1. Regulatory Basis, Reference Documents

FDA, Guidance for Industry Manufacturing, Processing, or Holding Active Pharmaceutical
ICH Q7A, Section XIV-B (Reprocessing)
ICH Q7A, Section XIV-C (Reworking)

2. Purpose

This SOP describes how to document, investigate and to control batch deviations and/or reprocessing and/or reworking to ensure that quality, safety, purity and efficacy is maintained, and that the activities are in accordance with all applicable regulatory requirements embedded into the site systems.

3. Scope

This SOP covers marketed API's manufactured under Good Manufacturing Practices and API's for clinical trials and/or formal stability trials.

4. Responsibilities and Accountabilities

4.1 Quality Unit

The Quality Unit is responsible that all batch deviations are investigated, documented and trended.
The Quality Unit also ensures that a review of all batch deviations and/or reprocessing or reworking with respect to their impact on quality and GMP compliance of the affected batches is conducted.
The Quality Unit is responsible to inform Regulatory Affairs (RA) about incidences that may have potential regulatory impact.

4.2 Manufacturing Unit

The Manufacturing Unit reports into the system, designed to identify, document, investigate and control all batch deviations, and reprocessing/reworking operations. The Manufacturing Unit identifies and investigates all incidences in conjunction with the Quality Unit. The Manufacturing Unit is responsible for implementing appropriate corrective and preventative actions to avoid reoccurrence and assesses the efficacy of the corrective actions agreed with the Quality Unit.

4.3 Regulatory Affairs

The Regulatory Affairs (RA) department evaluates the potential impact of the batch deviation on any regulatory requirements for the markets served and advises the Quality Unit about mandatory regulatory requirements. This process is documented. Regulatory Affairs will advise the Quality Unit if and how the reprocessing or reworking should be reported (DMF, Annual Product Review or submitted in any other supplement).