

# DGM Service

## ISO 13485 CMDCAS - how to get started

### Background

Medical device manufacturers who wish to access the Canadian market must as part of the requirements to obtain and maintain a medical device licence from Health Canada, be registered in accordance to ISO 13485 by a Canadian Medical Devices Conformity Assessment System (CMDCAS) recognized registrar.

As a CMDCAS qualified registrar our partner **QMI** can assist you to gain access to the Canadian market.

Through our partnership with QMI DGM is able to qualify and provide auditor resources and to perform audits on behalf of QMI under the CMDCAS requirements. For your business this means that the same DGM auditor can assess your quality system for compliance to both the CE marking and the CMDCAS requirements during the same audit.

### What devices should be licensed ?

In Canada medical devices are categorized into four classes based on the level of risk associated with their use. Class I devices present the lowest potential risk (e.g. thermometers) and class IV devices present the greatest potential risk (e.g. pacemakers).

Class II, III and IV devices receive rigorous reviews, and must be licensed by Health Canada before being sold on the Canadian market.

Class I devices do not require licenses, but manufacturers must ensure that devices are designed and manufactured to be safe, as required by the Canadian Medical Devices Regulations.

### Estimate of cost

Before initiating the CMDCAS registration process you would probably wish to have an estimate of the costs involved.

On request we will e-mail you a questionnaire to be filled in by you. The completed questionnaire provides QMI/DGM with important information about your company and your products. It allows us to identify the specific auditor competences required for your particular assessment and will form the basis for estimating the costs involved in the registration process.

### Application

If you have decided to use **QMI** as your registrar you shall fill in the QMI Application for Registration form and sign the CMDCAS Program Registration Agreement which has been forwarded to you together with the estimate of cost.

### Document review

Upon receipt of the application your auditor contacts you to discuss the registration process, your audit readiness and any possible concerns you may have.

Your auditor will review your quality system documentation in order to make sure that it meets the requirements of ISO 13485 CMDCAS. The document review can be carried out on-site or off-site at your choice.

### Audit

Although the document review indicates that a sound quality system exists on paper, it is the implementation of the system which demonstrates your company's commitment to quality.

Our auditors will observe your system in action and conduct informal interviews to establish conformity with the applicable standard.

Prior to the audit you will receive an audit plan specifying in basic detail the dates and approximate times anticipated for auditing each process and activity.

### **Post-audit meeting**

A meeting is held with your Management to present the audit findings and conclusions in relation to your quality system's conformity to the standard. The meeting will highlight the positive aspects of your quality system and possible non-compliances will be discussed in detail.

At the conclusion of the post-audit meeting the auditor will provide a preliminary statement of recommendation for registration and explain the continuation of the registration process.

### **Reporting**

After the audit you will receive a report which will bring all aspects of the audit into perspective. The audit report reflects the audit results and the essence of the discussions at the post-audit meeting.

### **Registration**

When possible non-compliances have been closed QMI will issue a CMDCAS Certificate of Registration valid for 3 years.

### **Medical Device License**

With your ISO 13485 CMDCAS registration certificate at hand you may now apply for a Medical Device License at Health Canada. For further information see [http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index\\_devices\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_devices_e.html).

### **Surveillance**

QMI/DGM carries out periodical audits of the quality system in order to ensure that the quality system is effective and constantly meets the requirements of

the applicable standard. You may choose between annual and half-yearly surveillance audits.

### **Reassessment**

At the end of each three-year period a reassessment of the entire system including a document review is performed. The reassessment visit is designed to give you every confidence that your quality system continues to meet the requirements of the standard.

### **Upgrade audits to ISO 13485:2003**

The new ISO 13485:2003 which is similar in structure to ISO 9001:2000 replaces ISO 13485:1996 and ISO 13488:1996.

All manufacturers of class II, III and IV medical devices holding licenses or applying for licenses must complete the transition to ISO 13485:2003 by March 15, 2006.

All existing customers are encouraged to develop transition plans and inform their auditor of their timelines for transition to ISO 13485:2003.

### **More information**

For more information about ISO 13485 CMDCAS, please contact

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