1 Purpose

The purpose of this procedure is to describe how stability studies carried out at contractors shall be managed.

2 Scope and Applicability

All stability studies on commercial products that are conducted by contract manufacturers or contract laboratories.

3 Definitions

3.1 Stability Master Plan (SMP)

A plan that details the stability studies required to maintain compliance with companyôs regulatory and GMP obligations and commitments and assigns each study to a specific Commercial Stability Site.

3.2 Stability Protocol

A stability protocol is a detailed plan used to generate and analyze stability data in support of the shelf (expiry) life of a drug product or retest period of an Active Pharmaceutical Ingredient (API) in a single specified market. It should include time points and conditions employed, and methodology used to generate stability data.

3.3 Integrated Stability Protocol

An integrated stability protocol is a detailed plan used to generate and analyze stability data in support of the retest period of an Active Pharmaceutical Ingredient (API) or the shelf (expiry) life of a drug product. It should whenever possible incorporate the stability requirements of more than one drug product containing the same API and/or the requirements of more than one market in a single plan/document.

3.4 Lead Team/Site

Refers to the team/site that is accountable for conducting specified Quality Assurance activities as recorded in the quality assurance contract (agreement) between the sponsor and the contractor.

3.5 Quality Agreement Co-ordination (QAAC) Team/Site

The team/site assigned by Supply & Capability (S&C) to co-ordinate Good Manufacturing Practice, GMP related interactions and issues between an established contractor and sponsor when the contractor supplies products assigned to more than one Lead Site or is geographically and/or culturally remote from the assigned Lead Site.

3.6 Bulk Package

The package used to store and/or transport an API or drug product such as

It is the responsibility of the Lead team/site to link the contractor activities with Companyôs QA processes, e.g.

- Change Management.
- Management of Stability Master Plans and protocols.
- OOS reporting and Issue Management.
- Data reporting

Contractor

4.6 It is the responsibility of the contractor to conduct studies according to the study plan and protocol agreed with the sponsor company and in compliance with cGMP codes relevant to the markets being supplied.

4.7 It is the responsibility of the contractor to carry out a laboratory investigation into any óOut of Specificationô (OOS) results, or adverse trend likely to lead to an OOS result within or at the shelf life of the product, to confirm, or otherwise, their validity and to report confirmed OOS results, and/or adverse trend likely to lead to an OOS result within or at the shelf life of the product, to the Lead team/site within 3 working days (within 1 working day for products marketed in USA).

4.8 It is the responsibility of the contractor to report all data from ongoing studies to the Lead team/site at least annually or more frequently if required by the Lead Site.

5 Procedure

5.1 QA Agreement

The Lead Team/Site (or Quality Assurance Agreement Co-ordination Team/Site if one is assigned) shall develop a QA Agreement with the contractor that identifies the need, if any, for the contractor to conduct stability studies on material made by the contractor, or in the case of contract laboratories, on study batches provided by the sponsor.

5.2 Stability Plan and Stability Protocol

The Lead team/site shall arrange for a stability plan and stability protocol to be produced and approved through sponsorôs business processes and agree these with the contractor.

5.3 Technology Transfer

The Lead team/site will transfer the technology identified in the stability protocol to the contractor (normally confined to test methodology).

5.4 Study Batches

5.4.1 Products made at the Contractor

The contractor shall select bulk, primary or secondary packaged samples (as required by the study protocol), typical of its manufacture, for stability studies.

Study batches should be less than 6 months old when stability studies are initiated. If a contract manufacturer/packager is not required to perform stability studies it

