



## **Quality control**

1- Each holder of a manufacturing authorisation should have a Quality Control Department. This department should be independent from other departments, and under the authority of a person with appropriate qualifications and experience, who has one or several control laboratories at his disposal. Adequate resources must be available to ensure that all the Quality Control arrangements are effectively and reliably carried out.

2-The principal duties of the head of Quality Control are summarized. It is necessary to appoint person responsible for QA/QC activity (QA/QC Manager). This person develops QA/QC plan, and manages the process of quality control and assurance, as well as documents the findings and results of the checks, by completing the checklist and attendant file . The QA/QC Manager checking quality for inventory should perform ideally the following general activities:

! Understand the procedures described .

! Check spreadsheets for each source category follow these procedures; both general procedures and specific checks .

! Document the findings and results of the checks, by completing checklist and attendant file, including the summaries of results and problems to be corrected. The careful documentation is important for potential

improvements in the inventory and lightening the work of developers of next inventory.

! Take any corrective action as needed, documenting (in the appropriate place on

the checklist and attendant file) the actions taken and the results.

! All documentation (including the final completed checklist and attendant file)

should be placed in the project file, with copies given to the responsible agencies.

Also the draft attendant file for the next inventory should be prepared.

The Quality Control Department as a whole will also have other duties, such as to establish, validate and implement all quality control procedures, keep the reference samples of materials and products, ensure the correct labelling of containers of materials and products, ensure the monitoring of the stability of the products, participate in the investigation of complaints related to the quality of the product, etc. All these operations should be carried out in accordance with written procedures and, where necessary.

3-Finished product assessment should embrace all relevant factors, including production conditions, results of in-process testing, a review of manufacturing (including packaging) documentation, compliance with Finished Product Specification and examination of the final finished pack.

4- Quality Control personnel should have access to production areas for sampling and investigation as appropriate.

**The proposed cycle of QA/QC activity for inventory consists of 6 steps:**

**Step 1.** QA/QC Manager develops QA/QC Plan. Inventory Team leader approves it. QA/QC Manager reviews the draft attendant file for the

previous inventory and prepares preliminary attendant file for current inventory.

**Step 2.** According to QA/QC Plan the inventory (or part of inventory) is sent for check and review.

**Step 3.** QA/QC Manager obtains the results of check and review. It is reasonable to submit these results in EXCEL tables.

**Step 4.** QA/QC Manager registers findings in the checklist and attendant file, as well as processes this information and makes decision about corrective actions.

**Step 5.** The person responsible for corrective actions carries out this work and reports to QA/QC Manager for updating checklist and attendant file.

**Step 6.** QA/QC Manager prepares the QA/QC chapter to the Inventory Report and a draft attendant file for the next inventory

### **Sampling**

The sample taking should be done in accordance with approved written procedures that describe:

- 1- the method of sampling;
- 2- the equipment to be used;
- 3- the amount of the sample to be taken;
- 4- instructions for any required sub-division of the sample;
- 5- the type and condition of the sample container to be used;
- 6- the identification of containers sampled;
- 7- any special precautions to be observed, especially with regard to the sampling of sterile or noxious materials;
- 8- the storage conditions;
- 9- instructions for the cleaning and storage of sampling equipment.

Reference samples should be representative of the batch of materials or products from which they are taken. Other samples may also be taken to monitor the most stressed part of a process (e.g. beginning or end of a process). Sample containers should bear a label indicating the contents, with the batch number, the date of sampling and the containers from which samples have been drawn.

Reference samples from each batch of finished products should be retained till one year after the expiry date. Finished products should usually be kept in their final packaging and stored under the recommended conditions. Samples of starting materials (other than solvents, gases and water) should be retained for at least two years after the release of the product if their stability allows. This period may be shortened if their stability, as mentioned in the relevant specification, is shorter. Reference samples of materials and products should be of a size sufficient to permit at least a full re-examination.

### **Testing**

1-Analytical methods should be validated. All testing operations described in the marketing authorisation should be carried out according to the approved methods.

2-The results obtained should be recorded and checked to make sure that they are consistent with each other. Any calculations should be critically examined.

3- The tests performed should be recorded and the records should include at least the following data:

- a) name of the material or product and, where applicable.
- b) batch number and, where appropriate, the manufacturer and/or supplier;
- c) references to the relevant specifications and testing procedures;

- d) test results, including observations and calculations, and reference to any certificates of analysis;
- e) dates of testing;
- f) initials of the persons who performed the testing;
- g) initials of the persons who verified the testing and the calculations, where appropriate;
- h) a clear statement of release or rejection (or other status decision) and the dated signature of the designated responsible person.

4-All the in-process controls, including those made in the production area by production personnel, should be performed according to methods approved by Quality Control and the results recorded.

5-Special attention should be given to the quality of laboratory reagents, volumetric glassware and solutions, reference standards and culture media. They should be prepared in accordance with written procedures.

6-Laboratory reagents intended for prolonged use should be marked with the preparation date and the signature of the person who prepared them. The expiry date of unstable reagents and culture media should be indicated on the label, together with specific storage conditions. In addition, for volumetric solutions, the last date of standardisation and the last current factor should be indicated.

7-Where necessary, the date of receipt of any substance used for testing operations (e.g. reagents and reference standards) should be indicated on the container. Instructions for use and storage should be followed. In certain cases it may be necessary to carry out an identification test and/or other testing of reagent materials upon receipt or before use.

8-Animals used for testing components, materials or products, should, where appropriate, be quarantined before use. They should be maintained

and controlled in a manner that assures their suitability for the intended use. They should be identified, and adequate records should be maintained, showing the history of their use

### **Documentation**

1- Laboratory documentation should follow the principles. An important part of this documentation deals with Quality Control and the following details should be readily available to the Quality Control Department:

a- specifications;

b-sampling procedures;

c-testing procedures and records (including analytical worksheets and/or laboratory notebooks);

d- analytical reports and/or certificates;

i- data from environmental monitoring, where required;

g- validation records of test methods, where applicable;

f-procedures for and records of the calibration of instruments and maintenance of equipment.

2- Any Quality Control documentation relating to a batch record should be retained for one year after the expiry date of the batch and at least 5 years after the certification.

3- For some kinds of data (e.g. analytical tests results, yields, environmental controls,...) it is recommended that records be kept in a manner permitting trend evaluation.

4- In addition to the information which is part of the batch record, other original data such as laboratory notebooks and/or records should be retained and readily available.