GD211 Training

Module 3

Information about the audit



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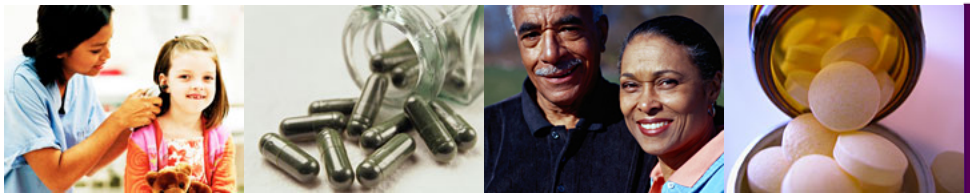
Information about the audit

The audit report should describe in adequate detail the nature and parameters of the audit performed.

Key facets to address include:

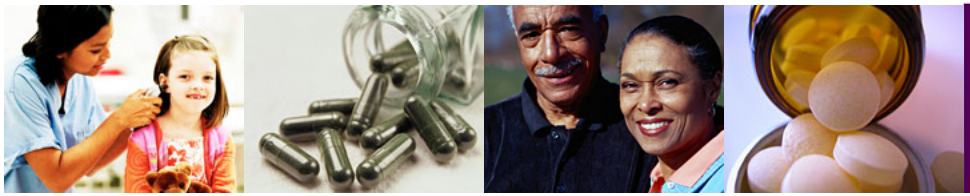
- the type, criteria, objectives, and scope of the audit
- identification of the audit team
- any preliminary document review



Audit Type (2.3.2 a)

The audit report should identify the type of audit performed (for example, initial certification, surveillance, re-certification, etc.).

Where the type of audit varies depending on the criteria, this should be clarified in the report.

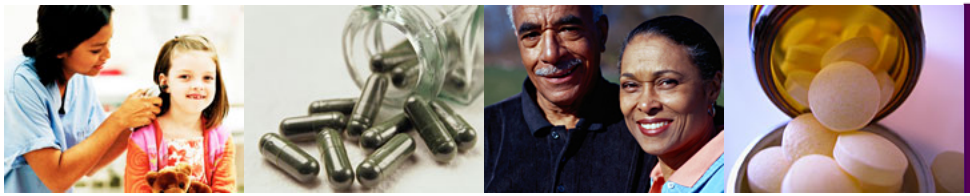


Audit Criteria (2.3.2 b)

The audit criteria should be listed in the audit report.

For audits under Canadian Medical Devices Conformity Assessment System (CMDCAS), this includes:

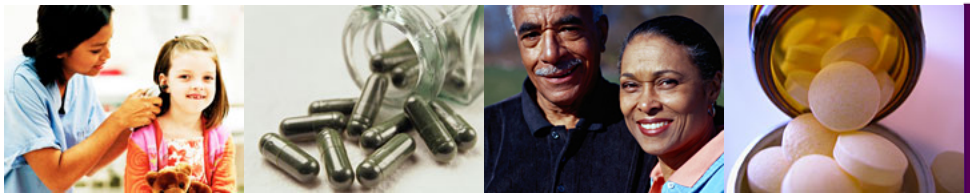
- ISO 13485:2003
- The applicable requirements of Part 1 of the *Medical Devices Regulations*
- The manufacturer's Quality Management System (QMS) documentation



Audit Criteria (2.3.2 b)

For audits that may be used by the United States Food and Drug Administration (FDA), the audit criteria would include:

- 21 CFR 820
- 21 CFR 806
- 21 CFR 803
- Other relevant regulations



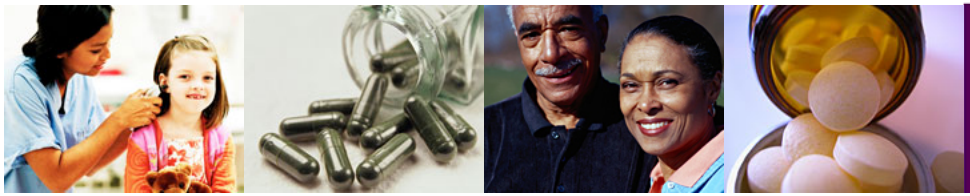
Audit Objectives (2.3.2 c)

The audit objectives should be listed in the report. This includes, as a minimum, the following:

a) The assessment of the (ongoing) conformity of the manufacturer's QMS with ISO 13485:2003; and

b) The assessment of the (ongoing) capability of the QMS to ensure compliance with the applicable regulatory requirements.

Note: the applicable regulatory requirements should be clearly identified in the audit criteria.

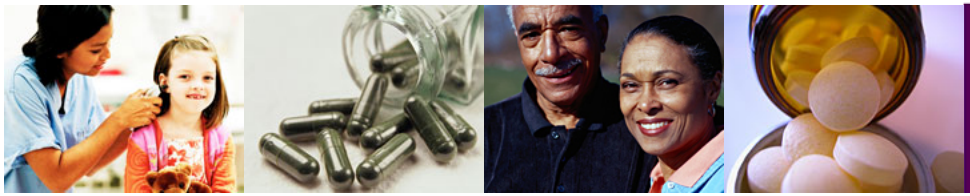


Audit Scope (2.3.2 d)

The report should include the scope of the audit.

"*The audit scope shall describe the extent and boundaries of the audit, such as physical locations, organisational units, activities and processes to be audited."* ISO/IEC 17021:2011 (9.1.2.2.3)

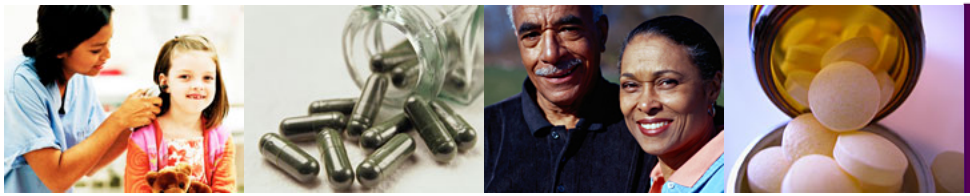
Note: The scope of the audit is not the same as the scope of certification.



Audit Scope (2.3.2 d)

Examples:

“This surveillance audit is limited to the management activities (resource management, management review, planning), the production line of the <Device Name> CK-MB rapid assay, the incoming inspection, and QM activities (internal audit, Material Review Board, CAPA, post-market surveillance incl. complaint handling) located in the main building at <Address 1> and its annex <Address 2>.”



Audit Scope (2.3.2 d)

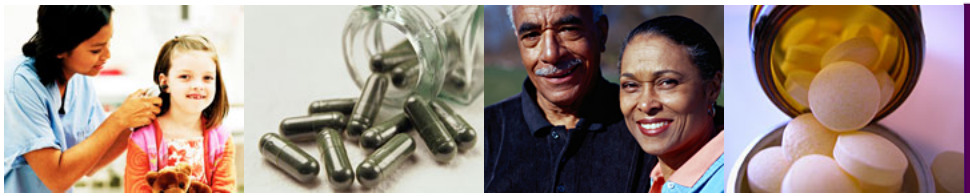
"The scope of this audit is focused on the mandatory management processes, polymer powder production, infrastructure, calibration, and customer related processes. All activities take place in the <Site Address> facility."

See Study Guide for further examples




Audit Dates (2.3.2 e)

The dates of the on-site audit should be included in the audit report. This should also include the number of auditor-days on-site.



Identification of the audit team (2.3.2 f)

The report should identify all members of the audit team and describe their respective role (for example, team leader, technical expert, etc.).

Any observer present that is not affiliated with the auditee should also be listed.

When interpreters/translators are used, they should be identified along with their affiliation.

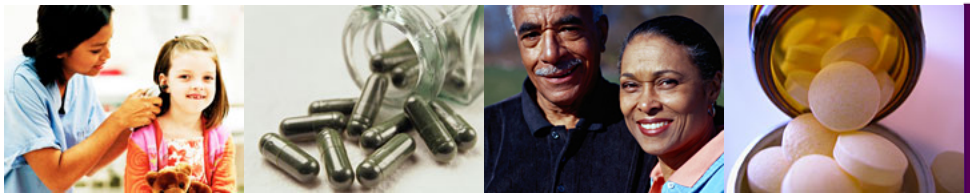



Audit Language (2.3.2 g)

The language(s) used during the audit should be indicated in the report.

This also includes languages used informally to interview some employees.

Reminder: Be sure to mention interpreters/translators, even if they are employees of the auditee.



Document Review Results (2.3.2 h)

When a review of the manufacturer's QMS documentation is performed prior to the audit, this should be mentioned in the report.

Reference to the document review report (if any) and the results of the review should be made in the report.