1. Regulatory Basis, Reference Documents

21CFR210, 211, 600, and 820

2. Purpose

The Corrective and Preventive Action (CAPA) system assures the tracking and trending of issues requiring mid-term and long-term corrective actions. This procedure will provide guidance on the requirements and use of the system as well as the procedure for processing CAPAs.

3. Scope

This system will be used to track and trend corrective and preventative actions planned to address known issues or to implement quality improvements. These requirements apply to all GMP operations and areas.

This may include, but is not limited to:

- Deviations/Non-conformance – Procedure
- Product Complaints – Procedure for Handling Product Complaints
- External and internal audit observations
- Annual Product Reviews – Annual Product Review
- Regulatory Issues
- Any issues that require mid-term and long-term corrective or preventative action, with formal tracking and documentation
- Recommendations of executed validations

4. Responsibilities and Accountabilities

4.1 Responsible Area Manager

The manager (or his/her responsible designee) of the department where the issue is identified is responsible for preparing an action plan as described in this procedure. The Head of the area or Product/Process Team Leader of the department where the issue is identified is responsible for reviewing and approving the plan by signoff. The Head of the department is responsible for ensuring adequate support to complete the actions according to the approved plan.

4.2 Quality Assurance

Quality Assurance (QA) is responsible for issuing a CAPA number and maintaining the CAPA log.
Quality Assurance (QA) representing the area where the CAPA is issued is responsible for handling and maintaining the official CAPA form until complete.
Quality Assurance (QA) representing the area where the CAPA is issued is responsible for identifying lots that are to be placed on hold and entering these lots into the CAPA log.
The Head of QA or designee is responsible for approving the action plan.