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Instructions

The purpose of this template is to assist with the creation and application of system development deliverables according to the Software Development Life Cycle (SDLC) practice. The sections in blue font provide instructions, and should be removed. Upon use of this template, consideration should be taken for the departmental and site-level procedures that govern the deliverables of the system. Please see below for instructions regarding this template:

* **Blue-colored text** provides instructions for the author to better understand the template and its use. All blue-colored text should be removed from this document upon completion.
* Black-colored text provides sample wording that can be used, removed, or altered as necessary. Different sections may be added, altered, or removed as necessary as well. The document may be modified to fit its intended use.
* Red-colored text provides sample information that for a more complete understanding of the intended use of various portions of the document. This text must be removed from the document upon completion.
* Highlighted text should be replaced by the author with the correct information.

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# Introduction

Use this section to describe this document and its purpose. This section should name the system to which it pertains.

This Configuration Specification (CS) document is created as part of the implementation of the Test Management system (CI: 123-ABC-TEST), and it will describe the specific hardware and software configurations necessary for the operation of the Test Management system.

## Relevant Documents

List the documents that are relevant to the creation of this CS document. This should include at minimum the Requirement Specification (RS) and Functional Specification (FS) documents, if they will be created for this system.

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# Scope

Describe the scope of this document in this section. The scope may:

* Provide a general overview of the configurations planned for the system
* Outline how the configurations will be implemented
* Describe the process for determining necessary configurations
* Explain the relevancy of the “Relevant Documents” that are listed in the previous subsection
* Define the intended audience of this document
* Describe the system environments (e.g. Development, Test, Production, etc.) that are relevant to this document
* Provide any other relevant information

This document pertains to the <System Name> system, which is developed and supplied by <Vendor Name>. The system uses a <platform type (SaaS, PaaS, commercial-off-the-shelf, etc.)> platform with standard features and functionalities that are configurable. This CS document only defines the configuration items for this system that are used by <Company Name>.

# Configuration Factors

## Configuration Decisions

Describe any vital configuration decisions or approaches and provide the reasoning behind them. Generally describe the software features that will be configured for this system, and describe the software features that will be excluded from configuration in this document.

## Assumptions, Dependencies, and Constraints

Describe any relevant assumptions made for this system and its configuration. Also describe any related dependencies or constraints for the configuration of this system.

## System Architecture

Briefly describe any configuration items that pertain to the system architecture, if applicable. This includes elements related to the composition of the system and the elements of which it is made.

## Interfaces

Describe any configuration elements that are related to the interfaces of the system, if applicable. This information includes configuration elements pertaining to the interaction of this system with any other systems as well as the data flow between them.

# Configuration Specifications

This section should list the configurations to the system and provide necessary details and references so that they may be properly implemented, tracked, and tested. Subsections may be created/modified/removed as necessary to provide better organization. The below subsections are examples and may not be applicable to every system/implementation. It may be useful to use the same sections/subsections as present for the specifications in the FS and RS documents. By all means, be sure to capture and describe all relevant configurations in this section.

These specifications should explain the configurations made to the system. A configuration is a change made to a system using the standard system functionalities. The specifications in this document should properly define the configurations to be made to the system as they pertain to the system expectations and functionalities as defined in the RS and FS documents, respectively. These specifications are tracked with a unique identifying Configuration Specifications ID (CS ID) that will be used to track the requirement from initial creation through development, testing, and operation.

When writing these specifications, follow the guidelines below:

* Clear – use clear, concise, and unambiguous language
* Complete – be detailed to describe all necessary aspects of the system specification
* Consistent – use consistent language so that the specifications do not contradict each other
* Attainable – define specifications that are attainable for the system
* Testable – define specifications that may be tested to verify correct functionality

Specifications may include statements, diagrams (flow maps), sample screenshots, user stories, etc.

GxP-relevant systems must document specifications in a manner such that they are traceable from creation through design, testing, and operation.

This section describes the relevant configurations of the system. It is divided into subsections in order to align with the system FS and RS documents.

## System Processes

In the following section, describe any configurations related to the system processes.

| **CS ID** | **FS ID** | **RS ID** | **Specification Description** |
| --- | --- | --- | --- |
| Provide the CS ID | Provide the FS ID(s) to which this specification pertains | Provide the RS ID(s) to which this specification pertains | Provide a description of the configuration specification. This description should be detailed and concise, in order to properly configure the system.  |
| CS-SYS-01 | FS-SYS-01 | RS-SYS-01RS-SYS-02 | The homepage of the system must display the tabs “Main”, “Users”, and “Documents” at the top of the page. |
| CS-SYS-02 | FS-SYS-02 | RS-SYS-03 | The homepage of the system must display the date in the format DD-MMM-YYYY at the top of the page. |

## System Roles and Authorizations

Use this section to describe the configurations to the roles/authorizations of the system.

| **CS ID** | **FS ID** | **RS ID** | **Role** | **Specification Description** |
| --- | --- | --- | --- | --- |
| Provide the CS ID | Provide the FS ID(s) to which this specification pertains | Provide the RS ID(s) to which this specification pertains | Describe the system role to which this specification pertains | Provide a description of the configuration specification. This description should be detailed and concise, in order to properly configure the system.  |

## System Access

Use this section to describe any configurations related to system access i.e. password control, account locking, etc. This section may refer to a separate SOP, if relevant.

| **CS ID** | **FS ID** | **RS ID** | **Specification Description** |
| --- | --- | --- | --- |
| Provide the CS ID | Provide the FS ID(s) to which this specification pertains | Provide the RS ID(s) to which this specification pertains | Provide a description of the configuration specification. This description should be detailed and concise, in order to properly configure the system.  |

## Data Use

This section should describe the configurations pertaining to the data that is relevant to the system (e.g. data created/transported/modified/deleted by the system).

### Electronic Records and Signatures

Describe any configurations pertaining to electronic records and/or signatures.

| **CS ID** | **FS ID** | **RS ID** | **Specification Description** |
| --- | --- | --- | --- |
| Provide the CS ID | Provide the FS ID(s) to which this specification pertains | Provide the RS ID(s) to which this specification pertains | Provide a description of the configuration specification. This description should be detailed and concise, in order to properly configure the system.  |

### Data Security and Data Privacy

Describe any configurations related to data security or data privacy.

| **CS ID** | **FS ID** | **RS ID** | **Specification Description** |
| --- | --- | --- | --- |
| Provide the CS ID | Provide the FS ID(s) to which this specification pertains | Provide the RS ID(s) to which this specification pertains | Provide a description of the configuration specification. This description should be detailed and concise, in order to properly configure the system.  |

### Audit Trail Functionality

Describe any configurations related to the functionality of the Audit Trail for the system.

| **CS ID** | **FS ID** | **RS ID** | **Specification Description** |
| --- | --- | --- | --- |
| Provide the CS ID | Provide the FS ID(s) to which this specification pertains | Provide the RS ID(s) to which this specification pertains | Provide a description of the configuration specification. This description should be detailed and concise, in order to properly configure the system.  |

## System Interfaces

Describe any configurations pertaining to interfaces of the system.

| **CS ID** | **FS ID** | **RS ID** | **Data Direction** | **Source / Target** | **Specification Description** |
| --- | --- | --- | --- | --- | --- |
| Provide the CS ID | Provide the FS ID(s) to which this specification pertains | Provide the RS ID(s) to which this specification pertains | Describe the direction of data flow i.e. “Data In”, “Data Out”, “Data In/Out”, etc. | Specify the source or target system to which this configuration pertains | Provide a description of the configuration specification. This description should be detailed and concise, in order to properly configure the system.  |

## System Performance and Operation

Describe any configurations pertaining to the performance (e.g. number of concurrent users) or operation (e.g. operation language) of the system.

| **CS ID** | **FS ID** | **RS ID** | **Specification Description** |
| --- | --- | --- | --- |
| Provide the CS ID | Provide the FS ID(s) to which this specification pertains | Provide the RS ID(s) to which this specification pertains | Provide a description of the configuration specification. This description should be detailed and concise, in order to properly configure the system.  |

## Hardware Configurations

In the following subsections, describe any hardware configurations necessary for this system.

### Hardware Integration

Use this section to describe the configurations associated with the integration of hardware with the system or with other hardware components.

| **CS ID** | **RS ID** | **Specification Description** |
| --- | --- | --- |
| Provide the CS ID | Provide the RS ID(s) to which this specification pertains | Provide a description of the configuration specification. This description should be detailed and concise, in order to properly configure the system.  |

# Abbreviations, Acronyms, and Definitions

|  |  |
| --- | --- |
| **Term** | **Meaning** |
| <Abbreviation, acronym, word, or phrase> | <Definitions> |
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# References

Provide any necessary references to other documents that are made within the document.

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| **Document Title** | **Document ID** | **Document Version** |
| <Document Title> | <Document ID> | <Reference Document Version Number> |
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# Revision History

Provide the document history in this section, with information about the version changes including the author, date of approval, and description of changes.

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| **Version** | **Author** | **Date (DD-MMM-YYYY)** | **Changes** |
| 1.0 | <Author Name> | 02-JAN-2015 | Initial release of the document. |