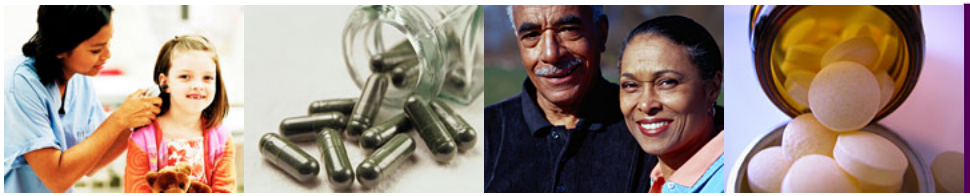
Summary

As the ultimate users of reports and certifications, regulators require that reports contain sufficient information to identify the manufacturer, describe the parameters of the audit, support findings, and to conclude on the overall conformity and compliance of the manufacturer.

The application of this guidance will lead to reports that consistently address these needs.

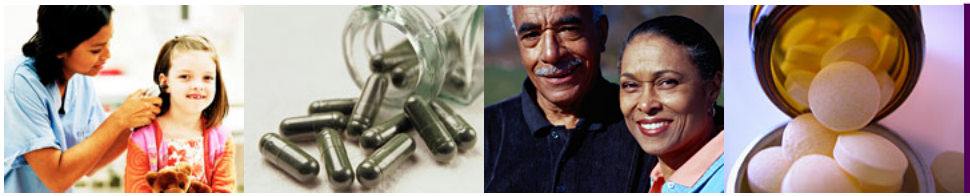


Summary

Every audit is different and no guidance document can address all possible situations.

Therefore, report authors should be guided by the principles presented earlier when preparing reports:

- fair presentation
- evidence-based approach
- responsibility
- positive reporting



Contact Information

Quality System Section
Medical Devices Bureau
Health Canada
(613) 952-8250

ISO13485CMDCAS_SCECIM@hc-sc.gc.ca

http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/index-eng.php




Contact Information

United States Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance

(301) 796-6556

Robert.Ruff@fda.hhs.gov