



Health
Canada Santé
Canada

*Your health and
safety... our priority.*

*Votre santé et votre
sécurité... notre priorité.*

GD211 Training

Module 2

Information about the manufacturer



Canada 

Overview

Information about the manufacturer

Manufacturer's name and address

Company identification number

Corporate Identity of the manufacturer

Description of the manufacturer

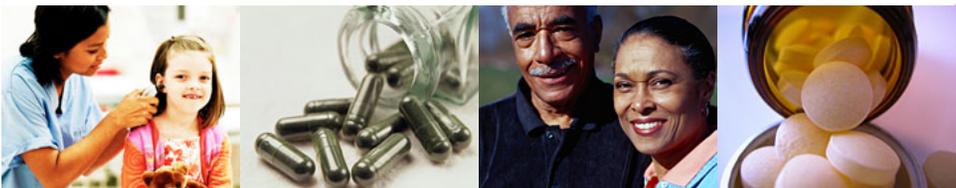
Scope of certification

Identification of critical suppliers

Contact person for the Quality Management System (QMS)

Status of any relevant QMS certification

Exclusions and non-applications of requirements in the Quality Management System (QMS)

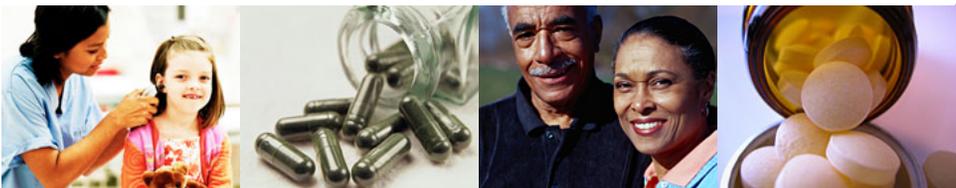


Information about the manufacturer

The audit report should contain information that unambiguously identifies the manufacturer under audit.

Key facets to address include:

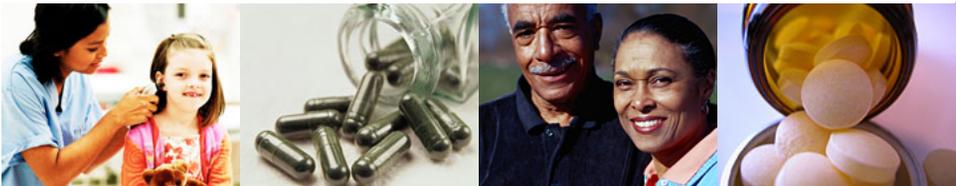
- The physical attributes of the manufacturer (location, size, etc.)
- The devices covered by the quality management system
- The scope and nature of the quality management system



Manufacturer's name and address (2.3.1 a)

The name and address of the manufacturer subject to the conformity assessment procedure, as it will appear on the registration certificate, should be included in the report.

This should include the address of all locations/facilities covered by the registration and included on the certificate.

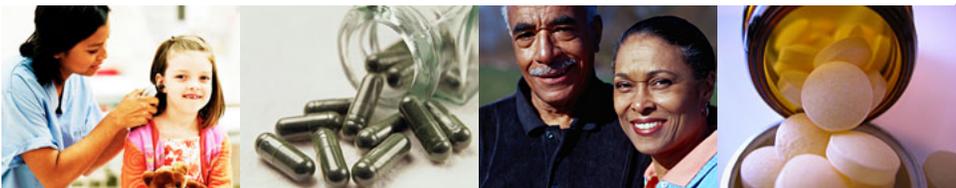


Company identification number (2.3.1 b)

The Health Canada assigned company identification number (CID) should be included in the report in association with the name and address of the manufacturer.

This can easily be obtained from the Medical Devices Active Licence Listing (MDALL) website (<http://www.mdall.ca>).

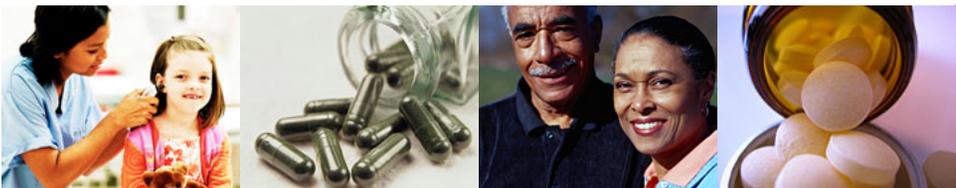
If the manufacturer has no licences (and therefore no CID), an annotation of 'N/A' (or 'not applicable') should be included in the report.



Corporate Identity of the manufacturer (2.3.1 c)

When a manufacturer has multiple names or identities these should be clarified. This clarification also extends to any relationship with sister, parent and daughter companies, including subsidiaries, acquisitions, business units, and joint ventures.

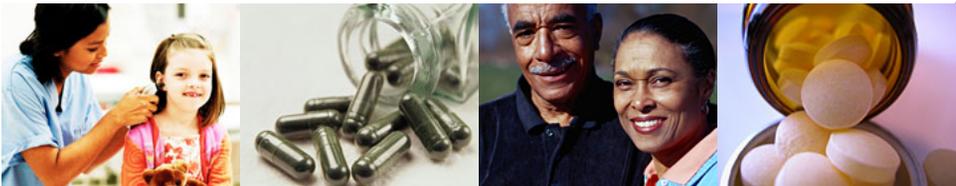
When preparing this section, auditors should be mindful to frame the explanation in the context of the QMS being audited and its associated scope of activities.



Corporate Identity of the manufacturer (2.3.1 c)

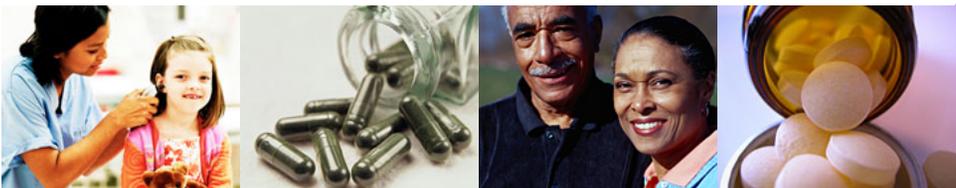
This section is not intended to be an in-depth analysis of the corporate holdings of the manufacturer. It should however address the following questions:

- Under what names does the manufacturer present itself to the marketplace?
- Under what names does the manufacturer market its devices?
- Are there any regional/geographical delineations to the names used?



Corporate Identity of the manufacturer (2.3.1 c)

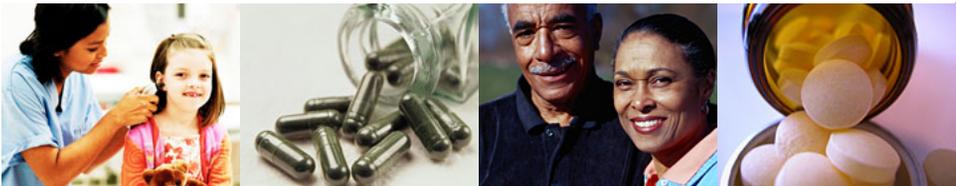
- Does the manufacturer market itself as part of a broader corporate group?
- Does the manufacturer market itself under a name or mark that it doesn't own?
- What is the involvement of related companies (parent, sister, daughter, etc.) in the design, manufacturing, or distribution of devices controlled by the QMS under audit?



Corporate Identity of the manufacturer (2.3.1 c)

This item can be omitted from surveillance audit reports if:

- a) this has been previously described in a certification or re-certification audit report, and
- b) there has not been any changes to the information since it was last reported.

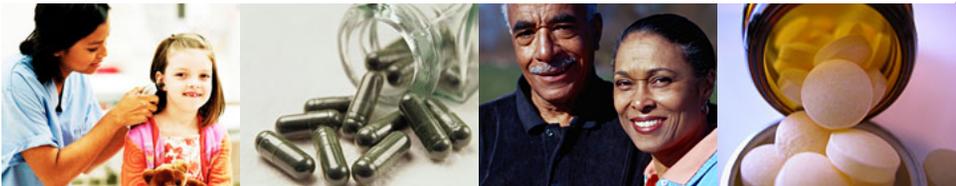


Corporate Identity of the manufacturer (2.3.1 c)

Examples:

“<Company> operates as <Company> in Canada but also markets some of its products under <Other Brand> in the US.”

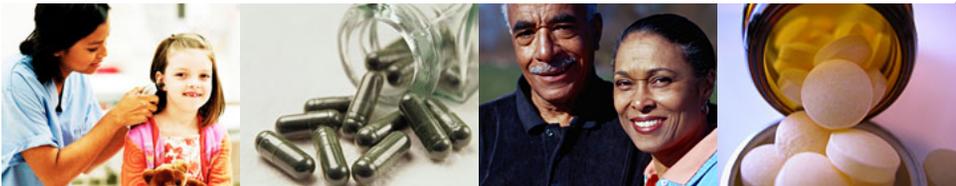
“<Company> operates as <Brand Name>. Devices are sold under the <Brand 1> banner in North America and Japan and <Brand 2> in Europe and Latin America.”



Corporate Identity of the manufacturer (2.3.1 c)

“<Company> is a wholly owned subsidiary of <Big Group> and labels its product as <Company>, a <Big Group> company. Devices are sold under the generic <Big Group Brand> trademark owned by <Big Group>. <Company> uses marketing and distribution channels of <Big Group> for all of its products.”

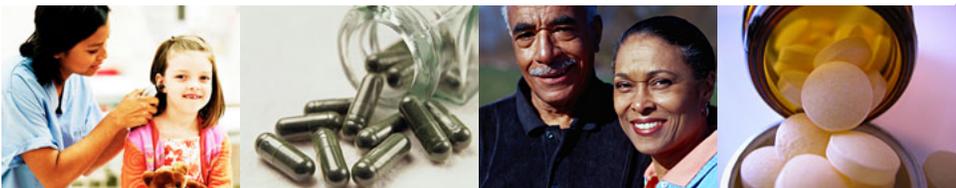
See Study Guide for further examples.



Description of the manufacturer (2.3.1 d)

The audit report should provide a clear and accurate description of the manufacturer and its activities. This description should address the following points:

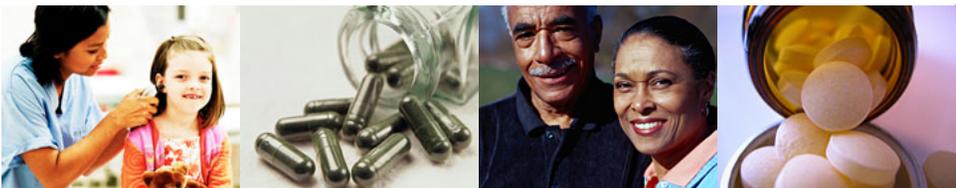
The number of employees should be reported. This should, where applicable, differentiate between full-time and part-time employees. The report should also mention temporary employees and off-site employees.



Description of the manufacturer (2.3.1 d)

The description of the manufacturer should indicate the number of shifts. Where there is a single shift, the report should state as such.

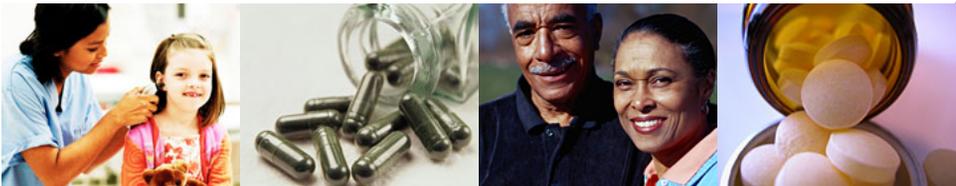
If more than one shift exists, the report should detail the time periods of the shifts (start and end times) and the number of employees on each shift.



Description of the manufacturer (2.3.1 d)

The report should include an overview of the activities and processes undertaken in the manufacturer's facilities.

This should address major functional areas (for example, design) as well as major manufacturing/production activities (for example, coating, moulding, assembly, fermentation, packaging, etc.).

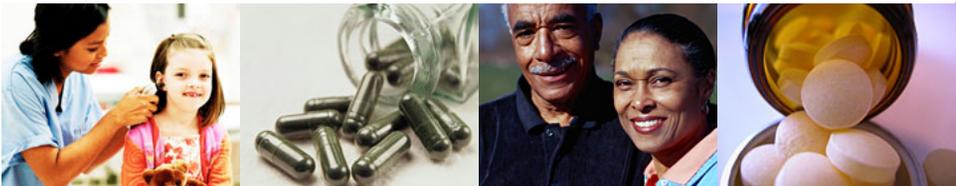


Description of the manufacturer (2.3.1 d)

Key outsourced activities should be mentioned in the overview of activities and processes.

Examples of this include:

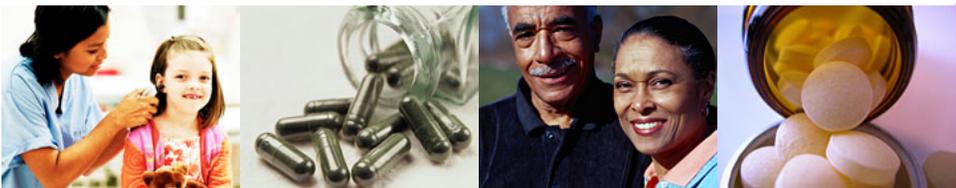
- Sterilisation
- printing and population of printed circuit boards
- development of firmware
- specialised coating processes



Description of the manufacturer (2.3.1 d)

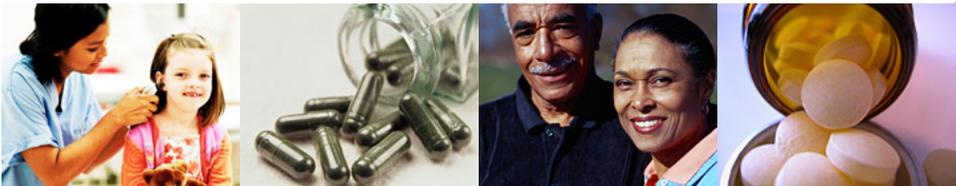
The name and title of the most senior manager(s) of the location(s) audited should be included in the description.

If the conformity assessment procedure covers more than one physical site, all covered sites should be described. A description of the relationship between sites, their roles within the QMS and any shared QMS functions should also be included.



Description of the manufacturer (2.3.1 d)

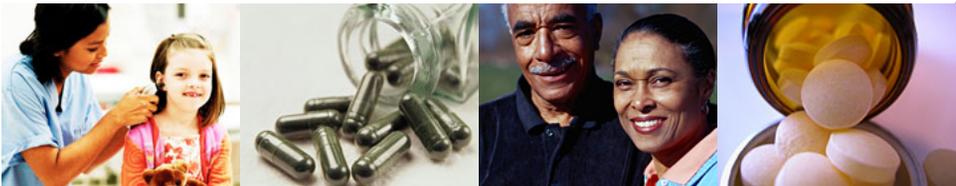
For surveillance audit reports, the description of the manufacturer can be limited to those parts that fall within the scope of the audit.



Description of the manufacturer (2.3.1 d)

Example: (See *Study Guide* for further examples.)

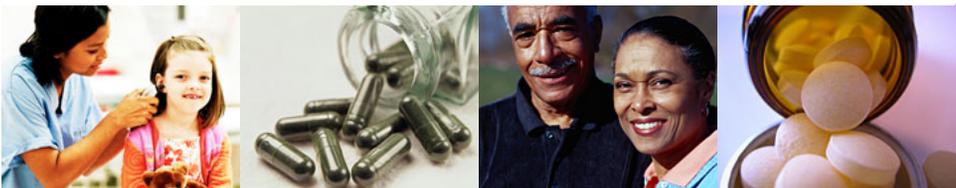
“<Company> is a small privately-held company employing 42 people on a single shift at its <City> location. The company designs and manufactures acrylic teeth for restoration. All activities are performed in-house in its 40,000 square foot facility. Key activities involve production of polymer powder, mould design and machining, injection moulding, and setting. The most senior manager at the site is <Name>, the Chief Executive Officer and owner of the company.”



Scope of certification (2.3.1 e)

The report should include the scope of certification as it appears on the certificate of registration. This includes activities and generic medical device groups or families.

Where the scope of certification changes during the audit (as in during an expansion to scope), the report should clearly identify this and allow the reader to determine what the scope of registration was before the audit and what it is after the audit.

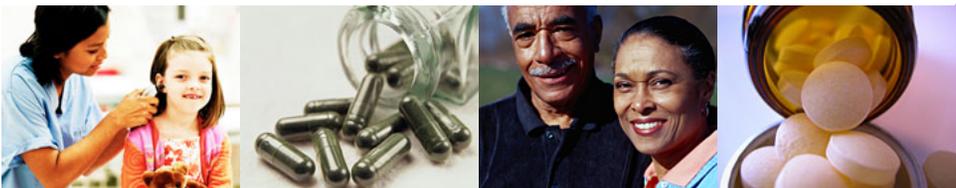


Scope of certification (2.3.1 e)

In the case of a certification involving multiple locations, the report should provide the overall scope of certification as well as the site-specific scopes.

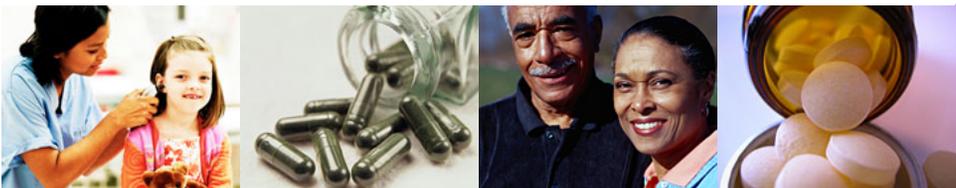
If the scope of listing is prohibitively long, it can be contained in an appendix to the report and referred to in the body of the report.

For guidance on certification scope, see GD207.



Identification of critical suppliers (2.3.1 f)

The report should identify the name, address, and product or service of critical suppliers that provide products or services used in the audited processes. The involvement of a supplier can be through an outsourced process such as sterilisation or software development.

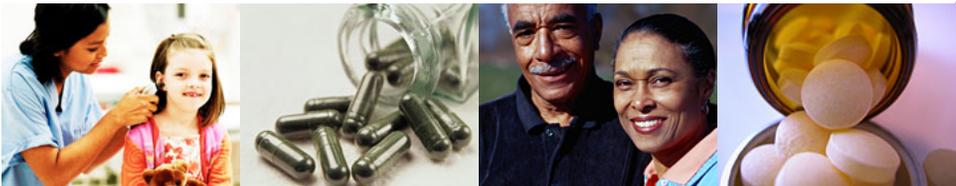


Identification of critical suppliers (2.3.1 f)

Critical Supplier:

A supplier delivering materials, components, or services, that may influence the safety and performance of the product.

See definition in GD211

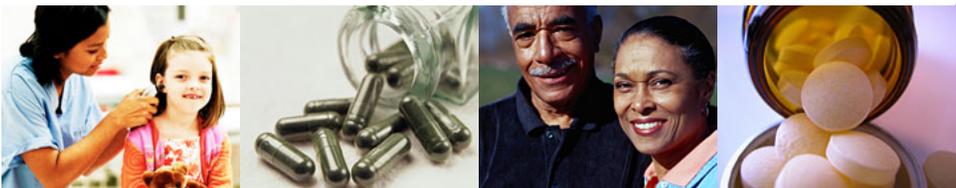


Identification of critical suppliers (2.3.1 f)

The report only needs to include those suppliers that are involved in the audited processes.

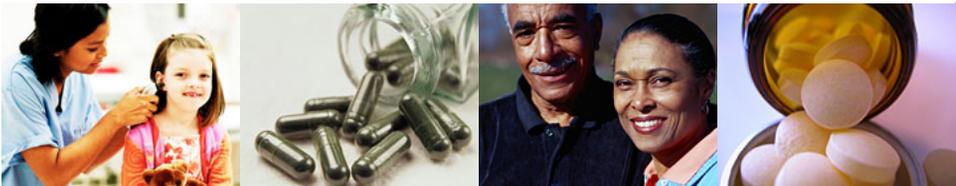
The supplier of parts/services for a production line that is not part of the scope of the audit (that is, not audited this time) does not need to be included in the report.

However, they may still be mentioned/included if they were part of the sample used when auditing supplier control.



Identification of critical suppliers (2.3.1 f)

The identification of critical suppliers can be done under a separate heading or integrated in the audit summaries (audit trail).

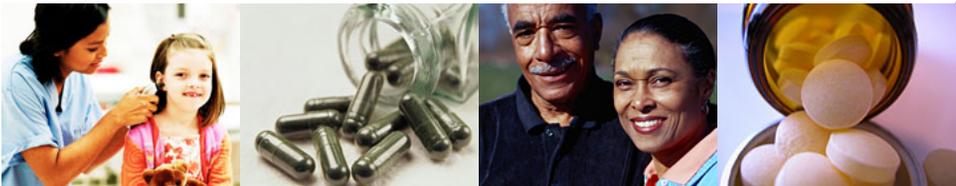


Contact Person for the QMS (2.3.1 g)

The name and contact information of the contact person for the QMS should be included in the report.

This person is not necessarily the QMS management representative. Nor is it automatically the Quality Manager.

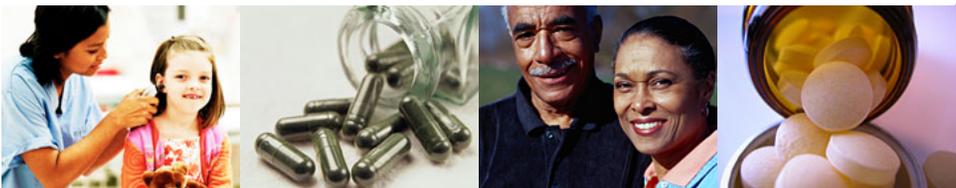
Contact information should include a phone number and/or email address.



Status of any relevant QMS certification (2.3.1 h)

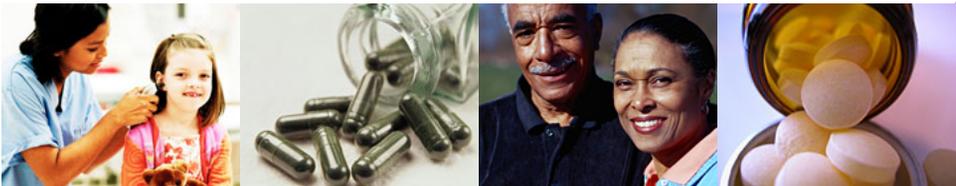
If not apparent anywhere else in the report, the status of any relevant certification or registration of the QMS of the manufacturer should be listed.

Relevant certifications are those related to medical device regulatory schemes (e.g. EU Medical Device Directive) A certification does not have to be the subject of the audit of the report to be relevant. A certification should cover the same manufacturer, facilities, and devices (or very similar ones) to be considered relevant.



Status of any relevant QMS certification (2.3.1 h)

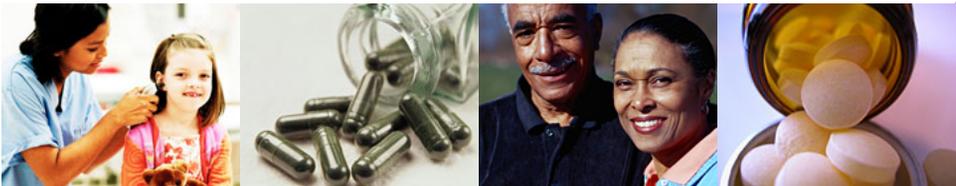
‘Status’ means whether the certification is in good standing or is under suspension or if it has been withdrawn.



Exclusions and non-applications of requirements in the QMS (2.3.1 i)

Where the manufacturer has claimed an exclusion or non-application of requirements, these should be identified in the report.

The report does not need to include the justification for non-applications (although auditors are welcome to include this.)



Exclusions and non-applications of requirements in the QMS (2.3.1 i)

Reminder:

- According to ISO 13485, only 7.3 can be excluded “... *if allowed by regulations.*”
- Other requirements can be found to be non-applicable based on activities or devices involved, but cannot be otherwise excluded.

