

**Use of
GHTF Study Group Guidance Documents
In
Canadian Medical Device Regulatory
Framework**

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Background

- Simple overview of use of documents in Canadian medical device regulatory framework
- Use of documents range from Adoption to Incorporation of Principles
- Only documents classified as Final considered
- 15 documents from all 4 Study Groups



Study Group 1

Guidance document	Canadian Position
N011R16 - <i>Summary Technical Documentation For Demonstrating Conformity to the Principles of Safety and Performance of Medical Devices (STED)</i>	Currently part of an International pilot program. May be implemented in future.
N015R16 - <i>Medical Device Classification</i>	<u>Not adopted</u> : Existing Canadian regulations contain a number of rules that are similar to GHTF
N020R5 – <i>Essential Principles of Safety and Performance of Medical Devices</i>	<u>Principles incorporated</u> into Canadian Medical Devices Regulations (section 10 – 20 , Safety and Effectiveness Requirements)



Study Group 1

Guidance document	Canadian Position
N009R6 – <i>Labelling for Medical Devices</i>	<u>Principles incorporated</u> into Canadian Medical Devices Regulations
N012R10 – Role of Standards in the Assessment of Medical Devices	<u>Principles adopted</u> : Policy document published on the recognition and use of standards



Study Group 2

Guidance document	Canadian Position
N6R2 – <i>Comparison of the Device Adverse Reporting Systems in USA, Europe Canada, Australia & Japan</i>	<u>Used as a starting point</u> in the development of other SG2 documents that Canada has adopted
N7R1 – <i>Minimum Data Set for Manufacturer Reports to Competent Authority</i>	<u>Document Adopted</u> : Existing Canadian guidance on reporting to Health Canada harmonized with GHTF guidance
N8R4 – <i>Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices</i>	<u>Document Adopted</u> : Existing Canadian guidance on Vigilance Reporting harmonized with GHTF guidance



Study Group 2

Guidance document	Canadian Position
N9R10 – <i>Global Medical Device Competent Authority Report</i>	<u>Document Adopted</u> : Current Format for exchange of reports between Competent authorities adopted.
N21R8 – <i>Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative</i>	<u>Document Endorsed</u> : Much of the GHTF guidance incorporated into Canadian regulations or guidance documents



Study Group 3

Guidance document	Canadian Position
<i>N99-8</i> <i>Guidance on Quality Systems for the Design & Manufacturing of Medical Devices</i>	<u>Document Endorsed</u> : GHTF guidance incorporated in ISO guidance to ISO 13485:200X
<i>N99-9</i> <i>Design Control Guidance for Medical Device Manufacturers</i>	<u>Document Endorsed</u> : GHTF guidance incorporated in ISO guidance to ISO 13485:200X
<i>N99-10</i> <i>Process Validation Guidance for Medical Device Manufacturers</i>	<u>Document Endorsed</u> : GHTF guidance incorporated in ISO guidance to ISO 13485:200X



Study Group 4

Guidance document	Canadian Position
(99) 28 - <i>Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: <u>General Requirements</u></i>	<u>Principles incorporated</u> in Canadian registrar accreditation policy (CMDCAS, audit process, auditor competence etc.)
(00) 3 - <i>Training Requirements for Auditors</i>	<u>Principles incorporated</u> in Canadian registrar accreditation policy (auditor training)

