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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 Design Specification (DS) document is created as part of the implementation of the Test Management system (System ID: 123-ABC-TEST), and it will describe the scope of the software customizations necessary for the operation of the Test Management system.

## Relevant Documents

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

|  |  |
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| **Document Name / Document ID** | **Version** |
| Document Name / Document ID | Version Number of the document |
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# Scope

Describe the scope of this document in this section as it applies to the system. This may be used to specify the exact design elements that are relevant to this document.

This document will describe the specific software customizations that must be developed in order to meet the system specifications that are outlined in the RS and FS documents for this system. The scope of the customizations described in this document encompasses the entirety of the system, as all necessary software customizations and enhancements that require development will be described.

# System Diagram

Use this section to provide a diagram of the system, as necessary. If included, this diagram should be relevant to the design specifications described in this document. For example, this may include a diagram of the system and its interfaces to other systems if customizations are necessary for the data flow.

# Design Factors

## Design Decisions

Describe any vital design decisions or approaches and provide the reasoning behind them.

## Assumptions, Dependencies, and Constraints

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

## System Architecture

Briefly any factors for the system design that relate to the system architecture, if applicable.

## Interfaces

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

# Data Structure

This section should contain information about the structure and relationship to data elements that are used by the customized portions of the system. This may include information about the use of each data element as well. If necessary, this section may be split into several subsections to define additional tables/structures/etc. that pertain to the system customizations.

|  |  |
| --- | --- |
| **Data Element** | **Use** |
| Define the data element | Define the use of the data (creation, update, read-only, deletion, etc.) by the design element. |
|  |  |

# Design Specifications

This section should list the customizations (design features) made 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 customizations in this section. If necessary, include figures/screenshots to provide further details of the intended customizations.

These design specifications should explain the software customizations that must be made to the system. A customization is a system feature or modification that requires custom coding or some special implementation. The exact customization elements should be described 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 Design Specifications ID (DS 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 customizations made to the system. It is divided into subsections in order to align with the other system specification documents.

## System Processes

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

| **DS ID** | **FS ID** | **RS ID** | **Specification Description** |
| --- | --- | --- | --- |
| Provide the DS 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 design specification. This description should be detailed and concise, in order to properly customize the system. |
| DS-SYS-01 | FS-SYS-01 | RS-SYS-01 | Sample description |
|  |  |  |  |

## System Roles and Authorizations

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

| **DS ID** | **FS ID** | **RS ID** | **Role** | **Specification Description** |
| --- | --- | --- | --- | --- |
| Provide the DS 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 design specification. This description should be detailed and concise, in order to properly configure the system. |

## System Access

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

| **DS ID** | **FS ID** | **RS ID** | **Specification Description** |
| --- | --- | --- | --- |
| Provide the DS 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 design specification. This description should be detailed and concise, in order to properly customize the system. |

## Data Use

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

### Electronic Records and Signatures

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

| **DS ID** | **FS ID** | **RS ID** | **Specification Description** |
| --- | --- | --- | --- |
| Provide the DS 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 design specification. This description should be detailed and concise, in order to properly customize the system. |

### Data Security and Data Privacy

Describe any customizations related to data security or data privacy.

| **DS ID** | **FS ID** | **RS ID** | **Specification Description** |
| --- | --- | --- | --- |
| Provide the DS 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 design specification. This description should be detailed and concise, in order to properly customize the system. |

### Audit Trail Functionality

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

| **DS ID** | **FS ID** | **RS ID** | **Specification Description** |
| --- | --- | --- | --- |
| Provide the DS 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 design specification. This description should be detailed and concise, in order to properly customize the system. |

## System Interfaces

Describe any customizations pertaining to interfaces of the system.

| **DS ID** | **FS ID** | **RS ID** | **Data Direction** | **Source / Target** | **Specification Description** |
| --- | --- | --- | --- | --- | --- |
| Provide the DS 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 customization pertains | Provide a description of the design specification. This description should be detailed and concise, in order to properly customize the system. |

## System Performance and Operation

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

| **DS ID** | **FS ID** | **RS ID** | **Specification Description** |
| --- | --- | --- | --- |
| Provide the DS 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 design specification. This description should be detailed and concise, in order to properly customize the system. |

# Abbreviations, Acronyms, and Definitions

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

# 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. |