- The applicant/change requester notifies the Change Control System Owner (Quality Assurance) at the same time that a change proposal / request has been raised.
- The applicant/change requester ensures that a change is not implemented until the change has been evaluated and approved by Quality Assurance.
- The applicant/change requester coordinates the implementation of an approved change request.
- The applicant/change requester pro-actively follows up actions required to ensure the completion and formal close out of the change request in a timely manner/following the implementation target dates in section 3 on the attached change control form.

4.2 Area Experts / Accountable Area Leaders

Area Experts / Accountable Area Leaders must assess if the change request might impact their areas. This assessment must be documented by the Area Experts / Accountable Area Leaders in Section 2 on the attached change control form.

4.3 Quality Assurance

The Quality Assurance (QA) Department is the owner of the change control system and maintains the Change Control register file. QA assigns individual numbers for each change request and ensures that documented evidence exists for the assessment. Finally QA tracks the close out of changes and communicates proposals, amendments, approvals, rejections and close outs to all affected parties.

The Quality Assurance Department must perform the following assessments and approvals:

- Understands and agrees on the scope of the change prior to approving the request.
- Ensures changes are not duplicated and do not adversely impact other areas and other changes.
- Take accountability that the impact of the change has been appropriately evaluated which includes but in not limited to:
    - Ensuring that regulatory compliance with all submitted and approved registrations e.g. New Drug Applications (NDA), Manufacturing Authorization Applications (MAA), Investigational New Drug Application (IND) and Clinical Trial Exemptions (CTX) is not impacted.
    - Ensuring that GMP/GLP conditions are maintained.
    - Ensuring that documentation is clear and complete.
    - Ensuring that appropriate reviews are complete.
    - Ensuring that validation status is maintained, and if not appropriate re-validation activities are initiated.
    - Ensuring that personnel are appropriately trained ar prior change implementation.
    - Evaluating if stability program is impacted.