GD211 Training

Module 1
Introduction



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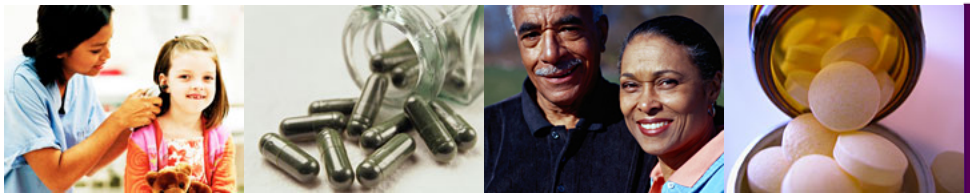
How to use this training

- This training is primarily designed for auditors.
- It can be used for self-study or in a classroom setting.
- There are five presentation modules in this course.
- There are three components to this course:
    1. the five presentations modules
    2. the guidance document GD211
    3. the Study Guide



Introduction

The guidance document *GD211: Guidance on the content of quality management system audit reports*

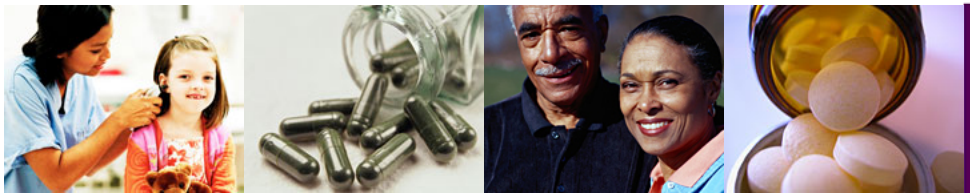
is largely based on the technical content of the Global Harmonization Task Force (GHTF) guidance document SG4/N33/R16:2007 *Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers* – ***Part 3: Regulatory Audit Reports.***




Introduction

The main objective in adapting the GHTF guidance was to develop an adoption that would be relevant to the Canadian regulatory context.

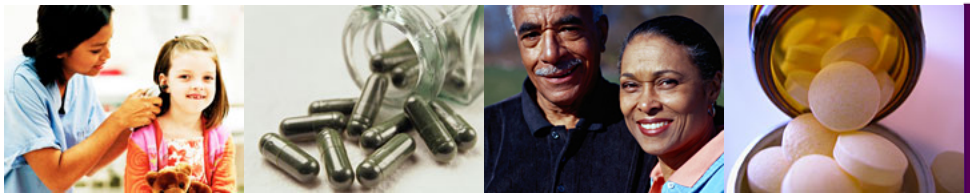
The guidance document was developed in collaboration with Health Canada recognised registrars and other stakeholders.



Objective of guidance

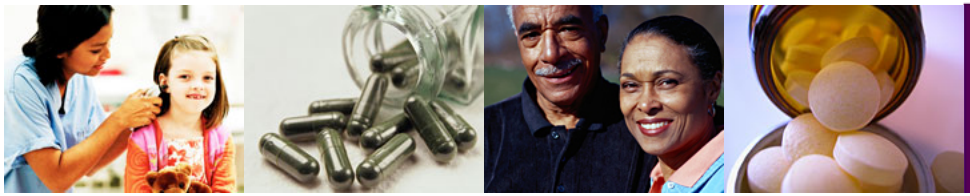
The primary objective of this guidance document is to establish the minimum content of quality management system audit reports.

This will improve the quality and usefulness of audit reports as well as the credibility and reliability of certifications.



Principles

Because no guidance document can address all possible situations, the principles of fair presentation, evidence-based auditing, responsibility, and positive reporting should guide auditors when preparing audit reports.

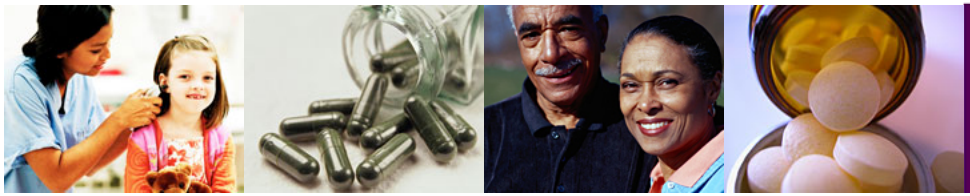


Principles

Fair presentation: *the obligation to report truthfully and accurately*

Audit findings, audit conclusions and audit reports reflect truthfully and accurately the audit activities.

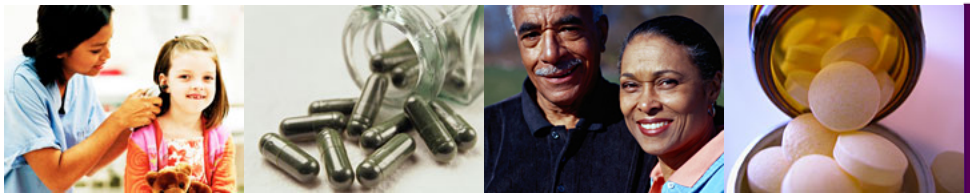
Significant obstacles encountered during the audit and unresolved diverging opinions between the audit team and the auditee are reported. (ISO 19011:2002)



Principles

Evidence-based approach: *the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process*

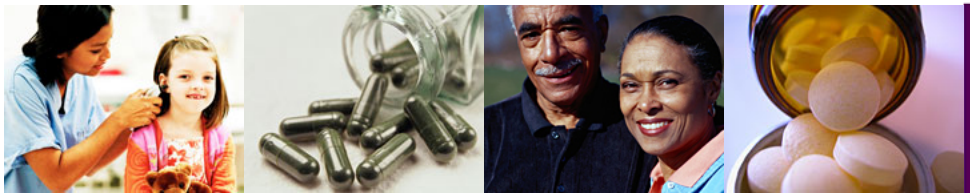
Audit evidence is verifiable. It is based on samples of the information available, since an audit is conducted during a finite period of time and with finite resources. The appropriate use of sampling is closely related to the confidence that can be placed in the audit conclusions. (ISO 19011:2002)



Principles

Responsibility

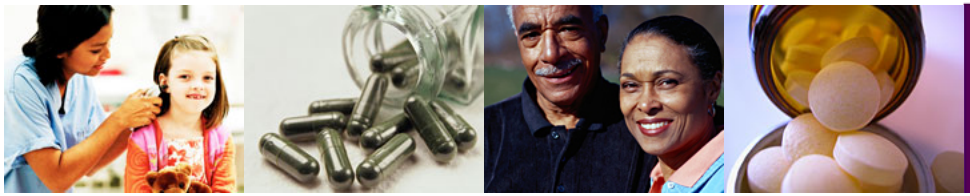
The certification body has the responsibility to assess sufficient objective evidence upon which to base a certification decision. Based on audit conclusions, it makes a decision to grant a certification if there is sufficient evidence of conformity, or not to grant certification if there is not sufficient evidence of conformity. (ISO/IEC 17021:2006 4.4.2)



Principles

Positive Reporting

In order to support responsible certification by the certification body, auditors include sufficient audit evidence in their reports to substantiate their audit findings and conclusions.



Users of reports

It is important to remember that in a regulatory context, the regulator is the ultimate user of certification and audit reports.

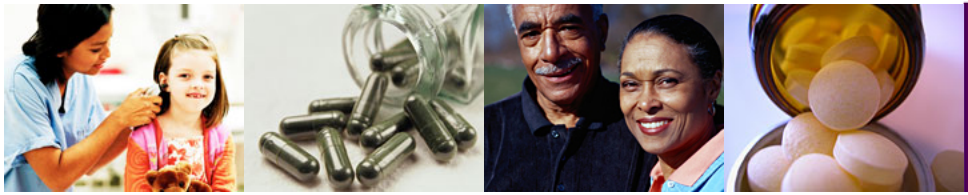
Regulators rely on these audit reports and certifications to allow market access to manufacturers and devices, to recognise certification bodies, and to investigate post-market issues.




Report format (2.1)

Reports should be typed and in a format that can be stored and transferred electronically.

Ideally, reports should be text-searchable. They should also be in a widely available format [for example, Portable Document Format (PDF), Microsoft® Word, etc.].



Report format (2.1)

Ideally, reports should be a single document. Recognising that this is not always possible, attempts should be made to minimize the number of documents that constitute a report.

Where supporting documents are used, they should be appended to the report. All appendices should be identified and referenced in the report.




Parts of a report

All the content listed in GD211 should be included in every report. The suggested grouping and ordering of items is strongly preferred.

The main parts (or chapters) of a report are as follows:

- Information about the manufacturer
- Information about the audit
- Audit findings
- Conclusions