### Compliance Findings (GAMP5 & CSA Standards)  
  
1. \*\*Issue:\*\* The document lacks a clear risk assessment for the changes being implemented, particularly regarding the impact on patient safety and product quality.  
 - \*\*Section:\*\* Scope Description  
 - \*\*Regulatory Reference:\*\* GAMP5 Step 1 - Perform Initial Risk Assessment and Determine System Impact  
 - \*\*Correction:\*\* Include a detailed risk assessment that identifies potential hazards associated with the changes and their impact on patient safety and product quality .  
  
2. \*\*Issue:\*\* The testing strategy does not specify the use of robust scripted testing for high-risk features, which is necessary to ensure thorough validation.  
 - \*\*Section:\*\* Test Strategy  
 - \*\*Regulatory Reference:\*\* CSA Guidance - Robust scripted testing should be employed for high-risk features.  
 - \*\*Correction:\*\* Revise the testing strategy to include robust scripted testing protocols for all high-risk features identified in the change request .  
  
3. \*\*Issue:\*\* The document does not provide sufficient detail on the acceptance criteria for the testing phases, particularly for User Acceptance Testing (UAT).  
 - \*\*Section:\*\* User Acceptance Testing  
 - \*\*Regulatory Reference:\*\* CSA Guidance - Acceptance criteria must be clearly defined for all testing phases.  
 - \*\*Correction:\*\* Clearly outline the acceptance criteria for UAT, including specific metrics for success and failure .  
  
4. \*\*Issue:\*\* There is no mention of independent review and approval of test cases, which is a critical component of the validation process.  
 - \*\*Section:\*\* Testing Overview  
 - \*\*Regulatory Reference:\*\* CSA Guidance - Independent review and approval of test cases is essential.  
 - \*\*Correction:\*\* Implement a process for independent review and approval of all test cases prior to execution .  
  
5. \*\*Issue:\*\* The document does not adequately address the management of defects identified during testing, which is crucial for maintaining compliance.  
 - \*\*Section:\*\* Defect Management  
 - \*\*Regulatory Reference:\*\* GAMP5 - Defects must be reported and managed according to established procedures.  
 - \*\*Correction:\*\* Establish a clear defect management process that includes reporting, tracking, and resolution of defects identified during testing .  
  
6. \*\*Issue:\*\* The document lacks a comprehensive outline of the roles and responsibilities for the validation effort, which can lead to confusion during execution.  
 - \*\*Section:\*\* Roles  
 - \*\*Regulatory Reference:\*\* CSA Guidance - Clearly defined roles and responsibilities are necessary for effective validation.  
 - \*\*Correction:\*\* Provide a detailed list of roles and responsibilities for all team members involved in the validation process .  
  
These findings highlight critical areas where the document does not align with GAMP5 and CSA standards, necessitating revisions to ensure compliance and effective validation of the changes proposed in the CMMS 2024 Bucket Change 1.  
  
To assess the alignment of the provided document with the Test Plan Template, I will identify any structural issues, including misaligned or missing headings, incorrect section ordering, and structural inconsistencies. Below is a summary of the findings:  
  
### Structural & Consistency Findings  
  
1. \*\*Issue\*\*: Missing Section Headings  
 - \*\*Description\*\*: The document lacks specific section headings that are typically required in a Test Plan Template, such as "Test Objectives," "Test Environment," and "Test Schedule."  
 - \*\*Location\*\*: The document does not have these sections explicitly defined.  
 - \*\*Correction\*\*: Add the missing section headings to align with the Test Plan Template. For example:  
 - \*\*Test Objectives\*\*: Define the objectives of the testing process.  
 - \*\*Test Environment\*\*: Describe the environments used for testing (Development, Validation, Production).  
 - \*\*Test Schedule\*\*: Outline the timeline for testing activities.  
  
2. \*\*Issue\*\*: Incorrect Section Ordering  
 - \*\*Description\*\*: The order of sections does not follow the typical structure of a Test Plan Template. For instance, "Testing Overview" appears before "Scope" and "Purpose," which is unconventional.  
 - \*\*Location\*\*: Sections "Testing Overview" and "Scope" are out of order.  
 - \*\*Correction\*\*: Rearrange the sections to follow a logical flow, typically starting with "Purpose," followed by "Scope," and then "Testing Overview."  
  
3. \*\*Issue\*\*: Structural Inconsistencies  
 - \*\*Description\*\*: The document has repeated sections for "Risks and Assumptions" and "Out of Scope," which should be consolidated into a single section to avoid redundancy.  
 - \*\*Location\*\*: Sections titled "Risks and Assumptions" and "Out of Scope" appear multiple times.  
 - \*\*Correction\*\*: Combine these sections into one comprehensive section that addresses all risks, assumptions, and out-of-scope items.  
  
4. \*\*Issue\*\*: Lack of Clear Acceptance Criteria  
 - \*\*Description\*\*: While acceptance criteria are mentioned, they are not clearly defined in a separate section, making it difficult to identify them quickly.  
 - \*\*Location\*\*: Acceptance criteria are scattered throughout the document.  
 - \*\*Correction\*\*: Create a dedicated "Acceptance Criteria" section that clearly lists all acceptance criteria for each testing phase (IQ, OQ, UAT).  
  
5. \*\*Issue\*\*: Inconsistent Terminology  
 - \*\*Description\*\*: The document uses different terms for similar concepts, such as "Validation" and "Operational Testing," which may lead to confusion.  
 - \*\*Location\*\*: Various sections use inconsistent terminology.  
 - \*\*Correction\*\*: Standardize terminology throughout the document to ensure clarity and consistency.  
  
### Summary of Corrections  
- Add missing section headings for "Test Objectives," "Test Environment," and "Test Schedule."  
- Rearrange sections to follow a logical order: Purpose, Scope, Testing Overview.  
- Consolidate repeated sections for "Risks and Assumptions" and "Out of Scope."  
- Create a dedicated "Acceptance Criteria" section.  
- Standardize terminology throughout the document.  
  
By implementing these corrections, the document will align more closely with the Test Plan Template, ensuring clarity and consistency in the validation process.  
  
### System Name Consistency Check Report  
  
\*\*Official System Name:\*\* Computerized Maintenance Management System (CMMS)  
  
#### Inconsistent References Found:  
  
1. \*\*Incorrect Name Used:\*\* CMMS 2024 Bucket Change 1  
 - \*\*Sentence:\*\* "For the Computerized Maintenance Management System (CMMS) 2024 Bucket Change 1 (CHGXXXXX), this combined Test & Validation Plan describes the implementation strategy..."  
 - \*\*Correction:\*\* Replace with "For the Computerized Maintenance Management System (CMMS), this combined Test & Validation Plan describes the implementation strategy..."  
  
2. \*\*Incorrect Name Used:\*\* CMMS  
 - \*\*Sentence:\*\* "The CMMS platform is accessible to all, but access is limited depending on the user group assigned."  
 - \*\*Correction:\*\* Replace with "The Computerized Maintenance Management System (CMMS) platform is accessible to all, but access is limited depending on the user group assigned."  
  
3. \*\*Incorrect Name Used:\*\* CHGXXXXX  
 - \*\*Sentence:\*\* "This change (CHGXXXXX) plan outlines the validation process and deliverables required to execute the updates required per change control CHGXXXXX."  
 - \*\*Correction:\*\* Replace with "This change (Computerized Maintenance Management System change) plan outlines the validation process and deliverables required to execute the updates required per change control CHGXXXXX."  
  
### Summary of Findings  
The document contains several references to the system name that do not match the official name "Computerized Maintenance Management System (CMMS)." It is recommended to standardize the references throughout the document to ensure consistency and clarity.  
  
If you need further assistance or additional checks, feel free to ask!  
  
Change Description: Prevent New Users from Taking Active License:   
Chosen Requirement: BR 9.2 (FR 6.8.3)   
AI Chosen Impacted Requirements:  
- BR 4.51 — The system shall compare the current process settings of each piece of equipment selected in the IEL with the incoming process settings for the new campaign. - Certainty Score: 85  
- FR 6.1.13 — The system enables authorized users to generate Bill of Equipment records detailing lists of Equipment validated for use in manufacturing a specific product and the status of the Equipment; as well as to associate the Equipment on the BOE with the attribute settings required by the BOE. - Certainty Score: 80  
- BR 3.62 — A record of initial process settings shall be able to be viewed in the change request. - Certainty Score: 75  
- FR 6.3.67 — IEL will include a tab detailing a comparison between initial (Equipment) settings and BOE settings. - Certainty Score: 70  
- BR 4.52 — The system shall generate work orders to change any current process settings which differ from the incoming campaign’s process settings. - Certainty Score: 65  
  
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Change Description: Calibration Standards Tab Update:   
Chosen Requirement: BR 4.3 (FR 6.4.10)   
AI Chosen Impacted Requirements:  
- BR 4.52 — The system shall generate work orders to change any current process settings which differ from the incoming campaign’s process settings. - Certainty Score: 85  
- FR 6.4.68 — A settings comparison tab is available on the Equipment Change Request screen. - Certainty Score: 80  
- FR 6.1.14 — A settings tab on the BOE will detail existing Equipment attribute settings relevant to manufacture of the corresponding product. - Certainty Score: 75  
- BR 4.51 — The system shall compare the current process settings of each piece of equipment selected in the IEL with the incoming process settings for the new campaign. - Certainty Score: 70  
- FR 6.3.63 — Protected “PM Due” and “PMCAL Due” checkboxes will be added to the Equipment screen as indicators of Preventative Maintenance or Calibration Overdue status of corresponding Equipment. - Certainty Score: 65  
  
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Change Description: View All Equip Update Requests Screen Updates:   
Chosen Requirement: BR 3.1 (FR 6.3.1)   
AI Chosen Impacted Requirements:  
- FR 6.1.13 — The system enables authorized users to generate Bill of Equipment records detailing lists of Equipment validated for use in manufacturing a specific product and the status of the Equipment; as well as to associate the Equipment on the BOE with the attribute settings required by the BOE. - Certainty Score: 85  
- BR 4.51 — The system shall compare the current process settings of each piece of equipment selected in the IEL with the incoming process settings for the new campaign. - Certainty Score: 80  
- FR 6.3.63 — Protected “PM Due” and “PMCAL Due” checkboxes will be added to the Equipment screen as indicators of Preventative Maintenance or Calibration Overdue status of corresponding Equipment. - Certainty Score: 75  
- BR 4.52 — The system shall generate work orders to change any current process settings which differ from the incoming campaign’s process settings. - Certainty Score: 70  
- FR 6.4.68 — A settings comparison tab is available on the Equipment Change Request screen. - Certainty Score: 65  
  
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Change Description: Audit Trail Report:   
Chosen Requirement: BR 4.50 (FR 6.4.65)   
AI Chosen Impacted Requirements:  
- UR-REG-34 — The system audit trail must provide secure (not editable), date and time-stamped record of the action (obtained from a secure, reliable source, i.e. the server and not the client PC) and the identity of the operator any time an electronic record is created, modified, or deleted. - Certainty Score: 90  
- FS-REG-34 — System shall have the ability to generate a secure audit trail report of the action from application server which must provide the time stamp information’s in non-editable format when a particular action is performed. - Certainty Score: 85  
- BR 4.51 — The system shall compare the current process settings of each piece of equipment selected in the IEL with the incoming process settings for the new campaign. - Certainty Score: 80  
- FR 6.4.65 — The system will be able to pass records of changes made to information on the screen of a work order of any type to an attached ‘Audit Trail Review’ tab. The system will then compile and display the records in an audit trail report in the ‘Audit Trail Review’ tab. - Certainty Score: 75  
- UR-REG-36 — The system must record the creation, change, and cancellation of access authorizations. - Certainty Score: 70  
  
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Change Description: Work Order Report Location Update:   
Chosen Requirement: BR 7.2 (FR 6.1.7)   
AI Chosen Impacted Requirements:  
- BR 4.51 — The system shall compare the current process settings of each piece of equipment selected in the IEL with the incoming process settings for the new campaign. - Certainty Score: 85  
- FR 6.1.13 — The system enables authorized users to generate Bill of Equipment records detailing lists of Equipment validated for use in manufacturing a specific product and the status of the Equipment; as well as to associate the Equipment on the BOE with the attribute settings required by the BOE. - Certainty Score: 80  
- BR 4.52 — The system shall generate work orders to change any current process settings which differ from the incoming campaign’s process settings. - Certainty Score: 75  
- FR 6.4.68 — A settings comparison tab is available on the Equipment Change Request screen. - Certainty Score: 70  
- FR 6.3.63 — Protected “PM Due” and “PMCAL Due” checkboxes will be added to the Equipment screen as indicators of Preventative Maintenance or Calibration Overdue status of corresponding Equipment. - Certainty Score: 65  
  
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Change Description: Forgot Password Button:   
Chosen Requirement: BR 10.1 (FR 6.1.9)   
AI Chosen Impacted Requirements:  
- BR 8.1 — The system shall provide security to allow or disallow functionality on the system level, site level, and user level. - Certainty Score: 85  
- FR 6.2.2 — The system will provide the ability to separate data by organization (site), allowing some users access only to their local data, while allowing authorized users to view all data within the database. This viewing will be permitted through validated system screens and reports only. - Certainty Score: 80  
- BR 10.1 — The system shall provide the ability to interface with active directory. - Certainty Score: 75  
- FR 6.1.12 — The system will allow users to search for other users in the system by using a lookup grid containing these fields: User Code, Employee ID, User Description, Role, Org, Default Org, and Out of Service. - Certainty Score: 70  
- BR 8.1 — The system shall provide security to allow or disallow functionality on the system level, site level, and user level. - Certainty Score: 65