

1 Purpose

The purpose of this guideline is to define the requirements for assessment of data and documentation prior to release.

2 Scope and Applicability

This guideline is applicable to the release of Active Pharmaceutical Ingredients, Bulk Formulated Products, Part Packs and Finished Packs from an Operations site. This Guideline does not include investigational new products.

3 Definitions

3.1 Qualified Person

A Qualified Person (QP) is an individual who is accredited to release medicinal products to the European Union market, according to the requirements defined in EU directive 2001/83.

4 Responsibilities

4.1 The site QA Manager is responsible for ensuring that there are procedures and systems in place that assure only materials fit for use are released to the appropriate Operations Site or market.

4.2 The site QA Manager is responsible for ensuring that the release procedures are followed and that any batch or lot failing to meet release criteria is the subject of a documented investigation.

5 Guideline

5.1 The review of the batch record must confirm compliance with the critical parameters of the process and include the suitability of starting materials, packaging materials and compliance with registered manufacturing, QC and QA processes.

5.2 Any recorded abnormalities, observations, Out of Specification (OOS) results or deviation reports must also be reviewed prior to determining the disposition of the batch. Investigations must extend to other batches of the formulated or packed product and API as necessary to ensure that no other batches are implicated.

A written record must be prepared, including identification of the root cause, conclusions and follow-up, to confirm that the investigation has been undertaken.

5.3 For aseptic products, data from environmental controls must form part of the release process.

5.4 For finished sales packs, examination of the final finished pack and associated labeling, leaflets etc., should form part of the review procedure.