Design Specification

<System Name>

This document defines the <system> that is proposed to serve the <organization/department/unit> for the purpose(s) of < >. Implementation of the system is scheduled for <date>. The estimated initial cost of system development is < >.

Written by: _____

Version: _____

Date: _____

Version Control:

Version	Date	Scope of Change	Name	Signature	Chapter/Page

Approval Path:

Name	Company	Date	Signature

T ABLE OF C ONTENTS

Design Specification   **<Organization>**   21/10/2012
<System Name>   Version: M.N
E_GxP_Wdoc01 20121021.docx   **1. Goals**   Page 2 of 9

1. Goals

1.0 Overview – Highlights

1.0.1 Introduction

1.0.2 Document Overview

1.0.3 Glossary

1.1 Client / Main User

1.2 Goals and Objectives

1.3 Problems

1.4 Organizational Context

1.5 Time Frame

1.6 Feasibility and Risks Analysis

1.6.1 Risks – project feasibility

1.6.2 Cost/benefit – business feasibility

1.6.3 Product Risk management

Design Specification   **\<Organization\>**   21/10/2012
\<System Name\>   Version: M.N
E_GxP_Wdoc01 20121021.docx   **2. Application**   Page 3 of 9

2. Application

2.0 Overall Architecture – Highlights

2.0.1 Architecture Design Chart (PM 3.5)

2.1 Main Characteristics

2.1.1 Software Description (PM 3.2)

2.1.2 Operational Environment (PM 3.2.2)

2.1.3 Device Features Controlled by Software (PM 3.2.1)

2.1.4 Constraints

2.1.4.1 Regulation objectives

2.2 Users and Interfacing Systems

2.3 Subsystems

2.4 Operational Interface

2.5 Processes

2.6 Transactions

2.7 Modules (Programs)

2.8 Control Procedures

2.9 Subroutines (Common Objects)

Design Specification   **<Organization>**   21/10/2012
<System Name>   Version: M.N
E_GxP_Wdoc01 20121021.docx   **2. Application**   Page 4 of 9

2.10   Coding Tables

2.11   Data Modeling (Logical Files)

2.12   Database (Physical Files)

2.13   Data Dictionary (Fields)

2.15   Reports (and Queries)

2.16   Input (Forms)

2.18   Safety Requirements

2.18.1 Startup Requirements

2.18.2 Shutdown Requirements

2.18.3 Failure and Recovery Requirements

2.18.4 Sensors and Alarms Requirements

2.18.5 Maximum and minimum ranges of allowed values

2.18.6 Error Handling Requirements

2.18.7 Safety Certification Standards Requirements

2.19   Security and Privacy

2.20   Traceability Matrix

Design Specification   **\<Organization\>**   21/10/2012
\<System Name\>   Version: M.N
E_GxP_Wdoc01 20121021.docx   **2. Application**   Page 5 of 9

2.21 Workload, Performance, and Capacity

2.22 External Interfaces and Links

2.23 Special Requirements

2.24 Design Control Requirements

2.24.1 § 820.30(a) Design Control General

2.24.2 § 820.30(b) Design and development planning

2.24.3 § 820.30(c) Design input

2.24.4 § 820.30(d) Design output

2.24.5 § 820.30(e) Design review

2.24.6 § 820.30(f) Design verification

2.24.7 § 820.30(g) Design validation

2.24.8 § 820.30(h) Design transfer

2.24.9 § 820.30(i) Design changes

2.24.10 § 820.30(j) Design history file

Design Specification <Organization> 21/10/2012
<System Name> Version: M.N
E_GxP_Wdoc01 20121021.docx **3. Technology** and Infrastructure Page 6 of 9

3. Technology and Infrastructure

3.0 Architecture – Overview and Highlights

3.1 Hardware Components

3.2 Software Components

3.3 Peripherals

3.4 Special Equipment

3.5 Off-the-shelf Software

3.6 Consumables

3.9 Communications

3.10 Operating System

3.11 Database Management System (DBMS)

3.13 Development and Maintenance Tools

3.13.1 Development standards and programming standards (PM 3.6 B2)

3.15 Operation and Production Tools

Design Specification   **\<Organization\>**   21/10/2012
\<System Name\>   Version: M.N
E_GxP_Wdoc01 20121021.docx   **4. Implementation**   Page 7 of 9

4. Implementation

4.0 Overview – Highlights

4.1 Parties Involved

4.2 Work Plan

4.2.0 Development Methodology

4.2.1 Overall Development Plan

4.2.2 Detailed Plan

4.3 Next/Immediate Phase

4.4 Ongoing Operation

4.5 Documentation Index

4.5.1 Operational documentation

4.5.2 Development process documentation

4.6 Service and Maintenance

4.6.1 Help desk – Call center

4.6.2 Application maintenance

4.6.3 Infrastructure and technology maintenance

4.6.4 Ongoing Implementation

4.6.5 Everyday costs

4.7 Integration into the Organization – Deployment

4.8 Robustness and Reliability

4.8.1 Testing plan

4.8.2 Availability and survivability

4.8.3 Scope of Validation

4.8.3.1 In-Scope

Design Specification   **<Organization>**   21/10/2012
<System Name>   Version: M.N
E_GxP_Wdoc01 20121021.docx   **4. Implementation**   Page 8 of 9

4.8.3.2 Out-of-Scope

4.8.4 Related Validation

4.9 Configurations

4.9.0 List of configurations (installations)

4.9.1 Development and Testing configuration

4.9.2 Main (central) configuration — primary server

4.9.*X* Additional site configuration / distributed configuration *X*

4.98 Open Issues (and Alternatives)

4.99 Future Plans

Design Specification <System Name> E_GxP_Wdoc01 20121021.docx

<Organization>

5. Cost – Resources

21/10/2012
Version: M.N
Page 9 of 9

5. Cost – Resources

5.0 Executive Summary of Costs — Highlights

5.1 Set-Up Cost (Development and Installation)

5.1.1 First/upcoming version or delivery unit

5.1.2 Additional versions and delivery units

5.1.2.1 <first delivery unit>

5.1.2.*x* <subsequent delivery unit>

5.2 Ongoing Costs

5.2.1 First (upcoming) version or delivery unit

5.2.2 Additional versions and delivery units

5.3 Cost by Configuration

5.4 Price List

5.5 Cost Summary

5.5.1 Cost of ownership

5.5.2 Cost scheduling

5.98 Open Issues (and Alternatives)

5.99 Anticipated Future Costs