

MedManager

Canada's leading provider of online chronic disease management solutions



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Navigating Medical Device Licensing

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9:14AM August 21, 2006

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Health Canada Response

“Based on the information you have provided...a Class II device...software has data analysis capabilities with flagging of results and data graphing.”

August 22, 2006

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First Steps Post-Classification

Get a consultant?

- Not rocket science vs. efficiency and expertise

Designate an RAO

- Type A, process and control lover

Hire an external auditor

- Not all created equal...tougher is better
- An auditor is not your consultant

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Business Impact of ISO & Licensing

Costs

- Consultants, auditors, staff

Development/delivery time up 15%-25%

Culture

- Medical device company vs. software company

Employee Happiness

- Current vs. future hires

Fear of "Recall"

Improved:

- Processes
- Measurement
- Product
- Consumer safety



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To License or Not?

Major Regulatory / Enforcement Issues

- Loopholes for public sector "competitors"
- Outdated legislation
- Limited real-world application of the regulations and stakeholder relations
 - Patient Management Software vs. Health Management Software
 - Need to inform more stakeholders
- Buyers ignore the rules
- The barn door is open for the next year...what if Health Canada can't herd the horses?
- No forced removal unless there is evidence of risk to consumers

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Next Steps Recommendations

To companies:

Get on with certification and licensing

To industry:

Work with Health Canada to address the issues that threaten consumers with unsafe devices and compliant companies with an uneven playing field

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Questions, comments, ideas...

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