Health Canada / Santé Canada

Medical Devices Regulatory System in Canada

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12th AHWP Meeting
Chengdu, China (2007/10/23-27)

Health Products and Food Branch
Direction générale des produits de santé et des aliments

Outline

- Introduction
- Medical Devices Regulations
- Risk Based Classification
- Quality System Requirements
- Pre-Market Evaluation
- Post-Market Surveillance
- Special Control Sales

1. Introduction

Devices are regulated by HC

- **Canada is a confederation of provinces and territories**
- **Health Canada (HC) is a department of the Government of Canada and regulates the sale, advertising for sale and importation of medical devices**
- **Provinces and territories regulate the practice of medicine**

Regulatory Provisions

- **The Food and Drugs Act and Medical Devices Regulations are the tools used to ensure that safe and effective devices are available**

- **Manufacturers of devices apply to Health Canada to receive either a Licence or an Authorization to sell their devices.**

Regulatory Provisions (cont'd)

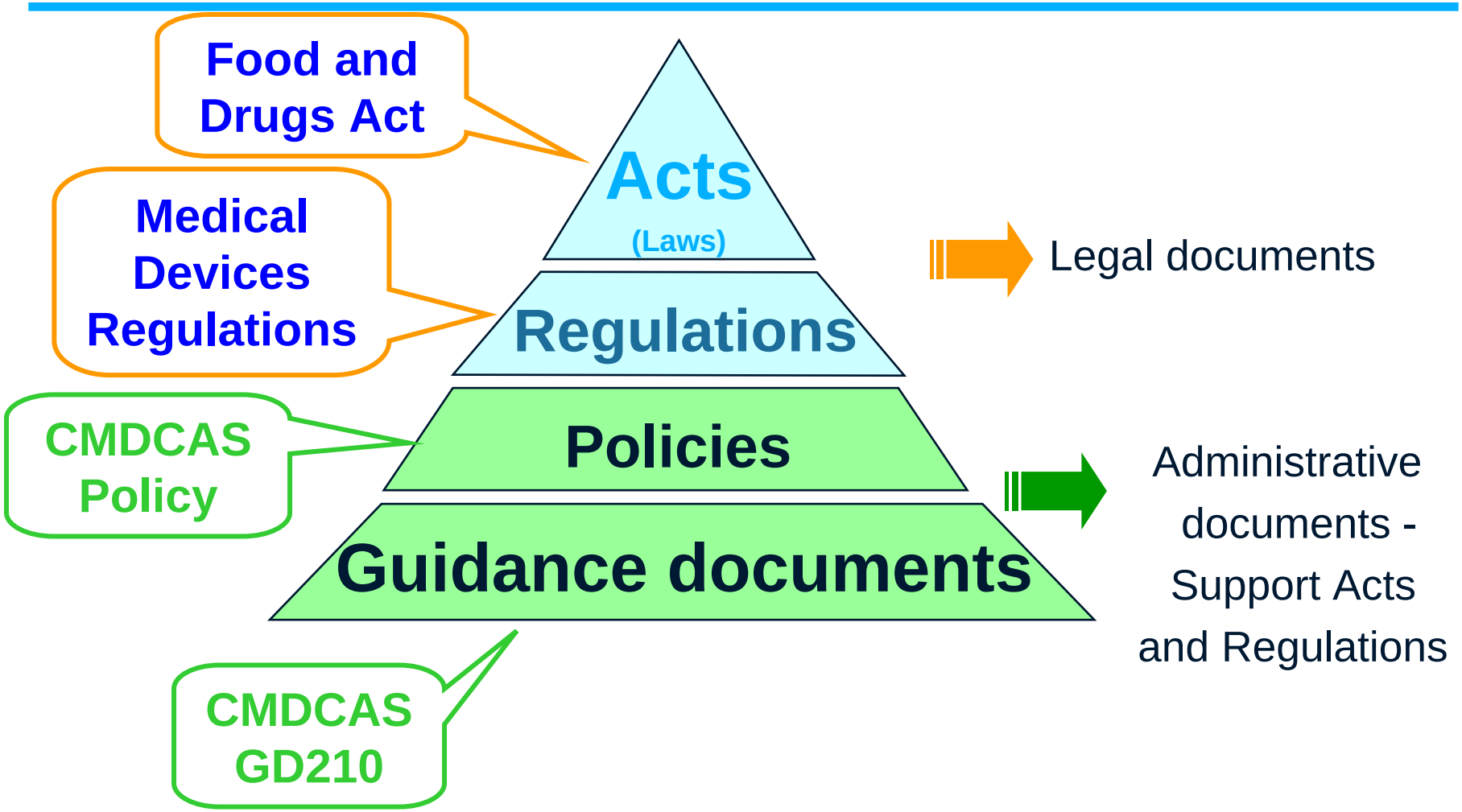
- **All devices offered for sale in Canada must comply with the *Food and Drugs Act***

  -Contains definition of a "device"; Prohibits misleading or false representation of medical devices; Defines the powers of inspectors.

- **Devices offered for sale in Canada must also comply with the *Medical Devices Regulations (MDR)***

  -Defines Manufacturer's Obligations; Safety and Effectiveness Requirements; Labeling Requirements; Licensing Class II, III and IV Devices; Quality Management System; Distribution Records; Complaint Handling; Mandatory Problem Reporting; Recall; Implant Registration, etc.

Structure of Dcumentation



2. Medical Devices Regulations

Medical Devices Regulations (MDR)

- **Interpretation** — **“Definitions”” (Section 1)**
- **Application** — **(Sections 2-5)**
- **Classification** — **(Sections 6-7)**
- **Part 1** — **General (Sections 8-68)**
- **Part 2** — **Custom-Made Devices & Devices to be imported or Sold for Special Access (Sections 69-78)**
- **Part 3** — **Devices for Investigational Testing (Sections 79-88)**

MDR (Cont'd)

- **Part 4** — Export Certificates (Sections 89-92)
- **Part 5** — Transitional Provisions (Sections 93-97)
- **Schedule 1** — Classification Rules for Medical Devices
- **Schedule 2** — Implants
- **Schedule 3** — Export Certificates for Medical Devices

Objectives of Regulatory Framework

- Risk based approach
- Quality systems approach
- Pre-market scrutiny
- Post-market surveillance
- Global harmonization
- Use of international standards
- Transparency and communication

3. Risk Based Classification

Risk Based Approach

- **Risk based classification**

  -Class I (low risk) to class IV (high risk), similar to that of GHTF

- **Class I: Establishment licence only**
- **Class II: Licence required, Pre-market Review not required**
- **Class III and IV: Licence and Pre-market review both required**

- Classification in US and China: I, II, III (no class IV)

- Classification in Europe: I, IIa, IIb, III (devices)

List A, List B (IVD Directive)

Devices on Canadian Market

Class IV – 5%

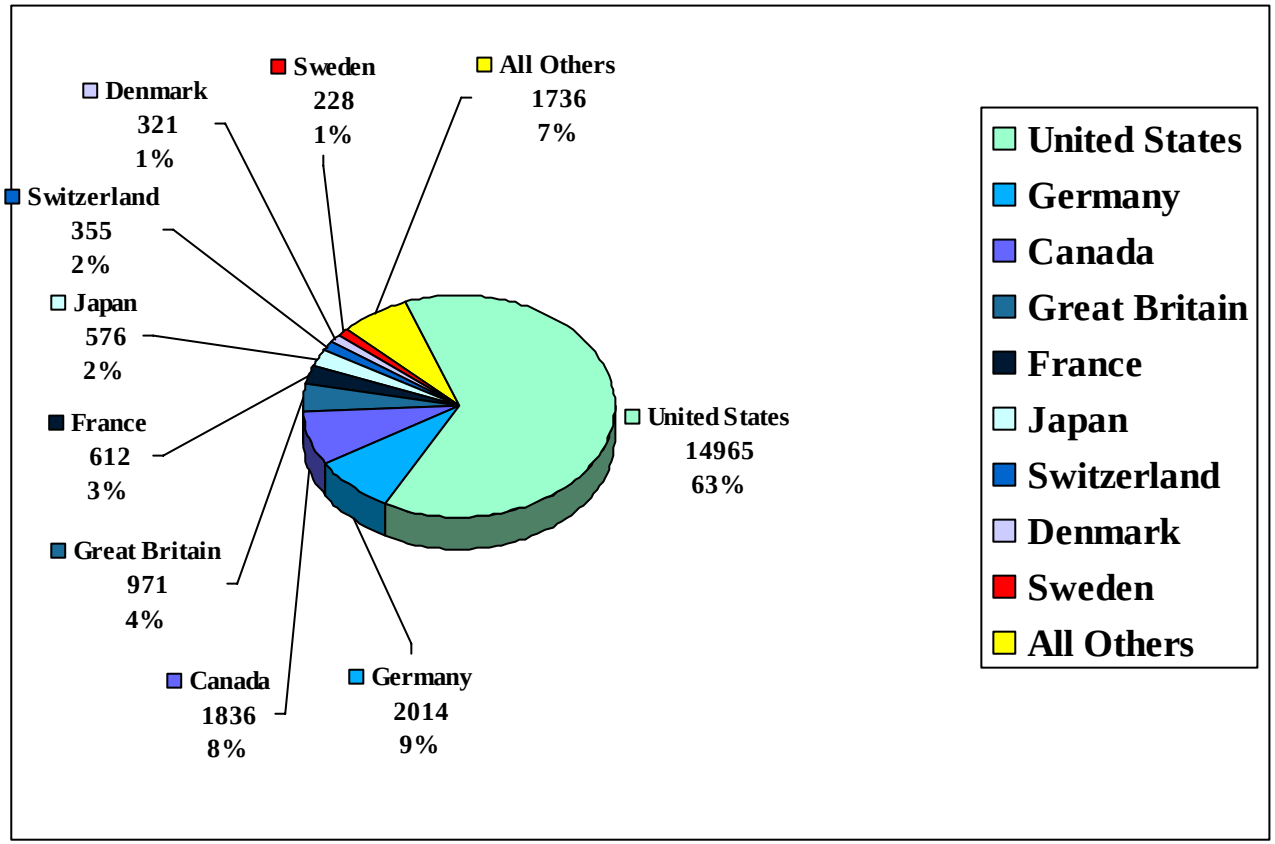
Class III – 15%

Class II – 40%

Class I – 40%

(NB: + 800K individual devices currently "licensed")

Licenses Held by Country of Manufacture



4. Quality System Requirements

QS Requirements

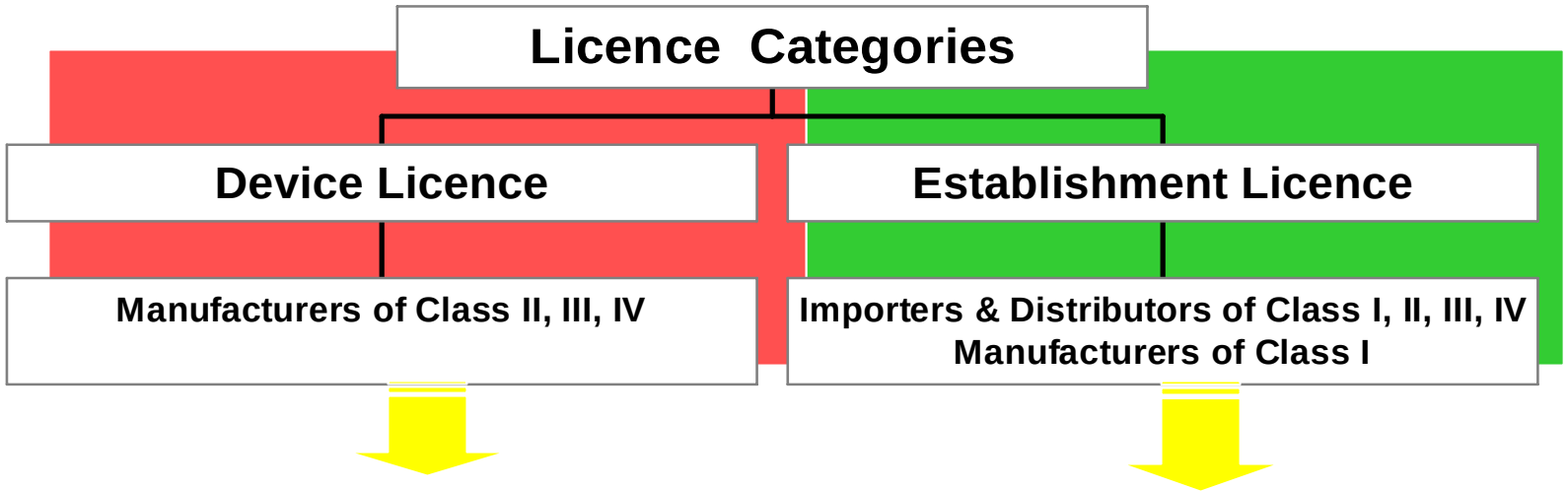
- **Regulatory QS requirements apply to:**

  ALL Canadian and foreign manufacturers of Class II, III and IV medical devices

- **Regulatory QS requirements DO NOT apply to:**

  Importers and distributors unless they meet the definition of a manufacturer

QS Requirements (Cont'd)



QS Requirements (Cont'd)

- **Class II devices**

  Valid certificate that manufacturing satisfies ISO 13485:2003: Allowed to exclude section 7.3 Design and development.

- **Class III and IV devices**

  Valid certificate that manufacturing satisfies ISO 13485:2003

CMDCAS System

- **Quality Management System must be audited and certified by a *Canadian Medical Device Conformity Assessment System* (CMDCAS) recognized registrar**
  - **Certificate valid for no more than 3 years**
  - **Certificate submitted to Health Canada with:**
    - **Device license application**
    - **After amendment to certificate**

Recognized Registrar

- KEMA
- LRQA
- AMTAC
- ITS
- DQS GmbH
- TÜV America
- TÜV RNA
- G-MED
- BSI
- SGS
- TÜV Nord
- NSAI
- QMI
- LGA
- UL Inc

CMDCAS: Structure

On-site monitoring of registrars by HC

- 1 Head Office Assessment /year
- 1 Witness Audit /year
- Additional assessments and audits performed, if required for regulatory needs

On-going monitoring by HC

- Requests for audit related documents (e.g. audit reports)
- Requests for registrar's procedures related to CMDCAS activities, if required for regulatory needs

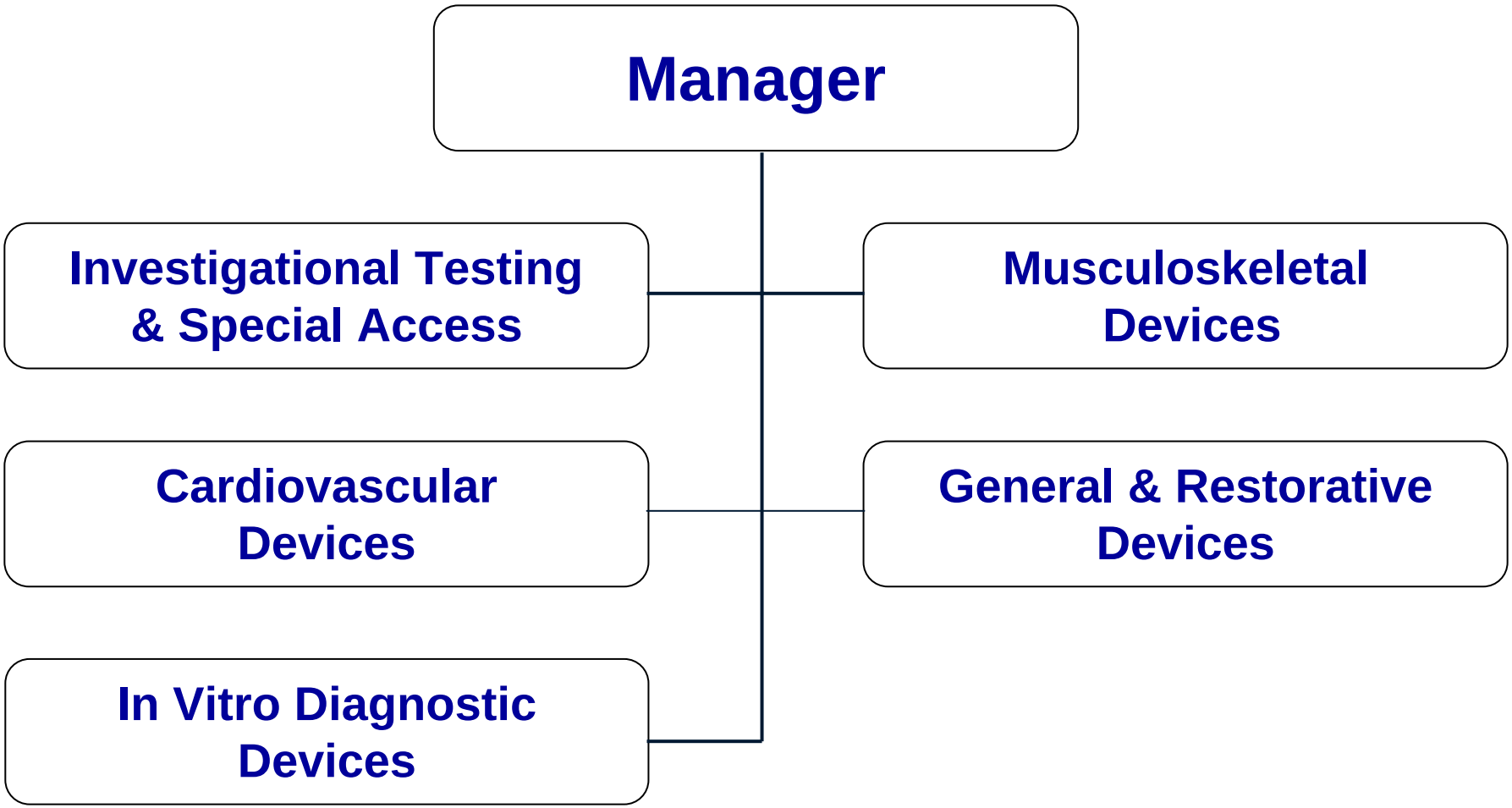
HC may cease to recognize a registrar at any time

CMDCAS vs other regulatory models used by GHTF members

	US	Australia	Japan	EU	Canada
Regulatory Body	Food & Drug Administration (FDA)	Therapeutic Goods Administration (TGA)	Ministry of Health, Labor and Welfare (MHLW)	Competent Authority (CA)	**Health Canada (HPFB)**
QS standard	21 CFR Part 820 (QSR)	ISO 13485 ('2003)	QS standard based on ISO 13485:2003	EN ISO 13485 (2003)	**ISO 13485 (2003)**
QS auditor	FDA	TGA	MHLW	Notified Body (NB) (3rd party)	**CMDCAS recognized registrar**
Pre-market reviewer	FDA	TGA	MHLW	NB (3rd party)	**Health Canada (HPFB)**
Post-market compliance & enforcement	FDA	TGA	MHLW	CA + NB (3rd party)	**Health Canada (HPFB)**

5. Pre-Market Evaluation

Device Evaluation Division



Current Team Members

45 - 50 employees with diverse expertise

- Medical doctors, Nurses, Pharmacists
- Biologists
- Microbiologists, Immunologists
- Physiologists
- Chemists
- Physicists
- Engineers (mechanical, electrical, & biomedical)
- Managers and administrators

Main Responsibilities/Activities

- **Pre-Market Evaluation (Class III & IV)**
- **Investigational Testing/Clinical Trial Review**
- **Special Access Programme**
- **Post-market Review/Health Hazard Evaluations (HHE)**
- **Communication & Information**
- **Policy and Guideline Development**
- **Participation on National and International Standard Development**
- **International Relations**

  -GHTF, Pan American Health Organization, MOUs with China, USA, Australia etc.
- **Litigation Support**

Safety & Effectiveness Requirements

- **Apply to all medical devices (Class I – IV) except those sold for:**
  - **Special Access;**
  - **Investigational Testing.**
- **Manufacturer must:**
  - **Ensure device meets these requirements;**
  - **Keep objective evidence that devices meet the requirements.**

Pre-Market Review Process

Pre-market

Post-market

Licence Applications

Application Verification

Application Screening

Application Review

Licence or Authorization

Public Access

Surveillance & Inspection, CDMCAS requirements

Investigational Testing Applications

Special Access Applications

Device Licence – Class II

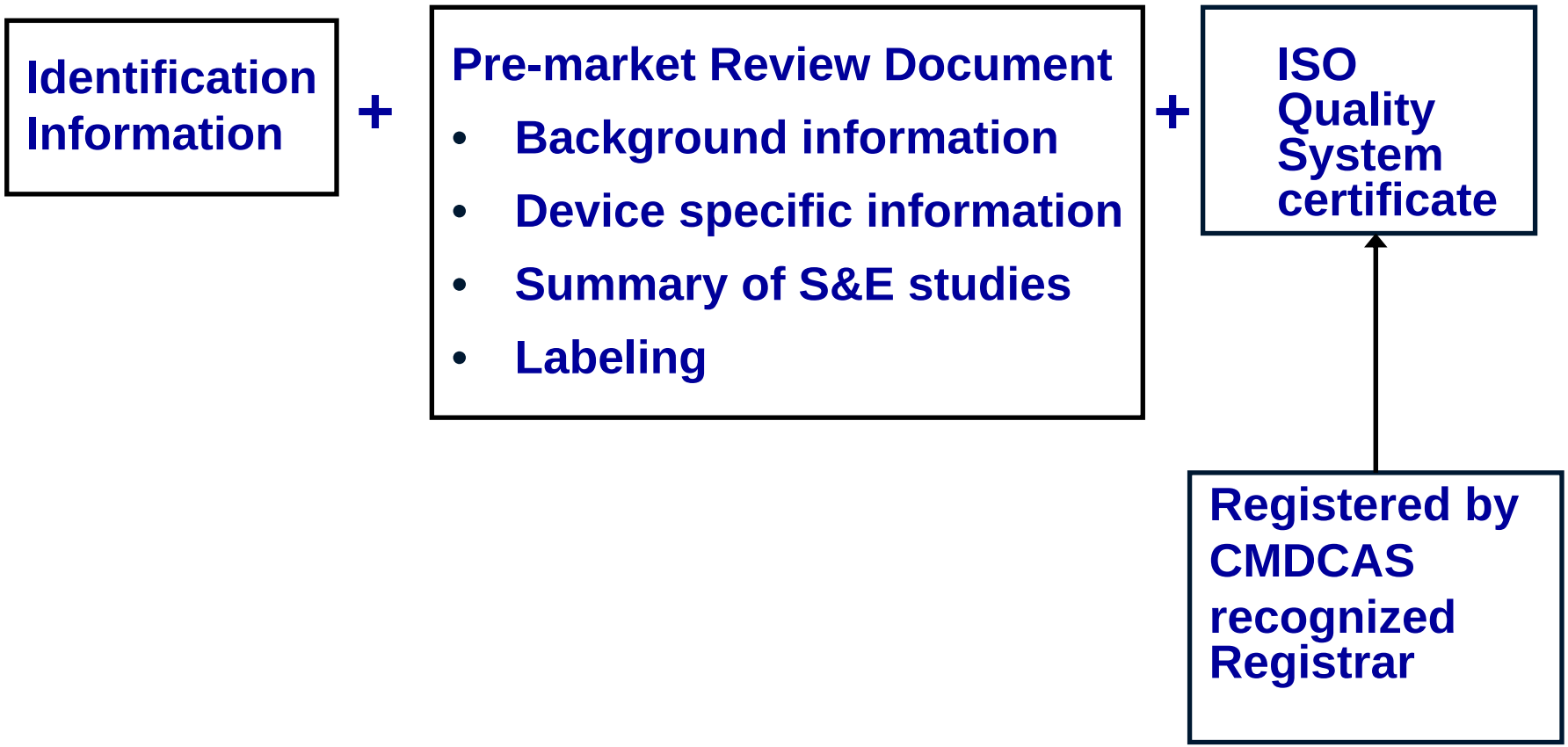
- Identification information
  - name & device identifier
  - name & address of manufacturer
- Labeled indications for use
- Attestation of compliance
  - S & E
  - Labelling
  - Procedures relating to
    - distribution records
    - problem reporting
    - Recalls
- List of standards

+

ISO Quality System Certificate

Registered by CMDCAS recognized Registrar

Device Licence – Class III



Device Licence – Class IV

Identification Information +

Pre-market Review Document

- Background information
- Risk assessment
- Quality Plan
- Device specific details
- Details of S &E studies
- Labeling

+ **ISO Quality System certificate**

Registered by CMDCAS recognized Registrar

Recommendation

- **Acceptance for licensing**
- **Additional information request**
- **Licence with conditions**
- **Refusal**

Performance Target

- **Licence:**

  -Class II – 15 days

  -Class III 75 days

  -Class IV – 90 days

  -Priority review – 45 days

  -Review of Additional Information – 45 days

6. Post-Market Surveillance

Post-Market Surveillance

- **Dept. involved: MDB, HPFBI, MHPD**
- **Covers:**

  -Distribution Records

  -Complaint handling

  -Incident reporting system:
  - **Volunteer report**
  - **Mandatory problem report**

  -Recall:
  - **Documented Procedure**

  -Implant Registration:
  - **Maintained by Manufacturer or Designate**

Mandatory Problem Reporting

- **Similar to EU Vigilance System**
- **Within 10 days: Incident leading to death or serious deterioration of health**
- **Within 30 days: If incidents were to recur, could lead to death or serious deterioration of health**

Risk Communication

- **Notice to Hospitals**
- **Public Advisories**
- ***It's Your Health* Articles**

7. Special Control sales

Special Access Program (SAP)

Key Activities:

Application assessments and guidance; advice, communication and liaison between physicians and product sponsors to ensure disclosure of risk/benefits of unmarketed products

Part 2 - Custom and Special Access

- **Custom-made devices other than a mass-produced medical device, must:**
  - **be manufactured in accordance with written instructions from a health care professional;**
  - **differ from devices generally available from a dispenser; and,**
  - **be for the sole use of a particular patient or professional.**
- **Special access to devices for emergency use or if conventional therapies have failed, are unavailable or are unsuitable can also be granted.**

Part 2 - Custom and Special Access

- **Applications in a prescribed format must be received from a health care professional.**
- **Authorization for sale will be granted to the manufacturer of the device.**
- **Mandatory problem reporting still applies to these devices.**

Obligations Under SAP

- **Sale is exempt from the safety, effectiveness and quality provisions of Part 1 of the Regulations.**
- **However, manufacturers are obliged to meet:**
  - **specific labeling requirements;**
  - **maintain adequate distribution records;**
  - **mandatory problem reporting of serious adverse events within 72 hours; and,**
  - **implant registration if applicable.**

Investigational Testing

Will be presented at panel discussion (October 25, 6:30-8:30 pm)

Further Information

Visit our website at:

http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_devices_e.html

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Ottawa welcomes you

Questions?