5 FLOWCHART

START

Step 1
Initiation of Lab Investigation
(Phase I)

Secondary Tasks allowed

Initiation of Related Proceses
allowed

SecondaryTasks are released

Step 2
Laboratory Investigation Conclusion (Phase I)
Initiator

Return to Initiation

Advance to Reviewer Approval

SecondaryTasks are released
DOC Processes move out of waiting

Return for
more information

Step 3
Reviewer Approval
Assigned Reviewer identified in step 1

Laboratory error confirmed (close process)

Approve

Step 4
QA Review
QA Approver Identified in step 1

Return for
more information

DOC Processes move out of waiting

Approve

Is Phase II Investigation Required?

No

Yes

Is Lab Inv. Req?

No

Yes

Release tasks

Step 5
Manufacturing Investigation (Phase II)
Assigned Manuf. Investigator identified in step 4

Step 6
Laboratory Investigation (Phase II)
Assigned Lab Investigator identified in step 4

Release tasks

Secondary Tasks are released

DOC Processes move out of waiting

Secondary Tasks are released

DOC Processes move out of waiting

Request Extension

Request Extension

Step ExtApp
Execution Extension Request Approval *(x)*
Assigned QA Approver identified at step 1

Approve OR Denied

Approve OR Denied

Investigation completed

Investigation completed

Step 7
QA Approval of Investigation
QA Approver Identified in step 1

Return for
more information

Approve

Additional Testing Needed

No

Request Extension

Yes

Step ExtApp
Execution Extension Request Approval *(x)*
Assigned QA Approver identified at step 1

Step 8
Additional Testing
PR_LIR_QC

Approve OR Denied

Additional Testing Done

Step 9
Interpretation of Investigation Results
and Release Decision
QA Approver Identified in step 1

DOC Processes move out of waiting

END