



FOR IMMEDIATE RELEASE

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Health Canada Notice: Medical Software Must be Licensed

A recent Health Canada notice has revealed that some types of software used in medical or clinical applications are now considered to be medical devices, and so must be licensed under the Food and Drug Act. This notice has significant implications with respect to a company's ability to market and sell a variety of clinical management software products in Canada.

Applying for a Medical Device License is a complex process, which includes implementing and documenting a Quality Management System and ISO 13485. For those who have never gone through this process, it is certainly daunting. Even those companies who have faced it before are finding themselves stretched for resources to get the work done by the deadline.

One cost-efficient and effective solution for companies going through Health Canada's licensing requirements can be found at The Clarkson Group, an Ontario based consulting firm. Recently The Clarkson Group added Paul Atkins, an experienced device licensing consultant, to their team. Paul, coupled with consultants who specialize in Quality Management Systems, can lead companies through the entire Health Canada licensing process, supplement a regulatory or quality team, or provide on-going services to help maintain ISO compliancy over the long term.

For further information, please contact Rob McLellan, P.Eng. at 647-478-3465.