



PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

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QUESTIONS AND ANSWERS ON TRACEABILITY OF MEDICINAL GASES

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Q1. What is traceability?

A1. Traceability is the ability to retrieve the history of the manufacturing and distribution operations of a batch of medicinal products.

The data recorded through the traceability system should allow efficient investigation in case an incident occurs and should allow recalls of (potentially) defective products.

In the case of packaged medicinal gases, the packaging components (shells and valves) are reusable. It is therefore necessary to record additional information, in particular in relation to the use and maintenance of these components.

Q2. Which items should be recorded in the case of medicinal gases filled into cylinders to enable traceability?

A2.

Packaging components (shells and valves)

Note: the cylinder is the combination of the shell and its valve

Shell

For safety reasons, shells are individually identified (specific reference). Individual traceability is therefore possible. The date of the last hydrostatic pressure test (or equivalent test) should be recorded.

Valve

Shells may be fitted with simple valves (e.g. pin index valve) or integrated valves. Integrated valves are individually identified (individual identification reference). Individual traceability is therefore possible. This is not the case for simple valves, which mostly have only a serial number corresponding to a group of valves.

The design of integrated valves, which are medical devices, is complex. These valves are also submitted to periodic preventive maintenance operations. In terms of risk, more serious incidents have been reported with cylinders having this type of valve.

Therefore:

In the case of simple valves, the type of valve should be recorded, as well as the name of the manufacturer and the serial number, if one is available.

In the case of integrated valves, traceability should be ensured for each valve. Records should include in particular the type of integrated valve (including the version), the individual identification reference of the valve, the name of the manufacturer, the date of the last (or next) preventive maintenance and details of any preventive maintenance performed on the valve.

Shell + valve

Each shell/valve combination should be traceable.

Finished product

The manufacturing batch records should include the individual identification references of the cylinders of each batch of finished product (see EU GMP Guide Annex 6 section 17 (g) and (m)).

Distribution

The distribution records should include the individual identification references of the cylinders delivered to each customer.

Q3. What means should be implemented to ensure traceability?

A3. In practice, *depending on the scale of operation* it may be difficult to ensure effective traceability without a computerised system. Use of bar codes or electronic chips on the cylinders may facilitate this. Any computerised system used to ensure traceability should conform to the requirements of Annex 11 of the EU GMP Guide.

Q4. What should be possible through the system of traceability?

A4. Should a manufacturer of a medicinal gas receive a serious complaint relating to the quality of the medicinal gas itself or the packaging components, the system in place should allow the identification of the affected cylinders and, where necessary, the recall of any affected cylinders from the market place.

A defect relating to packaging components may require identification of specific cylinders within a finished product batch or identification of cylinders present in a number of finished product batches in order to establish the extent of any recall required.

For example, an effective traceability system should allow effective recalls of cylinders fitted with defective valves based on:

- Specific type/version or manufacturer's batch for the valves
- Maintenance/calibration operations for the valves during a specific time period
