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| GENUS INNOVATION LIMITED |
| Project and Support Groups Quality Assurance Procedure |
| PRCD\_AUDITT.docx |
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| **Genus** |

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| Quality Assurance provides management with objective insight into Products and Processes to ensure they conform to specified Requirements, Established Plans, Standards and Procedures. |

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# Overview

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Quality Assurance provides management with objective insight into Products and Processes to ensure they conform to specified Requirements, Established Plans, Standards and Procedures.

# Objective

* To objectively evaluate the Process Areas and Work Products
* To provide stakeholders and management with objective insight into compliance
* To track and communicate issues to ensure that they are resolved

# Scope

This procedure applies to all the Development Projects and Support Groups of Genus.

# Inputs

* Audit Checklists
* Projects’ and Support Groups’ Work Products
* Organizational and Project Standards, and Process Definitions

# Entry Criteria/Triggers

* Audit Schedule
* The practitioners have undergone QMS trainings with focus on performing their processes.

# Tasks

| Sr. No | Task | Owner/Role |
| --- | --- | --- |
|  | Establish Quality Assurance Team |  |
|  | Appoint the QA team/ Audit Team based on the “Team Formation Guidelines” (GDLN\_TEAMNG). Call a kickoff and apprise the team of your expectations. | Senior Management |
|  | Prepare an audit plan for the overall audit function using “Audit Plan Template” (TMPL\_ADTPLN). Use past audit performance data for planning. This plan governs the overall operations of the audit function. This must include the overall vision and scope as well as the plans for budget, resources, quality, schedule, monitoring, measurement goals and operational definitions, training and others. |  |
|  | Audit Plan |  |
|  | Identify Resources such as Checklists, Standards and related documents needed to perform the Audit. | PPQA Manager / Project Manager |
|  | Prepare a schedule for conducting Audit, using template “Audit Schedule” (TMPL\_ADTSCH), hyperlinked from “Quality Assurance Plan” (TMPL\_ADTPLN) for planning the Audit activities. The project audits are scheduled within the Project Plan. The overall Quality assurance plan governs the Audit function. The same must be reviewed and approved by the Senior management.  The support groups must be audited at least once every Quarter. | PPQA Manager / Project Manager |
|  | Identify a PPQA Representative. The PPQA Representative shall additionally be responsible for providing process facilitation and assistance to the project team members.   * The PPQA personnel must not be directly supervised by any stakeholder or group being reviewed, and must maintain a reporting channel to Senior Management or the Quality Head that is independent of the project. | PPQA Manager / Project Manager |
|  | Update the Audit Plan section in the Project Plan (TMPL\_PRJPLN). The plan will be the basis for the monitoring and control of the QA activities. Update the overall “Quality Assurance Plan ” (TMPL\_ADTPLN). | PPQA Manager/ Project Manager |
|  | Review and approve the Audit Plan section in Project Plan. Also update the same in the “Quality Assurance Plan” (TMPL\_ADTPLN). | PPQA Manager |
|  | Inform Audit schedule to relevant Auditee / stakeholders. | PPQA Manager |
|  | **Perform Audits and Communicate findings** |  |
|  | Ensure the availability of the related Checklists, Standards and supporting documents required to conduct the audit, as required. | PPQA Member /Auditor |
|  | Objectively evaluate the identified work product.   * Auditor may refer to “Project Audit Checklist” (CHKL\_AUDITT) or other relevant checklists for Support Groups. The populated checklist or other artefacts for project audits is placed in the Project Repository, in line with the Configuration and Data Management Plan. | PPQA Member/Auditor |
|  | Discuss the audit findings with the Auditee and update the findings in the “Audit Non-Conformance Log”. | PPQA Member/Auditor |
|  | Classify findings as   * Minor / Major Noncompliance Issues. For definitions of minor/major Noncompliance, refer Guidelines. * Observations | PPQA Member/Auditor |
|  | Communicate the audit findings to the Auditee. | PPQA Member/Auditor |
|  | **Track the NCs to closure** |  |
|  | Discuss the timelines to close the NCs with the Auditee. | PPQA Member/Auditor |
|  | Take suitable corrective actions and resolve the Non Compliances. | Auditee |
|  | Ensure that audit findings are resolved and close them. | PPQA Member/Auditor |
|  | Perform root cause analysis for   1. all major NCs 2. recurrent NCs across instances   Use “Audit Reporting Tool” (TOOL\_ADTRPT) for recording and reporting the results of the root cause analysis.. | PPQA team |
|  | Update “Audit Non-Conformance Log”. | PPQA Member/Auditor |
|  | Track root cause analysis actions for the identified non-compliances. | PPQA head |
|  | Generate “Audit Report” using “Audit Reporting Tool” (TOOL\_ADTRPT). | PPQA Member/Auditor |
|  | Periodically send the “Audit Report” to Process Engineering (PEG) Head for identifying Candidate Process Improvement Opportunities. | PPQA Member/Auditor |
|  | Identify best practices and process improvement opportunities. Submit them to the Process Engineering Group (PEG) using “Process Improvement Proposals Database”. | PPQA Member/Auditor |
|  | **Senior Management review** |  |
|  | Discuss and review of Audit activities with Senior Management Periodically. This should be done typically in each Quarter. Use “Senior Management Review Agenda List” (TMPL\_PQARVW) | PPQA Manager |

\* Improvements/Suggestions are solicited on “Process Improvement Proposals Database”.  
\*For details on the Roles and Responsibilities of the practitioners, Refer "Roles and Responsibility" document in the QMS.

# Verification

* Review of Audit Plan by PPQA Manager.
* Review of the process and its work products by PPQA members.
* Review of the process and its work products by Senior Management.

# Guidelines

Refer "Configuration Management and Release Procedure" (PRCD\_CONFIG) for Access Rights, location of work products, naming convention and types of controls.

## Audit Guidelines

1. PPQA Manager selects the auditor and informs the selected auditor by E-Mail.
2. Auditor informs the Project Manager of the selected project of the schedule of the Audit.
3. Auditor performs the Audit.
   1. Objectively evaluate the work products of the project using the “Project Audit Checklist” (CHKL\_AUDITT).
   2. Identify possible inconsistencies with the Project’s Defined Processes.
   3. Evaluate the inconsistencies observed in consultation with the project’s relevant stakeholders.
   4. Arrive at a concurrence at the observations. If the concurrence cannot be reached, escalate the issues to the PPQA Manager and the operations head, if required.
   5. Classify the observations into major or minor non-compliance issues based on their impact or observations.
   6. Identify and arrive at the relevant stakeholders responsible for closure of NC’s and the schedule for closure.
   7. Inform the PPQA Manager of the audit results. The PPQA Manager will ensure that the NC’s are closed within scheduled timeframe. Repeated failure to meet the closure schedule will invite escalation to the operations head and absolution of the auditor from the project’s audit responsibilities. The PPQA Manager will hence be responsible for closures. The number of repetitions before the escalation is triggered is decided with mutual consent between the auditor and the PPQA Manager.
   8. Verify closure with respect to the decided closure schedule.
   9. Inform the PPQA manager of the successful closure of all NC’s
4. Inform the Process Engineering Group and communicate the Audit Report to them.

## Definitions

### Major noncompliance:

A major Non Compliance is one or more of:

* The absence of or total breakdown of a system to meet process requirements. A number of minor nonconformities against one requirement can represent a total breakdown of the system and thus be considered a major nonconformity.
* Any noncompliance that would result in the probable shipment of nonconforming product. A condition that may result in the failure or materially reduce the usability of the products or services for their intended purpose.
* A noncompliance that judgment and experience indicate is likely either to result in the failure of the quality management system or to materially reduce its ability to assure controlled processes and products.

### Minor noncompliance:

A minor nonconformity is a failure to comply processes which based on judgment and experience is not likely to result in the failure of the quality management system or to reduce its ability to assure controlled processes or products. It may be one of the following:

* A failure in some part of the organization's quality management system.
* A single observed lapse in following one item of a company's quality management system.

### Observation:

An Observation is remark or an inference that is made by observing the things. For e.g.

* MPP should be more detailed.
* Risk Statement should be more elaborated.

# Applicable Measurements

* Number of open Noncompliance Issues

# Exit Criteria/Outputs

* Audit plans, schedules, procedures and checklists
* Audit Report / Closed Audit NCs