



Order no.: {Order_Number}	CMDCAS Program CMDR Supplemental Audit Question List	
Applicant:	{Applicant_Name}, {Applicant_Street}, {Applicant_City}	
Audited company:	{Auditee_Name}, {CLIENT_NR_AUDITEE} {Auditee_Street}, {Auditee_City}	
Lead Auditor:	{Lead_Auditor}	
Auditor(s):	{Auditor}	
Type of Audit:	{Type_of_Audit}	
Audit Dates:	{Audit_period_from} - {Audit_Period_to}	

Auditor, (Name of person completing this question list): _____

Auditor Guidance


1. Incorporate the questions in this document into a process approach audit. Do not use this document as a stand-alone CMDCAS program audit based on clauses in ISO 13485.
2. Do not spend much audit time in a conference room. Visit people’s office / place of work to fully understand the process inputs and outputs.
3. Many of the questions on the following pages are worded as ‘yes’ or ‘no’ to clearly define requirements. However, ask open ended questions during the audit. Record how the requirement is met and the objective evidence reviewed.
4. Write Nonconformity Reports in context of the requirements of ISO 13485; (not the Canadian MDR)
5. If there is any conflict in the definitions between ISO 13485 and the CMDR, the CMDR definitions take precedence.
6. The CMDR intent of a regulatory “recall” is consistent with the ISO 13485 “advisory notice”.
7. The CMDR holds the “Manufacturer” responsible for the safety and effectiveness of the medical device including the design, fabrication, assembly, sterilization, shipping etc. The Manufacturer must demonstrate control over these processes, whether outsourced or not.
8. For Canada, it is NOT the auditor’s role to classify medical devices. Refer organization to Health Canada.

Evaluation:	0 = not applicable	1 = fulfilled	2 = minor nonconformity	3 = major nonconformity
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Requirement / Subject	Document.	E	Documents / Evidence Reviewed – Audit Notes	E
<p>4.1 General requirements</p> <p>If some of the CMDR requirements have been delegated by the legal manufacturer to another area of the organization, has the delegation of responsibility been clearly defined and documented? (e.g., submitting license applications, recalls, incident reporting, etc.)</p>				
<p>Does the manufacturer have control over all outsourced processes and are the control mechanisms identified within the QMS?</p> <p>Is objective evidence available at the legal manufacturer’s facility sufficient to demonstrate control over any outsourced/purchased product/service that could affect the safety and effectiveness of the finished device?</p>				
<p>4.2.1 General & CMDR [9] [10-20] [32]</p> <p>Does the manufacturer have technical files that contain, or refers to the location of the evidence of safety and effectiveness required in Sections 10 to 20? (e.g., records showing that essential requirements met in DMR, DHF, STED, etc.)</p>				

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Are the CMDR license application regulatory requirements documented in the QMS?				
<p>4.2.2 Quality Manual & CMDR [32(2)(f)]</p> <p>If the manufacturer excludes element 7.3 Design and Development from the scope of the QMS, does the quality manual contain a detailed justification of its exclusion based on CMDR Section 32(2)(f) allowable exclusion for Class II devices? [Note: exclusion not allowed for Class III or IV devices]</p>				
<p>4.2.3 Control of Documents</p> <p>Does the Manufacturer have the most recent consolidated version of the CMDR including any amendments published in Canada Gazette Part II?</p> <p>http://laws.justice.gc.ca/en/f-27/sor-98-282/text.html</p>				
<p>Quality Systems Certificates</p> <p>CMDR [43.1]</p> <p>If TÜV SÜD America issued a new or revised ISO 13485 certificate did the manufacturer submit to Health Canada within 30 days?</p>				

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<p><u>4.2.4 Control of Records</u> Has the Manufacturer defined the record <u>retention</u> period for <u>distribution records</u> in respect of a medical device for the longer of (a) the projected useful life of the device, or (b) two years after the date the device is shipped?</p>				
<p><u>5.1 Management commitment</u> Does objective evidence exist of top <u>management's commitment</u> to meeting the requirements of the <u>Canadian Medical Devices Regulations</u>? (e.g. Device Licensing, Mandatory Problem Reports, Recalls etc.)</p>				
<p><u>5.6.2 Review input</u> Is a review of new or revised <u>Canadian Medical Devices Regulations</u> part of the input to <u>management review</u>?</p>				
<p><u>6.2.2 Competence, awareness and training</u> Have appropriate personnel been <u>trained</u> on relevant <u>CMDR</u> requirements? (e.g., internal auditors, regulatory affairs personnel, etc.)</p>				

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<p>6.3 Infrastructure & CMDR [14]</p> <p>Does the manufacturer have and maintain the necessary infrastructure to ensure that the characteristics and performance of their medical device(s) is(are) not adversely affected by transport or conditions of storage?</p>				
<p>7.1 Planning of product realization & CMDR [32(4)]</p> <p>Does the Manufacturer have a quality plan (which is also submitted to Health Canada with Class IV medical device applications) that specifies the processes and resources for specific medical devices?</p>				
<p>Has the manufacturer used the Classification rules in Schedule 1 to appropriately classify any new devices?</p>				
<p>Is the manufacturer only selling licensed medical devices in Canada?</p>				

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<p>Does the Manufacturer <u>track changes</u> to the <u>information</u> and documents that had been <u>supplied</u> earlier to Health Canada but did not lead to a license amendment?</p> <p>Are these changes reported during the annual license renewal process required in section 43(1) (b)?</p>				
<p><u>7.3.2 Design and development inputs</u> & CMDR [10-20]</p> <p>Has the manufacturer determined the <u>design</u> and development <u>inputs</u> related to the regulatory <u>safety</u> and <u>effectiveness</u> requirements?</p> <p>For example, inputs related to:</p> <ul style="list-style-type: none"> • [11] Device must not adversely affect the health or safety of a patient • [13] Characteristics and performance of device must not deteriorate under normal use • [14] The characteristics and performance of a medical device shall not be adversely affected by transport or conditions of storage • [15] Compatibility – Materials used the manufacture of the device • [16] Minimum risks to a patient and other person from foreseeable hazards • [18] Compatibility between parts and components 				

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Has the manufacturer determined the device licensing requirements for Class II, III or IV devices?				
<p><u>7.3.6 Design and development validation</u> & CMDR [12] [20] [32(3)(f) & 32(4)(i)]</p> <p>Has design and development validation been carried out and does the medical device perform as intended ?</p> <p>Has design and development validation been performed on initial production medical devices or their equivalents?</p>				
Following any design and development changes, is the Technical File updated ?				
<p><u>7.4.1 Purchasing process</u></p> <p>Do manufacturers who use suppliers to provide finished devices have documented procedures in place to ensure that the finished device is safe and effective?</p>				

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<p>Has the manufacturer identified and evaluated the risk involved with the products / services being obtained when determining the level of control over the suppliers?</p> <p>Are the controls documented and implemented?</p>				
<p><u>7.4.2 Purchasing information</u></p> <p>Has the manufacturer contractually required QMS requirements for suppliers of finished devices or critical parts, components or services (e.g., sterilization)?</p>				
<p><u>7.5.2.2 Product requirements for sterile medical devices</u> & CMDR [17]</p> <p>Does the Manufacturer have documented procedures for the validation of sterilization processes?</p>				
<p>Was the sterilization process validated prior to initial use?</p>				

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<p>7.5.3.2 Traceability & CMDR [55-56] [66]</p> <p>Do device labels contain:</p> <p>a) the name of the device;</p> <p>b) the name and address of the manufacturer in sufficient detail to serve as a postal address.</p> <p>c) the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;</p> <p>Do Class III or IV device labels also contain the control number;</p>				
Has the Manufacturer identified the lifetime of the medical devices?				
Do the manufacturer and/or distributors have records of distribution of devices and are these records kept for the longer of, the projected useful life of the device as defined by the manufacturer, or two years after the device was shipped?				
Do distribution records contain sufficient information to permit a complete and rapid withdrawal of a Class II, III or IV medical device from the market?				

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<p>If the manufacturer sells an Implant device in Canada that is listed in Schedule 2 of the CMDR, does the manufacturer have procedures and records that satisfy the traceability requirements of section 66 (i.e., implant registration card)?</p> <p>Do the Manufacturer’s agents or distributors maintain distribution records of active implantable and implantable medical devices (as defined in section 3 of ISO 13485:2003) ?</p>				
<p><u>7.5.4 Customer Property</u></p> <p>How does the Manufacturer safeguard the name and address of the patient, unless disclosure is required by law?</p>				
<p><u>7.5.5 Preservation of Product & CMDR [14]</u></p> <p>Are the characteristics and performance of the medical device protected during transport or storage, taking into account the manufacturer’s instructions and information for transport and storage?</p>				

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<p><u>8.2.2 Internal audit</u></p> <p>Has the manufacturer conducted a full system internal audit demonstrating coverage of ISO 13485 and the Canadian Medical Device Regulations?</p>				
<p><u>8.5.1 Improvement - General & CMDR [63-65]</u></p> <p>Do the manufacturer and its Canadian importer have documented <u>procedures</u> for them to:</p> <p>1) carry out an effective and timely <u>recall</u> of the device following a consumer complaint or reported problem related to device performance or safety;</p> <p>2) <u>recall</u> or <u>correct</u> a device, or to <u>notify</u> its owners and users in Canada of its defectiveness or potential defectiveness after becoming aware that the device :</p> <p>(a) may be hazardous to health;</p> <p>(b) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or (c) may not meet the requirements of the <u>Food and Drugs Act</u> (R.S., c. F-27, s.1) or the MDR (SOR/DORS/98-282)</p>				

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<p>8.5.1 CMDR [57(a)] [57(1)(b)]</p> <p>Do the manufacturer and its Canadian importer and distributors maintain records of reported problems or consumer complaints relating to the performance characteristics or safety of the device?</p>				
<p>Are these problem reports or consumer complaints used as input into the corrective and preventive action system?</p>				
<p>Do the manufacturer and its Canadian importer have documented procedures to inform Health Canada of incidents that meet the mandatory reporting criteria found in Sections 59 to 62.</p>				
<p>8.5.3 Preventive Action</p> <p>Is there evidence of proactive processes to identify potential nonconformities? (e.g., using trend data to indicate control limits are being approached, FMEA's, considering other products or facilities when implementing corrective action, etc.)</p>				

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