

# Patient Management Software

## Large Company Perspective

Laila Gurney, M.Sc., RAC  
Director, RA (Canada)

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imagination at work

# GE Healthcare

- General Electric Company
- 46,000 employees world-wide
- 600 employees in Canada – Importer / Distributor
- Products: MR, CT, PET, NM, Ultrasound, XR (Mammography, Rad, R&F, Surgery, Interventional), Life Support Systems, Monitoring, Medical Diagnostics, **Healthcare IT**

# GE Healthcare

- Medical Device company
- Operating globally
  - Highly regulated environments (e.g. US, Canada, Australia, Japan, EU, China)
  - Emerging regulations (e.g. Latin America, Middle East, Africa, Russia, Asia Pacific, India)

# GE Healthcare Quality Vision

*We are committed to Quality and Compliance in every decision we make, every action we take... believing that this benefits patients, customers, and this business.*

# Medical Devices

- Meet regulatory requirements, industry standards and company procedures
- Design Controls
- Quality Management System (FDA QSR, ISO 13485:2003 CMDCAS)
- Internal and External audits (regulators, notified bodies / registrars)
- RFID (US FCC, Industry Canada, etc.)
- Electrical standards (CSA-like etc.)

# Medical device requirements in Canada (CMDR, SOR/98-282)

## All devices:

- Meet Safety and Effectiveness criteria of sections 10-20 of CMDR, as applicable (documented – Tech File)
- Meet labeling requirements of Sections 21-23 of CMDR, as applicable
- Distribution records, complaint handling, mandatory problem reporting, recall
- Establishment Licence (Importer, distributor, manufacturer of class I devices, if not selling through MDEL holder)

# Medical device requirements in Canada (CMDR, SOR/98-282)

## Class II – above PLUS:

- Medical Device Licence (manufacturer)
- Quality Management System (ISO 13485:2003 CMDCAS) – design may be excluded BUT....

**Class III and IV** → same as above (more rigorous premarket review and design included in ISO scope)

# Canadian History

- 2006 → Notice issued by Health Canada to update **KEYWORD** Index... the following product codes were revised/ added:
  - 74DQK COMPUTER, DIAGNOSTIC, PROGRAMMABLE
  - 80VHN COMPUTER, PATIENT DATA MANAGEMENT
- Both class II
- Teleconference with Health Canada to understand interpretation and compliance requirements
- Internal training, procedures → Compliance

# Regulation of Stand Alone Software (HIT)

- US FDA proposed rule 2008 → regulation of stand alone software as “Medical Device Data Systems – MDDS” – still under review by FDA
- Dr. Shuren’s (Dir, CDRH, US FDA) Feb. 23, 2010 testimony on risks and recommendations for regulatory pathways

## RISKS identified based on voluntary reports to date:

- (1) errors of commission,
- (2) errors of omission or transmission
- (3) errors in data analysis and
- (4) incompatibility between multi-vendor software applications and systems, which can lead to any of the above

## Regulatory Pathways:

- Focus on postmarket safety by requiring HIT device establishments to electronically register and list their HIT devices, and to submit Medical Device Reports (MDRs) to the FDA
- Focus on manufacturing quality and postmarket safety by requiring HIT device manufacturers to comply with the requirements described above, and also to adhere to FDA’s Quality Systems Regulation (QSR)
- Apply our traditional regulatory framework, in which HIT device manufacturers would be required to meet all the same regulatory requirements as other, more traditional devices, including risk-based premarket review

# Regulation of Stand Alone Software

Europe → Working group (Industry and regulators) – released document for commenting in February 2010

Document includes specific functionalities that are considered to be those of a medical device

Met several times since, most recently in July (Brussels)

Classification of stand alone SW as medical device → very prescriptive and helpful

# The Very Near Future....

- Ensure medical device quality, accountability (reportability, corrections / recalls) → protect health and safety of patients
- Regulation should be commensurate with risk
- Challenges:
  - Global Harmonization (role of GHTF, AHWP) → advocate for new regulations to be harmonized with no unique / disparate requirements
  - Fast evolving technology – sophisticated software, automation, interoperability, etc.