Article 45	Validation of Processes for Production and Service Provision
Article 46	Validation of Sterilization Process
Article 47	Identification
Article 48	Traceability
Article 49	Traceability of Specially Designated Medical Devices (Class III or IV (active implantable or implantable devices))
Article 50	Status Identification
Article 51	Customer Property



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Article 52	Preservation of Product
Article 53	Control of Monitoring and Measuring Devices
Article 54	Measurement, Analysis & Improvement
Article 55	Feedback
Article 56	Internal Audit
Article 57	Monitoring and Measurement of Processes
Article 58	Monitoring and Measurement of Product
Article 59	Monitoring and Measurement of Specially Designated Medical Devices (Class III or IV implantable, active implantable devices)
Article 60	Control of Nonconforming Product
Article 61	Analysis of Data
Article 62	Improvement (Advisory Notices)
Article 63	Corrective Action
Article 64	Preventive Action



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