

## **1 Purpose**

The purpose of this procedure is to describe the accountabilities and single process for the batch confirmation, certification and release by a Qualified Person (QP) within the European Union (EU).

## **2 Scope and Applicability**

Confirmation, certification and release processes for bulk production batches and finished product batches for supply into the EU (EC/EEA) market only.

Where national/local requirements are in place that conflict with this procedure, then these national and local requirements will apply.

## **3 Definitions**

### **3.1 Bulk production batch**

A batch of product, of a size described in the application for a Marketing Authorization, either ready for assembly into final containers or in individual containers ready for assembly to final packs. (A bulk production batch may, for example, consist of a bulk quantity of liquid product, of solid dosage form such as tablets or capsules, or of filled ampoules.)

### **3.2 Finished product batch**

In the context of this procedure the term means the batch of products in its final pack for release to the market.

### **3.3 Part Finished production batch**

In the context of this procedure the term means the different stages of manufacturing required to formulate a product batch prior to it being in its final pack for release to the market.

### **3.4 Certification of a finished product batch**

The certification, in a register or equivalent document by a QP, as defined in Article 51 of Directive 2001/83/EC before a batch is released for sale or distribution.

### **3.5 Confirmation**

An internal Certificate of Analysis or Certificate of Manufacture will be issued that confirms a process or test has been conducted in accordance with GMP and the relevant Marketing Authorization, as agreed in writing (QA Agreement) with the QP responsible for certifying the finished product batch before release.

### **3.6 Release for Sale**

responsible QP for each stage. A batch certificate will be supplied from the intermediate sites to the final releasing site to demonstrate GMP and Licensing requirements.

A register of QPs will be held centrally by QA.

## 5.2 Process

5.2.1 Each batch of finished product imported from a third country must be certified by a QP of the importer before release for sale in the EC/EEA.

5.2.2 Certification of a finished product batch against a relevant Marketing Authorization by a QP in the EC/EEA will not be repeated on the same batch provided that the batch has remained within the EC/EEA.

5.2.3 The overall manufacturing supply chain of a particular batch of product, regardless of how many sites are involved, will be understood by the QP who certifies that finished product batch before release. He/ She must be aware of the sites involved and be assured of the existence of QA agreements for the different intermediates.

5.2.4 Each QP who certifies a finished product batch for release will rely on confirmations by other QPs upstream in the supply chain for that finished product batch. This reliance will be based on confidence and knowledge of the corporate quality system.

5.2.5 Finished product batches will not be shipped ahead of QP certification, unless by prior agreement between QPs and only if adequate controls and agreements are put in place.

5.2.6 Each QP who confirms a bulk production batch or certifies a finished product batch for release is accountable for putting in place a QA Agreement with the receiver (i.e. production site for bulk production batches and registration holder for finished product batches). This is to ensure that QA accountabilities are clear, any local regulatory requirements are met and the key points of this procedure are recorded.

5.2.7 Each site will have in place a QP who is accountable for ensuring that there is a quality system in place. Before a batch is confirmed or certified for release (finished product batch) the QP or his nominated delegate is, for their stage of manufacture, accountable for ensuring that:

- The requirements laid down by Marketing Authorization Application (MAA) and Manufacturer's Authorization (MA) requirements for the medicinal product have been met for the batch concerned.
- The principles and guidelines of good manufacturing practice as laid down in Directive 91/356 and interpreted in the EC Guide to GMP have been followed.
- The principal manufacturing and testing processes have been validated.
- All the necessary checks and tests have been performed and account taken of the production condition and manufacturing records.
- Any planned changes or deviations in manufacturing or quality control have

products which could be rendered hazardous by a quality defect in the batch.

**Appendix 1. Flow sheet: When all manufacture occurs at a single authorized site.**

