Instructions: Complete this form using the instructions in blue text for each section. Periodically (annually or as changes occur) you will review and update information. Retain this document as a record of QMS planning in your Quality Management System.

|  |  |  |  |
| --- | --- | --- | --- |
| **Process Plan** | | | |
| **Process Name** | Design and Development | **Process Owner** | Jeff Frederick, Chief Information Officer |
| **Associated Process Documents & Records** | Quality Manual, Design Plans and Schedules | **Quality Objectives Supported** | * Proposal Win Rate – Over 40% * Customer Satisfaction – Zero complaints |
| **Key Resources** | IT staff, Corporate IT systems, backups, | **ISO 9001:2015 Clauses** | 4.4, 5.2, 6.1, 6.2, 7.1, 7.1.5, 7.1.6, 7.2, 7.3, 7.5, 8, 8.4, 8.7, 10.1, 10.2, 10.3 |
| **Outsourced Processes and Controls** | None | **Risks or Opportunities to consider** | Listed, progress tracked and reviewed as necessary in QMS Plan document |

**Process Diagram**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Internal and external customers  Upstream Process = (sometimes) Business Development | Customer specifications | 1. Review customer specifications  2. Develop design plans  3. Design and develop  4. Control design changes  5. Release | * Approved requirements * Test plans * New release | Internal and external customers  Downstream Process = Program Management | Management reviews, design specifications, plans and other design documents  Management Reviews |

Instructions: For this section, the Process Owner and Auditor(s) will fill this in together and note any actions needed.

**Process Review**

|  |  |  |  |
| --- | --- | --- | --- |
| **Process Owner:** | Joe Heary | **Associated CA’s or NC’s reviewed:** |  |
| **Auditor(s):** | Brenda Walguanery | **Documents and Records Reviewed (including previous audits):** |  |
| **Date Reviewed:** |  | **Date of Next Review:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Process Owner Questions** | **Yes** | **No** | **Notes/Action Needed** |
| 1. Is the Process Plan and Diagram (from pages 1-2) still current? (4.4.1) |  |  | If no, list actions being taken: |
| 1. Have there been any major changes since the last review? (4.4.1) |  |  | If yes, list actions being taken: |
| 1. Are the process measures still valid? (4.4.1, 7.1.5.1) |  |  | If no, list actions being taken: |
| 1. Are measure targets being met? (4.4.1, 7.1.5.1) |  |  | If no, list actions being taken: |
| 1. Are resources still adequate for the process? (7.1) |  |  | If no, list actions being taken: |
| 1. Are there any new risks in the process to consider? (6.1) |  |  | If yes, list actions being taken: |
| 1. Are any resources used for monitoring and measurement of the process fit for their purpose? (7.1.5.1) |  |  | If no, list actions being taken: |
| 1. Is there any key knowledge about the process to capture? (7.1.6) |  |  | If yes, list actions being taken: |
| 1. Are there any process improvements needed or opportunities to take advantage of? (4.4.1, 6.1, 10.3) |  |  | If yes, list actions being taken: |
| 1. **List any additional actions items such as:** documents or records to update; training or communication to be done. |  |  |  |

**Process Audit**

Instructions: For this section, the Auditor(s) will complete as they conduct the audit. Evidence listed should be specific and detailed. Each question should note either “OK” if all requirements were found to be compliant or “NC” if there was a nonconformity.

Process Documentation

|  |  |  |  |
| --- | --- | --- | --- |
| **ISO clause** | **Auditor Question** | **Evidence** | **OK or NC** |
| 4.4.2a  7.5.2  7.5.3 | 1. Specific to the Design and Development process - what controlled documents are in use?  Check for appropriate:   * identification and format * review and approvals * availability and suitability * protection and access * storage and retention * change control   **Look for:** Look at several documents. List names of specific documents reviewed and their revisions in use. Check for all of the bulleted requirements above. |  |  |
| 4.4.2b  7.5.2  7.5.3 | 2. Specific to the Design and Development process - what records are kept?  Check for appropriate:   * identification and format * review and approvals * availability and suitability * protection and access * storage and retention * change control   **Look for:** Look at several records. List names, dates and other identifiers of specific records reviewed that are in use. Check for all of the bulleted requirements above. |  |  |

Competence, Awareness and Communication

|  |  |  |  |
| --- | --- | --- | --- |
| **ISO clause** | **Auditor Question** | **Evidence** | **OK or NC** |
| 7.2 | 3. What evidence shows that competence of recently hired employees was verified against defined criteria for their position? | This is covered in HR/Recruiting Audit Plan. | NA |
| 5.2.2b  7.3 | 4. Are employees (who work in the Design and Development process) aware of:   * The quality policy * Relevant quality objectives * Their contribution to the QMS * The benefits of improved performance * The negative effects of not conforming to QMS requirements?   **Look for:** Type the responses from one or two auditees regarding their awareness of the above. |  |  |

Process Conformity

|  |  |  |  |
| --- | --- | --- | --- |
| **ISO clause** | **Auditor Question** | **Evidence** | **OK or NC** |
| 8.3.1 – 8.3.6 | 5. Is the Design and Development process being followed as defined in the Quality Manual and related documents?  **Look for:** Read the appropriate Quality Manual sections shown under “ISO clause” (to the left) before completing these questions. List the Quality Manual Revision. |  |  |
| 8.3.2 | 6. What is the process for design planning? Are records maintained?  **Note:** This will be found in the CMMI Level 3 documentation under the ZAI Development Process.    **Look for:** Ensure that design reviews are properly recorded as part of the Design Plan. Evaluate a recently completed Design Plan and Schedule and ensure that it is complete as per the stage of design. Note the record #’s. |  |  |
| 8.3.3 | 7. How are design inputs defined and reviewed to ensure they are adequate, complete, unambiguous and not in conflict with each other?  **Look for:** List 1-2 examples of records reviewed of design requirements with specific references to projects, e.g. customer specifications, functional requirements, market/competitive research, etc. |  |  |
| 8.3.3  8.3.5 | 8. How are design inputs verified against design outputs?  **Look for:** List 1-2 examples of records reviewed of design verifications, including methods of verification, dates of approval, etc. This could include test results, pilot production run results, first piece inspection results, completed design plan forms, project files, or other appropriate documentation. |  |  |
| 8.3.5 | 9. How are design outputs validated against the intended use?  **Look for:** List 1-2 examples of records reviewed of design validations including methods of validation, dates of approval, etc. This could include customer test results, customer inspection results, simulation test results, life cycle test results, customer feedback, customer complaints and returns, completed design plan forms, project files, or other appropriate documentation. |  |  |
| 8.3.6 | 10. Is the design change process being followed as defined in the Quality Manual and related documents?  **Look for:** Review a recently completed Design change and ensure it was properly authorized and that records are retained. |  |  |
| 8.4 | 11. Are there any outsourced processes (by external providers) for the Design and Development process? If yes, how are they controlled?  **Look for:** Verify that any outside suppliers used during the process were properly selected, controlled and evaluated. Ensure they are listed above in the Process Plan on Page 1. |  |  |
| 8.7  10.2 | 12. Have any Corrective Actions or Nonconformances been generated that are related to this process?  **Look for:** Ensure that CA’s and NC’s are being recorded for issues that exist. Note any that are recent or in process. If none, mark “N/A”. |  |  |

Process Evaluation

|  |  |  |  |
| --- | --- | --- | --- |
| **ISO clause** | **Auditor Question** | **Evidence** | **OK or NC** |
| 4.4.1  6.2  9.1.1 | 13. Have all Measurement Plans for this process been reviewed as required? | See Quality Management Audit Plan – all key measures are defined in Quality Manual, tracked in Key Measurement Worksheet, and a topic in each Management Review minutes. | NA |
| 10.1  10.3 | 14. Are there any suggested process improvements?  **Look for:** Type in suggestions for improvement from the auditee(s) or from the auditor or type “No suggestions for improvement at this time.” |  |  |

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| --- | --- | --- | --- |
| **Audit findings summary** |  | | |
| **Corrective Actions Issued** |  | | |
| **Auditor Name**  **(Sign-off)** |  | **Date** |  |
| **Process Owner Name**  **(Sign-off)** |  | **Date** |  |