**Validation Plan**

**For: (Input System Name)**

**Document Revision History**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision** | **Date** | **Author / Company** | **Description of Revision Changes** |
| 001 |  |  |  |

Table of Contents

[1 Purpose and Scope 4](#_Toc213221076)

[2 Definitions 4](#_Toc213221077)

[3 System Description 4](#_Toc213221078)

[4 Risk Evaluation 4](#_Toc213221080)

[5 Validation Process 4](#_Toc213221081)

[6 Required Procedures 4](#_Toc213221082)

# Purpose and Scope

The purpose of this validation plan is to outline the documents that will be created to ensure the system is properly validated based on risk and complexity of the system.

# Definitions

| Term | Definition |
| --- | --- |
|  |  |
|  |  |

# System Description

## XXX

## 

# Risk Evaluation

|  |  |
| --- | --- |
| **Risk** | **Evaluation** |
| Regulatory Risk |  |
| Complexity Risk |  |

# Validation Process

The following documents will be created during the validation process:

|  |  |
| --- | --- |
| Document Name | Justification for document |
|  |  |

# Required Procedures

## The following Standard Operating Procedures shall be written for the system:

|  |  |
| --- | --- |
| Document Name | Justification for document |
|  |  |