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11th GHTF Conference

Washington DC, October 3-4, 2007

Workshop

Quality Systems Auditing - *The Canadian Experience*

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Chair SG3



Canada 

outline

overview of regulations and audit
process...

auditing projects with other regulators...

experience...

next steps...



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Overview of regulations

Canadian Medical Devices Regulations

- Promulgated in 1998. Calls for “manufacturer” to be certified to ISO 13485:2003. QMS sections enforced January 1, 2003
- Devices classified “Class I to IV”. Rules based classification system used (Class I low risk – Class IV highest risk)
- Class II to IV Devices must be licensed before first sale
- Depending on device class, licence applications contain an attestation, or evidence, that the device meets safety and effectiveness requirements. Existing licence must be amended before manufacturer makes “significant change”



Overview of regulations

Canadian Medical Devices Regulations

- Licence applications must contain a valid (CMDCAS) ISO 13485:2003 certificate. Certificates are valid for no more than 3 years.
- Third parties audit and certify quality management system (QMS)
- Third parties called “CMDCAS recognized registrar” (Canadian Medical Device Conformity Assessment System). Fifteen organizations presently recognized by Health Canada
- Manufacturer (as defined in regulations) must maintain a certified ISO 13485:2003 QMS as long as device(s) is(are) sold in Canada



The numbers...

2,455 “manufacturers” holding 24,196 active licences

2,427 certificates in HC data base

Devices imported from 45 countries

Top 5 locations of licence holders (US, EU, Canada, Switzerland, Japan)

63 % (n=15388) of licences come from USA

51% (n=1275) manufacturers located in USA

900+ auditors trained by HC

40% of auditors give USA or Canada as mailing address



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Overview of audit process

Audits performed in accordance with existing ISO standards augmented with Health Canada requirements, GHTF guidance and International Accreditation Forum (IAF) guidance :

- ISO/IEC 17021 : Conformity assessment — Requirements for bodies providing audit and certification of management systems
- IAF Guide 2 : IAF Guidance on the Application of ISO/IEC Guide 62:1996 (NOTE: *only some of the Annexes of this document are used*)
- ISO 19011 : Guidelines for quality and/or environmental management systems auditing



Overview of audit process

Audits performed in accordance with existing ISO standards augmented with Health Canada requirements, GHTF guidance and International Accreditation Forum (IAF) guidance (contd.):

- GHTF SG4(99) 28 Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements
- GHTF SG4(00) 3 Training Requirements for Auditors (Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements - Supplement 2)
- Health Canada / GD210: ISO 13485:2003 Quality Management System Audits Performed by Health Canada Recognized Registrars
- Health Canada / GD207 : Guidance on the content of ISO 13485 quality management system certificates issued by CMDCAS recognized Registrars



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Registrar ISO/IEC 17021 plus IAF
GD2:2005

Audit process
HC GD210

Audit process ISO
19011



Certificates
HC GD207

Auditor Training
GHTF SG4(00) 3

Audit process GHTF
SG4(99) 28



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Overview of audit process

Objectives of all audits under CMDCAS must include:

- A determination of the conformity of the manufacturer's QMS to ISO 13485:2003, and
- An assessment of the inclusion and effective implementation of the applicable provisions of the Canadian Medical Devices Regulations throughout the manufacturer's QMS

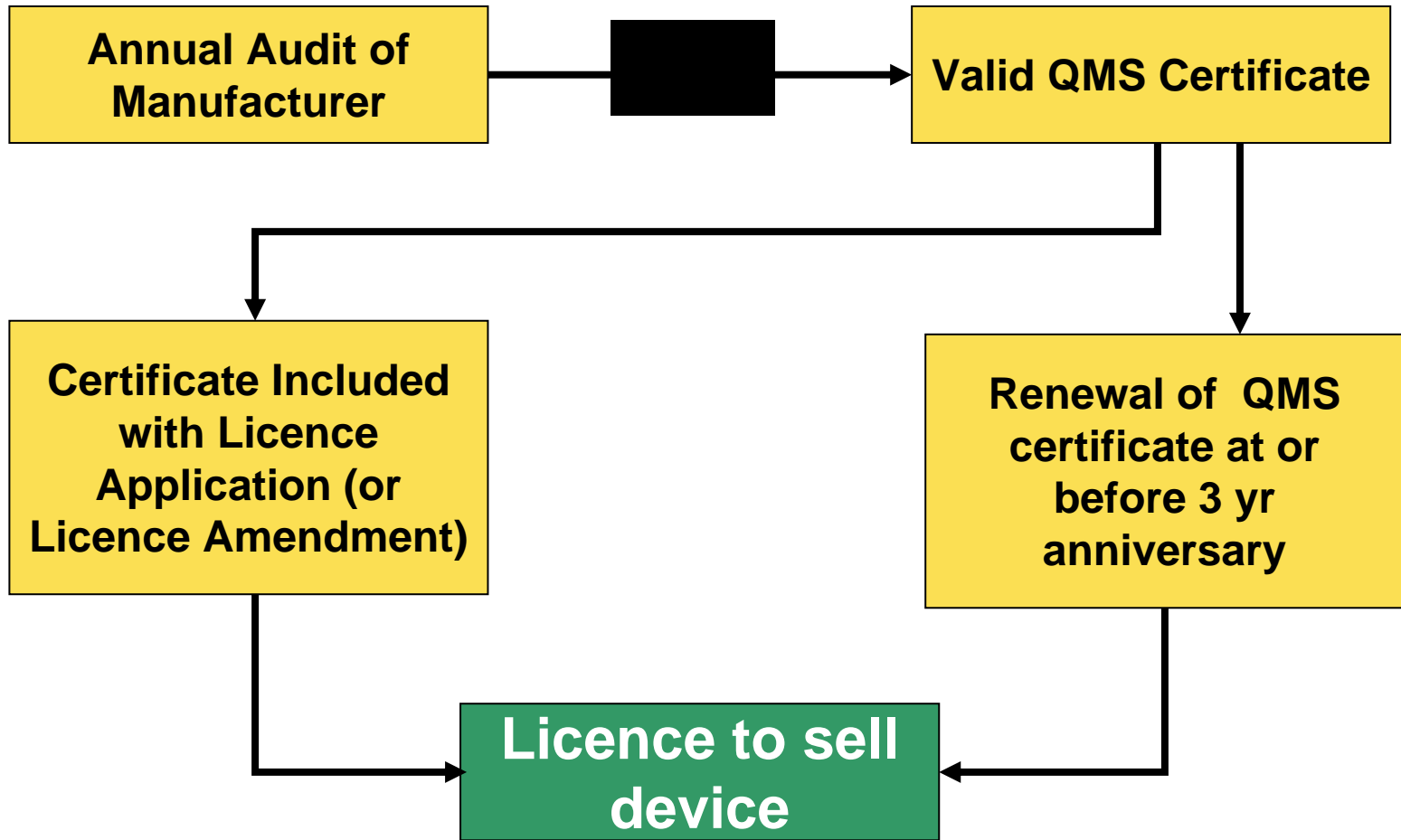
Under CMDCAS, third party auditors are not Government Inspectors! They do not have any regulatory powers. Auditors "...evaluate the capability of the management system to ensure compliance with statutory, regulatory and contractual requirements.." (ISO 19011, para. 6.2.2 b)

Nonconformities are always cited against a section of ISO 13485:2003 and are supported by objective evidence and links to regulatory requirements where appropriate.



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Link between audit and licence



QMS related arrangements with other regulators

Health Canada involved in cooperative arrangements with the TGA (Australia), and FDA (USA).

- TGA project is part of an MOU between Health Canada's Health Products and Food Branch (HPFB) and Australia's Therapeutic Products Administration (TGA).
- FDA project is a "Pilot" program designed to "further regulatory cooperation" and "reduce regulatory burden on industry".



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Cooperation with other regulators

“Pilot Multipurpose Audit Program” (PMAP) jointly developed by HPFB and FDA. Relies on FDA Accredited Persons and CMDCAS Recognized Registrars to perform audits.

Program developed because of increased regulatory cooperation that is being driven by a Memorandum of Understanding signed in 2003 between Canadian and US health departments and the more broader government level North American “Security and Prosperity Partnership” (SPP) signed in 2005.



Pilot Multipurpose Audit

Details

- Audits performed under PMAP must satisfy both FDA and HC requirements.
- Auditor prepares two reports. One in FDA format the other in Registrar's standard format. Report intended for FDA must conform to Accredited Persons requirements.
- Manufacturer must meet FDA and HC definition of manufacturer
- No country of origin requirement

Operational



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Cooperation with other regulators

Memorandum of Understanding (MOU) underpins arrangement between Canada's Health Products and Food Branch (HPFB) and Australia's Therapeutics Goods Administration (TGA).

- Audits performed under the MOU would encompass Canadian and Australian requirements and a single audit report would be produced
- HPFB accepts ISO 13485:2003 QMS certificates issued by the TGA's Manufacturers Assessment Branch (MAB) to Australian manufacturers.
- TGA accepts ISO 13485:2003 QMS certificates issued by qualified CMDCAS registrars to Canadian manufacturer



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HPFB-TGA MOU

Details

- MOU contains a country of origin clause. Only organizations that meet Canadian and Australian definition of manufacturer and are located in Canada or Australia/New Zealand can participate
- Device must meet Canadian and Australian definition of medical device and be authorized or eligible for authorization for sale in Canada and Australia
- Health Canada in process of recognizing MAB as a registrar

Under Development



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Mutual Recognition Agreements

- Canada has signed multi-sectoral MRAs with the EU, EEA-EFTA and Switzerland
- MRAs represent trade driven, legally binding international agreements negotiated between governments
- One of the sectoral annexes deals with the conformity assessment of medical devices
- To date, none of the MRAs are operational with respect to medical devices annex as confidence building phases have not taken place



Mutual Recognition Agreements

- **However**, many European Notified Bodies are also CMDCAS recognized or are affiliated with a registrar so they routinely perform “combined” audits for European and Canadian purposes reducing the need for these projects to be operational.
- Third parties like to offer “one stop shopping” for manufacturers seeking CE mark as well as QMS certificate for Canada.



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Experience to date...

Single audits that are intended to cover Canadian and European QMS requirements have presented some challenges, namely...

- Auditor's lack of understanding or misinterpretation of Canadian regulatory requirements (not widespread)



Experience to date...

- Assumption that European standards/guidance are equivalent to Canadian standards/guidance
- Manufacturers submit European versions of QMS certificates or certificates of conformity to a European Directive.
- Focus on European requirements with Canadian requirements treated as an “add on”
- Auditors use a “check list” approach
- Audit reports silent on Canadian requirements



Experience to date...

Projects with Australia and USA

- Both projects are still in their infancy
- A number of Canadian manufacturers have expressed some interest in participating



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Next steps...

- Advertise more to get wider acceptance of projects
- Increase use of GHTF SG 3 and SG4 guidance documents in audit process
- Educate stakeholders on value of joint audits
- Improve present projects based on lessons learned and stakeholder feedback
- Develop other projects ??



Challenges...

- Sufficient engagement by manufacturers.
- Possible revision to ISO 13485:2003 following upcoming changes to base ISO 9001.
- Keeping third party auditors (900+) up to date on audit criteria and regulatory requirements.
- **Ensuring that auditors have sufficient time to: prepare for and perform audits; produce meaningful audit reports; and properly close nonconformities.**



Contacts...

Quality Management Systems/CMDCAS/SCC

http://hc-sc.gc.ca/dhp-mps/md-im/qualsys/index_e.html

http://www.scc.ca/en/programs/iso_reg/medical.shtml

Projects

http://hc-sc.gc.ca/dhp-mps/md-im/activit/int/index_e.html



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