

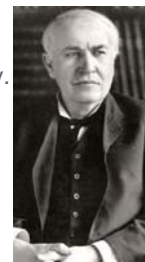
## How to Prepare for ISO 13485:2003 registration under the CMDCAS Program

*Patient Management Software Conference  
September 8, 2010*



## Intertek's Roots

- ↑ **2007:** All subsidiaries of Intertek Testing Services join to become one Intertek globally.
- 2002:** ETL SEMKO, as part of Intertek, becomes a public company.
- 1996:** Intertek Testing Services purchases Inchcape Testing.
- 1994:** Inchcape acquires SEMKO.
- 1988 & 1992:** Inchcape acquires ETL and Warnock Hersey.
- 1927:** Charles Warnock establishes building product testing company in Montreal, Canada.
- 1925:** SEMKO AB is founded in Kista, Sweden.
- 1896:** Thomas Edison founded Lamp Testing Bureau in USA, renames to "Electrical Testing Laboratories" in 1904.
- 1888:** Milton Hersey establishes chemical testing company in Montreal, Canada.



Thomas Edison

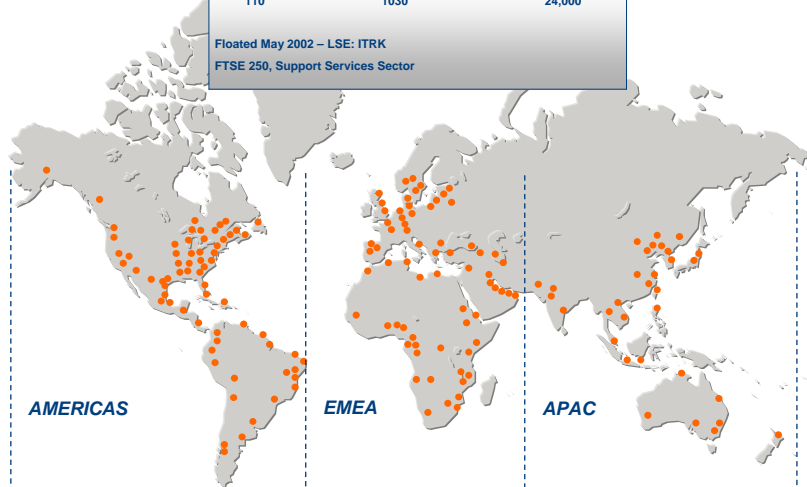


# Global Network: Intertek Group



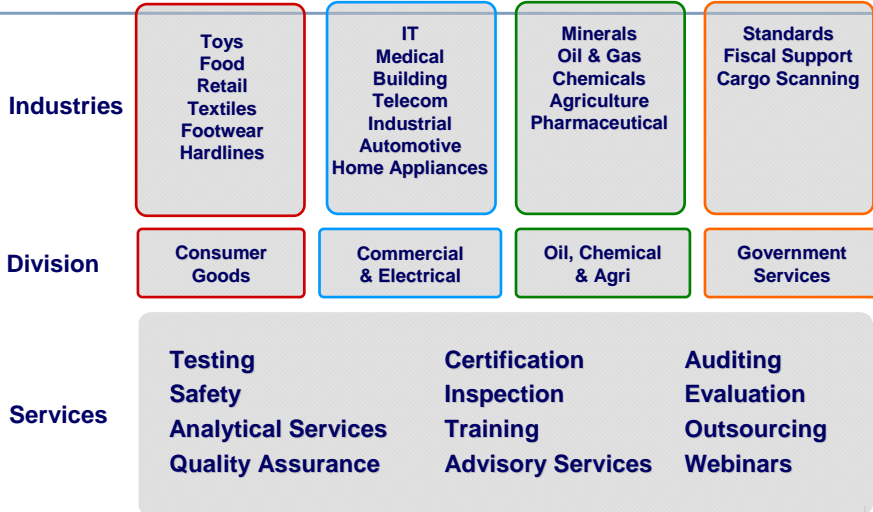
Countries	Locations	Staff
110	1030	24,000

Floated May 2002 – LSE: ITRK  
FTSE 250, Support Services Sector



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## We support our customers in their global trade



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## Your single source for auditing solutions



*Beyond certification, we provide customized auditing solutions to meet your needs*

ISO 9001 - Quality	AS9100, AS9110, AS9120 - Aerospace
ISO 14001 - Environmental	ISO/TS 16949 - Automotive
OHSAS 18001 - Health & Safety	ISO 22000 - Food Safety
ISO 13485/CMDCAS - Medical	ISO 20000 - IT Service
Medical Device Directive - Notified Body Services & CE Marking	ISO 27001 - Information Security
2nd party / Supplier Auditing	QC 080000 - HSPM
SA 8000 - Social Responsibility	Green House Gas Verification
Leadership in Energy and Environmental Design (LEED)	Variety of regional and national certifications

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## Core Medical Services



### Testing, Evaluation and Certification

- ETL Listed Mark for North American safety testing
- Testing for CE-marking requirements
- Testing to the CB Scheme
- Quality System registration
- Risk analysis
- Electromagnetic Compatibility (EMC)
- Notified Body reviews

### Regulatory Services

- FDA Third Party Reviewer for 510(k)
- CMDCAS registration in Canada
- Medical Device Directive (MDD)
- In Vitro Diagnostic Directive (IVDD)

### Knowledge-based Services

- Live seminars
- Online webinars
- Design Review services
- Global Market Access Program

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## Steps for selling Patient Management Software in Canada and other markets



4 basic steps for all markets – **planning is key!**

- **Step 1** – Determine if your product meets the definition of a medical device

(Patient management software that is sold for diagnostic or therapeutic purposes is considered a medical device as per Health Canada.

## Steps for selling Patient Management Software in Canada and other markets



4 basic steps for all markets – **planning is key!**

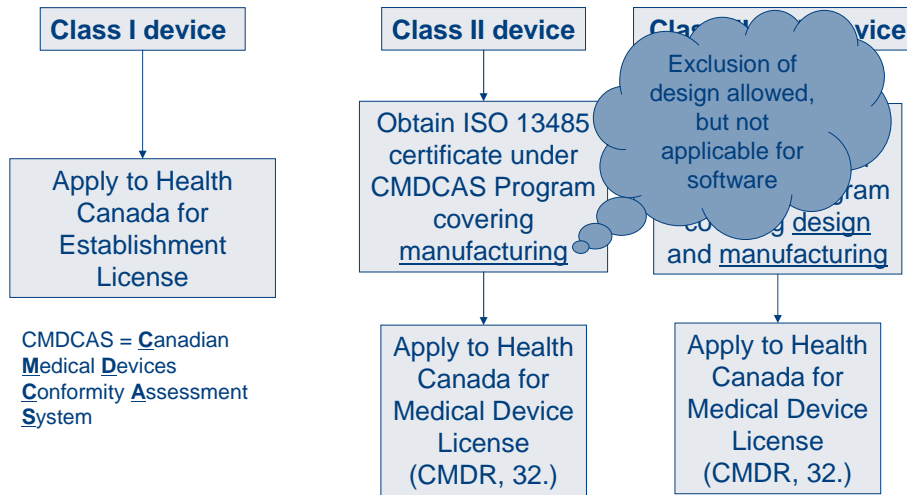
- **Step 2** - Classify your device, determine applicable requirements and conformity assessment route options

**1. Any patient management software used only for archiving or viewing information or images, and not involved in the primary acquisition, manipulation and transfer of data, is considered a Class I medical device.** Although Class I devices do not require a medical device license, manufacturers, distributors and importers are required to obtain an establishment license.

**2. Any patient management software involved in data manipulation, data analysis, data editing, image generation, recording of measurements, graphing, flagging of results or performing calculations is considered a Class II medical device,** as is any primary workstation that interfaces directly with a system (imaging or other type) by acquiring data and then sending data to an image generating, viewing or storage device. Prior to selling a device in Canada, manufacturers of Class II, III and IV devices must obtain a medical device license.

## Determine risk class and conformity assessment requirements in Canada

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## Steps for selling Patient Management Software in Canada and other markets

**Intertek**

4 basic steps for all markets – **planning is key!**

- **Step 3** - Prepare required technical documentation and implement quality management system requirements

This can be completed/accomplished in 3 ways:

1. Do it yourself !
2. Hire a consultant !
3. Hybrid of option 1 & 2

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## Steps for selling Patient Management Software in Canada and other markets

**Intertek**

4 basic steps for all markets – **planning is key!**

- **Step 4** – Maintain quality management system and perform post-market surveillance activities
- After certification Intertek must visit your facility at the minimum of once per 12 months to verify your management system is maintained and compliant.
- In the event your system no longer is maintained or compliant your firm runs the risk of have your certification suspended or revoked.

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## What is ISO 13485 ?

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- Specifies requirements for a quality management system for “the design and development, production, installation and servicing **of medical devices**, and the design, development, and provision of **related services**”
- Primary objective is to facilitate harmonized regulatory requirements for QMS
- Focus is on the provision of safe and effective devices
- Excludes some requirements of ISO 9001 and includes particular requirements for medical devices
- Interpretation document on the application of ISO 13485:2003: ISO/TR 14969

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**ISO 13485:2003 = ISO 9001:2008 – customer satisfaction - continual improvement + additional requirements specific to medical devices**



**4 Quality Management System**  
4.1 General Requirements  
4.2 Documentation Requirements

**5 Management Responsibility**  
5.1 Management Commitment  
5.2 Customer Focus  
5.3 Quality policy  
5.4 Planning  
5.5 Responsibility, authority and communication  
5.6 Management review

**6 Resource Management**  
6.1 Provision of resources  
6.2 Human resources  
6.3 Infrastructure  
6.4 Work environment

**7 Product realization**  
7.1 Planning of product realization  
7.2 Customer-related processes  
7.3 Design and development  
7.4 Purchasing  
7.5 Production and service provision  
7.6 Control of monitoring and measuring devices

**8 Measurement, analysis and improvement**  
8.1 General  
8.2 Monitoring and measurement  
8.3 Control of nonconforming product  
8.4 Analysis of data  
8.5 Improvement

**ISO 13485 promotes the adoption of a process approach**



- Identify processes (process = activity that receives inputs and converts them into outputs)
- Determine the sequence and interaction of processes
- Determine criteria and methods to ensure operation and control effectiveness
- Ensure availability of resources and information for operation and monitoring
- Monitor, measure and analyze processes
- Implement actions necessary to achieve planned results and maintain effectiveness of processes



“PLAN-DO-CHECK-ACT” methodology

## ISO 13485 used as a framework to address regulatory requirements

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- Title of standard is “Medical devices — Quality management systems — Requirements **for regulatory purposes**”
- ISO 13485 may be used as a framework by an organization to consistently meet all applicable regulatory requirements for all markets in which they are selling devices, not only CMDR
- Example: Links between ISO 13485 and CMDR in Annex A of Health Canada Guidance Document GD210



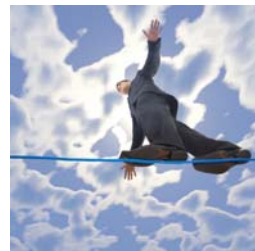
Adobe Acrobat  
Document

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## ISO 14971 - Risk Management for medical devices

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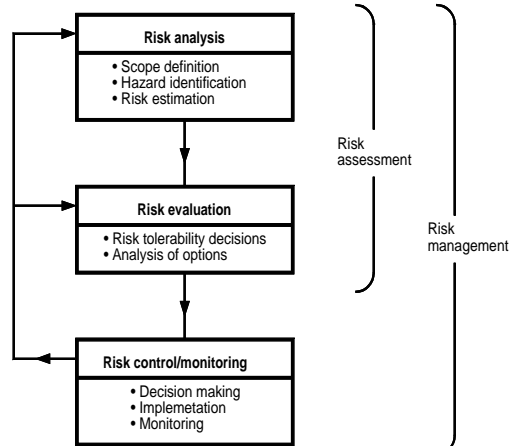
- Standard for the use of manufacturers
- Applies to all medical devices
- Applies over all life cycle of a medical device
- Does not apply to clinical decision making relating to the use of a medical device
- Does not set acceptable risk levels



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## Overview of risk management process

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Extract from ISO 14971

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Relying exclusively on design and development processes to control risk is not sufficient.

After release of the device to market, risk management activities should be linked to quality management processes, for example, production and process controls, corrective and preventive actions (CAPA), servicing and customer feedback

## Links between QMS and risk management system

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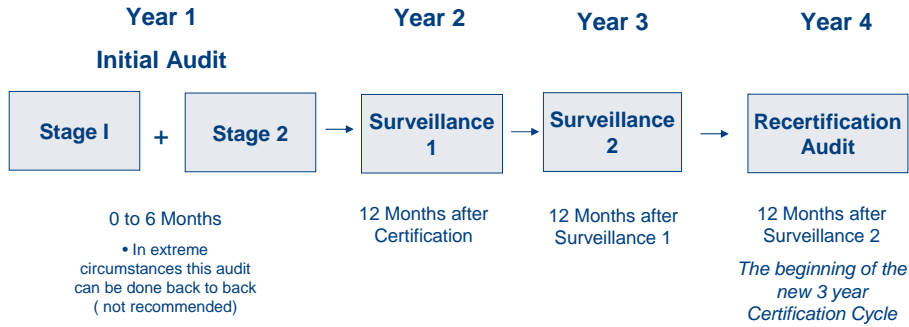
GHTF document GHTF/SG3/N15R8 “Implementation of risk management principles and activities within a Quality Management System”

- Intended to assist medical device manufacturers with the integration of risk management concepts into their quality management system by providing practical explanations and examples
- Available for free download at [www.ghtf.org](http://www.ghtf.org) under Study Group 3, Documents, Final Documents

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# ISO 13485/CMDCAS Certification Process



# ISO 13485/CMDCAS Certification Process



# ISO 13485:2003/CMDCAS certificate



## Certificate of Registration



The following organization's quality management system has been assessed and registered by Intertek Testing Services NA Ltd., a CMDCAS recognized registrar, as conforming to the requirements of:

**ISO 13485:2003**

**Organization:**

**Company Name Goes Here**

**Division Name**

Main site: First Address, City, State or Province, Post Code, Country

Additional site (if too many additional sites, list them in an annex to the certificate)

**The Quality Management System is applicable to:**

Scope Statement goes here. The (design and development,) manufacture, (installation, service) of (list of medical device product categories) **for the area of (specialty).**

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement.

Certificate Number  
US-9999  
Initial Certification Date  
January 1, 2000  
Certificate Effective Date  
January 1, 2000  
Certificate Expiry Date  
January 1, 2003



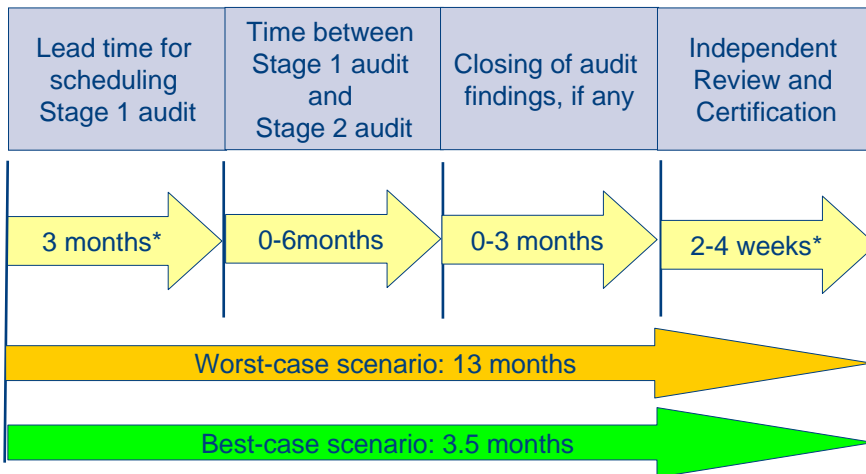
QP1106-CA-CMDCAS - Issue Date: 01/05/2008

<Name and Title of Signatory>  
Intertek Testing Services NA Ltd. - Lachine, QC, Canada

[www.intertek.com](http://www.intertek.com)

Intertek Testing Services NA, Inc.  
Boxborough, MA, USA

# ISO 13485/CMDCAS Certification Process Timelines



\*May vary in time and between certification bodies

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## Most common audit findings – Top 3



- Risk Management process: Risks/hazards not addressed, not recorded or risk management file not updated regularly, only risk analysis on product vs. risk management (throughout product realization)
- Inadequate control over suppliers: Selection, evaluation and re-evaluation criteria not defined, documented agreement missing or inadequate
- Applicable regulatory requirements not addressed or improperly addressed in QMS documentation, not keeping up to date with regulatory requirements

## Most common audit findings



- Infrastructure (maintenance, IT backup) and work environment (temporary personnel, training, cleanliness) not addressed
- Corrective action process: No proper root cause analysis, no verification of effectiveness of action taken
- Internal auditors not trained on regulatory requirements and scope of internal audits not covering regulatory requirements
- Competency records missing or not matching job description

## Most common audit findings

**Intertek**

- Design process: design plan not showing stages of design process, design plan not updated as the design progresses, incomplete design inputs (including risk management), design inputs not approved, or not traceable to verification activity
- Document control issues
- Quality objectives not adequately measured, or not established at relevant functions and areas of the organization

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## Example of time and costs

**Intertek**

Typical audit time and costs for **ISO 13485** certification for a company of 26-45 employees, moderate risk devices:

- Stage 1 audit: 2 man-days
- Stage 2 audit: 2.5 man-days
- Annual Surveillance audit: 1.5 man-days
- Recertification audit: 3 man-days

**Total** approx. 6.5K\$ 1<sup>st</sup> year; 15.5K\$ over 4 years

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## Example of time and costs

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- Stage 1 audit: 2 man-days
- Stage 2 audit: 3 man-days
- Annual Surveillance audit: 2 man-days
- Recertification audit: 3.5 man-days

**Total** approx. 7K\$ 1<sup>st</sup> year; 18K\$ over 4 years

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**For Further Information please contact:**

**Dion Goncalves**  
Canadian Manager Sales  
6225 Kenway Drive.,  
Mississauga, ON ., L5T 2L3  
905-678-7820 Ext: 4223  
Cell 416-716-3557  
[dion.goncalves@intertek.com](mailto:dion.goncalves@intertek.com)  
[www.intertek-sc.com](http://www.intertek-sc.com)

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