GD211 Training

Module 5
Conclusions



Overview

Conclusions

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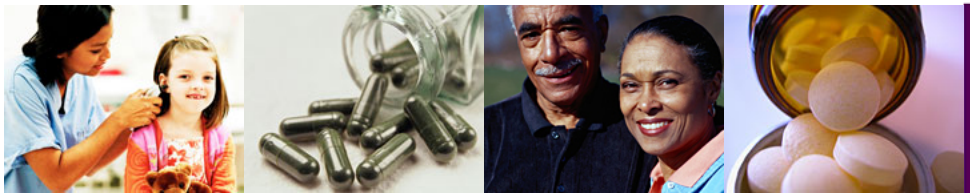
Conclusions

The audit report should provide clear conclusions about the conduct of the audit and its overall outcome and results. Conclusions provided in this section of the report should relate to the Quality Management System (QMS) as a whole.

Conclusions should not be contradictory to any of the findings in the report. They should not be ambiguous and they should not have double-meaning (for example, “notwithstanding the identified major deficiencies, the QMS conforms to the audit criteria”).



Conformity with Audit Criteria (2.3.4 a)

The report should include a conclusion regarding the conformity or nonconformity of the QMS with each set of audit criteria identified in “Information about the Audit”.

The conclusions should be clear as to the conformity status of the QMS.

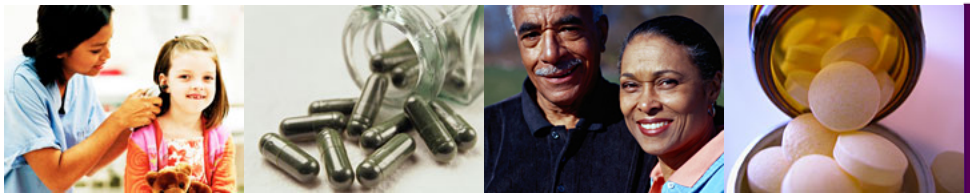
It is a best practice to use separate conclusions for each set of criteria.




Conformity with Audit Criteria (2.3.4 a)

Examples:

"Based on the interviews and evidence observed, it is concluded that the system is effectively implemented and remains in conformity with ISO 13485:2003. The identified nonconformities are deemed to be minimally significant and do not affect the finding of overall conformity."



Conformity with Audit Criteria (2.3.4 a)

"During the audit, the company was not able to provide sufficient evidence of conformity to numerous requirements of the audit criteria (see findings above for details.) Therefore, the audit team concludes that the QMS of the manufacturer is not in conformity with ISO 13485:2003."

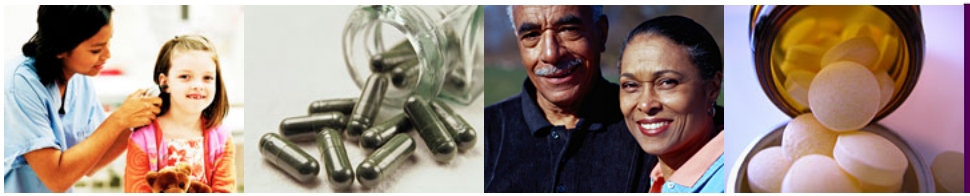
See Study Guide for further examples.




Effectiveness (2.3.4 b)

The report should include a conclusion regarding the effectiveness of the QMS in meeting quality objectives.

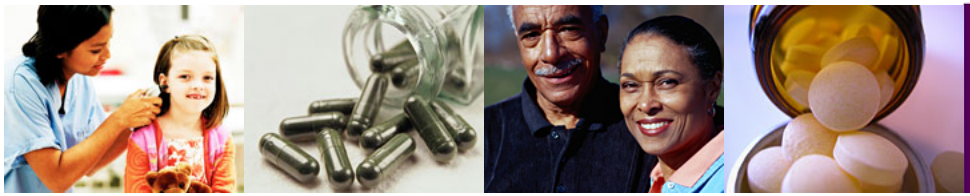
For regulators, the most important quality objective is compliance with regulatory requirements. If the audit included more than one set of regulatory requirements, this conclusion should address the ability of the manufacturer to comply with each set of regulatory requirements separately.



Effectiveness (2.3.4 b)

Examples:

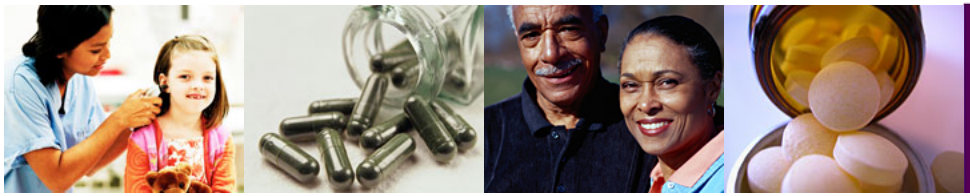
“The audit evidence reviewed clearly demonstrated that the company is meeting its quality objectives as set by management. The QMS is mature and the company’s quality culture leads to a high level of implementation. Regulatory processes are well implanted and the company has been diligent in addressing all regulatory requirements identified in the QMS. The audit team concludes that the QMS is effective.”



Effectiveness (2.3.4 b)

“Based on the evidence reviewed during the audit, the audit team cannot conclude that the QMS is effective in allowing the manufacturer to meet its quality objectives and comply with applicable regulatory requirements. In particular, several situations were uncovered (see issued nonconformities) where the manufacturer had failed to address regulatory requirements.”

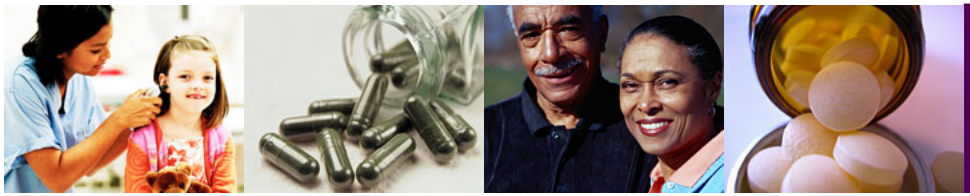
See Study Guide for further examples.



Confirmation of Audit Objectives (2.3.4 c)

The report should confirm that all audit objectives (as stated in the report) have been met.

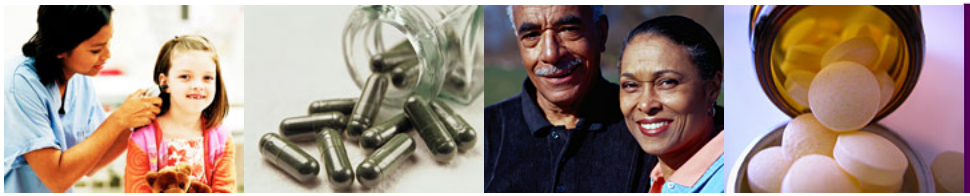
Where any audit objective has not been met, it should be identified and a reason for not meeting the objective should be given.



Confirmation of Audit Objectives (2.3.4 c)

Examples:

“It was not possible to complete all audit objectives. The audit team was unable to assess the effectiveness of the QMS in ensuring compliance to Part 1 of the CMDR since the manufacturer has not licensed any devices in Canada and therefore has not implemented any of the CMDR requirements fully. All other audit objectives were completed as planned.”



Confirmation of Audit Objectives (2.3.4 c)

"All audit objectives as stated above were completed. The audit was executed as planned."

"The audit was prematurely terminated due to a high number of major nonconformities and an imminent risk to public health. The audit objectives were therefore not achieved."

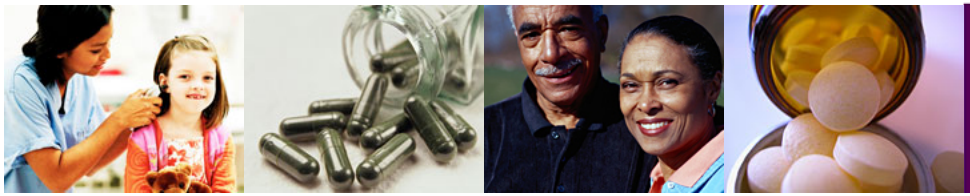
See Study Guide for further examples.




Reliability of Audit (2.3.4 d)

The report should outline any factor or situation encountered not previously mentioned that could decrease the reliability of the audit and its conclusions.

This could include such things as a shortfall in auditor time, a lack of a technical competence, the absence of a key auditee manager, unavailability of some records, limited sampling due to new activities, etc.

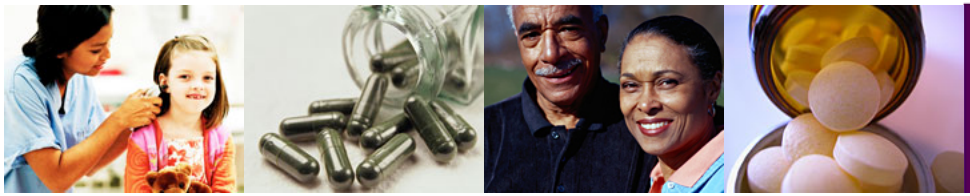


Reliability of Audit (2.3.4 d)

Examples:

“No factors were encountered that could reduce the reliability of the audit or its conclusions.”

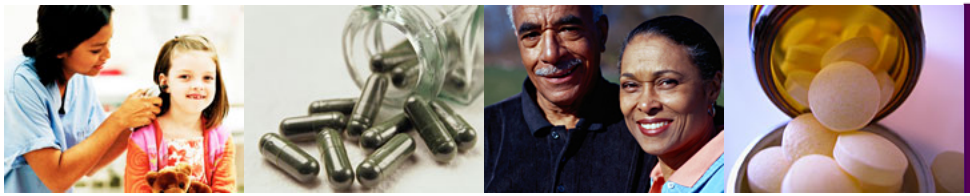
“The audit team had to rely on ad hoc Tagalog interpretation from production staff in order to interview certain operators.”



Reliability of Audit (2.3.4 d)

"Because the audit team opted to investigate the outsourcing of certain manufacturing steps previously done in-house, audit time allocated for the audit of resource management and training was reduced by 60% leading to a significant reduction in the number of records sampled."

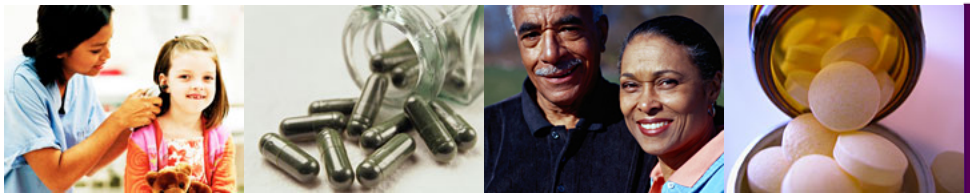
See Study Guide for further examples.



Recommendations (2.3.4 e)

The report should include the audit team's recommendations regarding the following items:

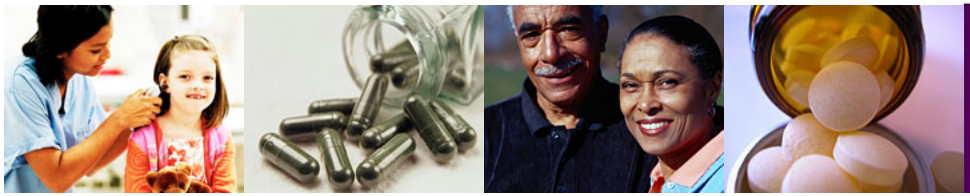
- follow-up actions by the registrar
- changes to the audit program
- changes in the number of auditor-days, etc.
- initial or continuing certification of the QMS regarding each set of criteria
- any conditions to be placed on the registration



Recommendations (2.3.4 e)

Examples:

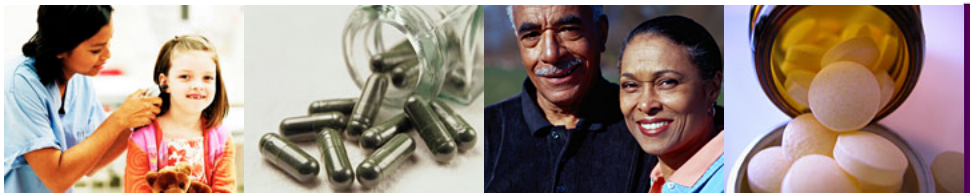
“Given that the audit objectives have been accomplished with no obstacles and that the QMS has been found to be in conformity with the audit criteria and to be effective, the audit team recommends to the certification body that the certification of <company> to ISO 13485:2003 under Canadian Medical Devices Conformity Assessment System (CMDCAS) be maintained. No additions or modifications to the audit programme are suggested.”



Recommendations (2.3.4 e)

"The audit team recommends the immediate suspension of the certification of <Company> until an on-site verification of the correction and corrective action of the four identified major nonconformities can be performed. <Certification Body> is urged to include specific competencies in the audit team dealing with sterilization and packaging issues given the observed conditions and findings listed above."

See Study Guide for further examples.



Identification and Dating

The final audit report should include the name(s) of the author(s) of the report. The report should be dated on its final date of issuance and include revision control information when appropriate.