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| --- |
| **BLUE TEXT**: Instructions regarding a document section. Remove the blue instructional before approving.  **RED TEXT**: Replace with Solution or Project specific content. Change the font color to black.  **BLACK TEXT**: Recommended language that can remain or be changed to meet the Project Team’s needs.  Using Templates   * Always retrieve the current template when creating new documents. * When modifying an existing document compare that document against the current template. Address any differences and update the document. * If certain sections of a template do not apply, enter “Not Applicable” beneath the Section Header and provide appropriate justification. Do not remove Section Headers. If all subsections under a higher level section are not applicable, remove the sub-section headers and include the justification under the remaining high level section header. For example, if there is a section 3, 3.1, 3.1.1, 3.1.2, and 3.2, and all are not applicable, remove the sections 3.1, 3.1.1, 3.1.2, and 3.2 and write Not Applicable” and the rationale under section 3. * If needed, add a section or sections to the appropriate area of the template. * Update the Table of Contents before circulating for approval. * Ensure the version number in the Page Header and the Revision History Table is correct * Ensure the Revision Date in the History Table is set to the date the document was last modified prior to routing for Approval. * Templates may be merged. If so, include all sections of each template.   **-- DELETE THIS INSTRUCTION BOX –** |

NO APPROVALS REQUIRED

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# Purpose

This document defines the SDLC elements necessary to declare Solution Version/Release # is fit for its intended use

# Scope

Enter scope, clearly defining the boundaries of the project. Identify known Master and/or Deployment Configuration Items affected by the project, including both the name and the CMDB ID Number. .

## Exclusions, Assumptions, and Limitations

Document any exclusions, assumptions and limitations

# Intended Use

Describe the business process at a high level and how this solution will automate that process in whole or in part. This may include the known system design or components, such as system architecture, hardware and software requirements and interfaces where applicable. Include dependencies that should be considered during the project. Also include any known site specific deployment and/or release dependencies.

# Requirements

If requirements are to be presented in this Plan document, and there are changes to requirements over the solution lifecycle, it is better to maintain requirements in separate documents for ease of control.

In some situations, such as solutions that are intended to be short lived, requirements are better to be included in this Plan document. If so, use the tables in the following subsections. Otherwise, delete the following subsections and enter the text

Requirements are maintained in Reference to the requirements document.

# Solution Profile

Document the results of the Solution Profiling activity, identifying the solution compliance domains.

If the solution will maintain or process any privacy information, consider;

* + Identify any Privacy records handled by the application
  + Identify the Business electronic signatures satisfied by the application
  + Identify any records this system serves as a System of Record for
  + Whether any audit trail will be included in the solution and, if so, what records it will apply to

# Design and Installation Information

If design specification installation information are to be presented in this Plan document, and there are changes to these over the solution lifecycle, it is better to maintain requirements in separate documents for ease of control.

In some situations, such as solutions that are intended to be short lived, design specifications are better to be included in this Plan document. If so, add that information here. Otherwise, delete enter the text

Design and Installation information are maintained in Reference to the design or installation information documentation here.

# Deliverables List

See Appendix A for a list of required elements for this project and how they will be documented.

For each element listed, Appendix A identifies if there is an existing document which will be produced or updated. Note that for each element type presented in the left-hand column, multiple documents may be created depending on the documentation approach selected by the project team.

# Deployment Strategy

Site specific activities and deliverables, if applicable, shall be determined by the Deployment team. The Site team will develop their own SDLC Planning according to IT procedures.

For GMP Solutions, require that the turnover to the site is documented and that the site QA has read, understands, and accepts the core validation package, including deviations and exceptions.

## Strategic Deployment Approach Overview

1) Configuration approach: Determine if deployments will require/allow local configuration of the solution

2) Deployment model: Determine the approach for deployment, such as phased approach, single deployment effort, and expected resourcing approach, including central and local resources

3) Localization approach: Determine whether, and to what extent, the solution will deliver local language capability

4) Additional characteristics: These may have been provided specific to the solution or deployment scope

## Training Impact

Document training requirements for both IT support resources and impacted clients. Include minimum required training completions rates for initial production use.

## User Access

Identify user access methodology, whether new, transitional, or continuing.

## Support Approach

Describe the process to manage support through the deployment and into “Business as Usual” (BAU). This may address items like the special support mechanisms immediately following certification, transition to BAU support and expected service levels. This may also include more that technical support (business ownership, help desk, etc.). Support requirements may have been generated from the Common Requirements Set (CRS).

This may also include to document or reference applicable security and account management procedures, service level agreements and related contracts and license agreements that govern relationships with service providers and suppliers for the product.

# Verification Approach

Describe how requirements will be verified. Identify how evidence will be captured.

If verification scripts are used, identify all scripts to be created, and any existing scripts to be re-executed, as part of this project. Document or provide location where verification evidence will be stored.

For very simple verification not using a script, executable statement can be in this document

Include formal verification environment information, and other related testing details as appropriate.

Include formal verification environment information.

# Verification Evidence

This section documents the evidence that was collected during the verification effort to demonstrate that requirements were satisfied. This could include checklists, screenshots, reports, and/or executed scripts, defect forms, and defect disposition. If not summarized in this section, indicate where this information is captured.

# Roles and Responsibilities

Describe the Roles and Responsibilities for developing, verifying, and implementing a Solution.

Add rows as necessary. If there are no document specific roles, delete the Table and change the second sentence above to:

“There are no additional roles specific to this document.”

| **Role** | **Responsibilities** |
| --- | --- |
|  |  |

# Terms and Definitions

The IT Glossary of Terms maintains the common terms in this document. Also identify any system or solution specific glossaries. Additional terms and definitions specific to this document are included below:

Include terms and acronyms. Add rows as necessary. If there are no document specific terms, delete the Table and change the second sentence above to:

“There are no additional terms and definitions specific to this document.”

| **Term or Acronym** | **Definition** |
| --- | --- |
|  |  |

# Supporting References

Include supporting references explicitly mentioned in this document, excluding glossaries identified in Section 5. Add rows as necessary. If there are no supporting references, delete the Table and add the following text:

“There are no supporting references specific to this document”

| **Identifier** | **Title** |
| --- | --- |
|  |  |

# Revision History

Update this table each time this document is revised. Where possible, include a Change Number or Project related to the document change. Entries should provide the reader with only an indication of what changed. Include section where a change took place. Add rows as necessary.

| **Version** | **Version Date** | **Revisions** |
| --- | --- | --- |
| 1.0 |  | Enter “Initial Release” or, if this document is replacing a previous document(s) as a release 1.0 of a new document, identify the predecessor documents. |

Appendix: Element Deliverables and Responsibilities Matrix

Complete the table for solution deliverables that will be updated or created for changes in scope. Additional deliverables can be included based on complexity and risk associated with your Solution change. For Elements that do not apply, list N/A with appropriate justification.

Be sure to add all optional deliverables that were generated during the initial planning effort.

In the Comments column, indicate whether a new document will be created or an existing document will be revised. If a document is to be revised, identify the document. Identify any documents that will be leveraged in addition to those that will be created or revised.

| **SDLC Elements** | **Justification / Comments,**  **Document Name and Location** | **Business Unit** | **IT Technical** |
| --- | --- | --- | --- |
| Plan |  |  | C |
| Requirements (include CRS) |  | C | C |
| Design/Installation Information (Custom/Configured) |  |  | C |
| Verification Evidence |  | C | |
| Acceptance Statement |  | A | C A |

C = Create

A = Approve

# Appendix X: Name of Appendix

Enter any supporting information best suited for an appendix. If there is no need for an appendix, remove this header and the page break before it. If there is only one appendix, recommend changing “Appendix X:” to “Appendix:”