Regulatory Basis:
FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

1 Purpose

The purpose of this guideline is to outline the content and approval process for analytical procedures, and to describe those activities that should be carried out to demonstrate that analytical procedures used in laboratories within R&D and manufacturing operations are suitable for their intended purpose.

2 Scope and Applicability

This guideline applies to qualitative or quantitative analytical procedures that are used to test finished drug product, in-process materials, excipients, raw materials, packaging materials and Active Pharmaceutical Ingredient (API), in support of regulatory registration documents and in cleaning validation.

Technology Transfer and Process Analytical Technology (PAT) are outside the scope of this document.

3 Definitions

3.1 Analytical Procedure

A controlled document that describes in sufficient detail how a specific analysis is performed.

3.2 Analytical Procedure Validation

Confirmation that the performance characteristics of the analytical procedure meet the requirements for the intended application. This is usually established by laboratory studies.

3.3 Analytical Procedure Revalidation

Confirmation that the performance characteristics of the analytical procedure continue to meet the requirements of the intended application, following changes to the specific procedure or the synthetic route/method of manufacture of the test material. This is usually established by laboratory studies.

3.4 Validation Protocol

A validation protocol is written plan or protocol stating how validation, sampling and testing will be conducted, defining roles and responsibilities, and defining acceptance criteria. Analytical procedure validation protocols may be generic or specific and their content will depend on the phase of development or marketing.

4 Responsibilities

with increasing levels of detail as projects progress through development to the marketing phase. As a guide each of the validation characteristics listed above

