1. Regulatory Basis, Reference Documents

- CFR 314.70 “Supplements and other changes to an approved application”
- Commission Regulation EC 541/95 “Variation to the terms of a marketing authorization”
- ISO 9004 08.8 Design Change Control
  11.6 Process Change Control
- PIC – PH 1/96
- ICH Q7A chapter 13 ‘Change Control’

2. Purpose

The purpose of this SOP is to describe in detail the change control process flow, starting with a request for a change following necessary assessments and approvals. This standard process ensures that all planned changes related to any aspect of manufacture, testing and distribution are reviewed, assessed and approved by technical and quality competent site personnel, which includes Quality Assurance. The main task is to evaluate potential impacts followed by correlative consequences of the requested change on product quality, current Good Manufacturing Practice (cGMP), including qualification and validation and the regulatory file/dossier before approval and implementation of a change control request.

3. Scope

This procedure applies to all new and existing manufacturing/packaging processes, utilities, major equipment, computerized systems, facilities, drug products, drug substances, medical devices, raw materials, components, testing requirements, specifications and systems for marketed products and clinical trials (clinical, pre-clinical and stability with GMP implications). Documents and systems that may be impacted by a given change in any of these areas include, but are not limited to, all master documents, Marketing Authorization Applications (MAA’s), New Drug Applications (NDA’s), validation, stability protocols and control systems.

4. Responsibilities and Accountabilities

4.1 Applicant/Change requester

As a matter of principle every individual who had been trained on the change control SOP should use the change control form attached to this SOP to request a change in their respective area.
The applicant/change requester must follow the following order of events:

- The applicant/change requester formulates a change proposal / request and complete the Change Control form section 1 of the attached change control form.
- The applicant/change requester signs and dates the change control proposal / request.