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1 INTRODUCTION

Company will be performing a validation of their ABC system. We will be ensuring the ABC system operates per its intended use.

The intended use statement for the ABC system is as follows: The ABC system will be used by the logistics team at ABC Company for the purpose of tracking inventory operations throughout the product life cycle. This includes, but is not limited to, tracking of inventory receipts, inventory transfers, and shipping of inventoried parts used in ABC Company's regulated products requiring adherence to 21 CFR Part 11.

1.1 PURPOSE

The purpose of this ABC Validation Plan is to define the roadmap of validation activities as well as the validation deliverables to support the successful validation of the ABC system. Furthermore, this ABC Validation Plan will be the governing document for the validation of the ABC System.

1.2 SCOPE

This document applies to the ABC validation. Include Version.

1.2.1 In-Scope

Describe the scope of the Validation efforts. For example, which modules are in scope and what company sites and divisions are in scope.

Be sure to include all elements and interfaces that touch/use this system as their use will be called upon to support the validation efforts.

1.2.2 Out-of-Scope

Describe what areas are out of scope of the Validation efforts. For example, what modules are out of scope, what company sites and/or divisions are out of scope.

1.3 DEFINITIONS AND ABBREVIATIONS

The following definitions and abbreviations are used in this document.

Table 1: List of Definitions and Abbreviations

Abbreviation / Definition	Description
CSV	Computer System Validation
DR	Disaster Recovery
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
SOP	Standard Operating Procedure
TM	Traceability Matrix
Approver	Your signature attests that this VP was reviewed by the appropriate individual(s), and to attest they understand and acknowledge their responsibility. By signing you are approving this VP for the system documented within.
Author	Your signature indicates that this VP has been prepared in accordance with existing project standards and adequately meets the requirements for the system documented within.
Reviewer	Your signature indicates that you have reviewed this VP and based on your area of responsibility and discipline it is in accordance with existing project standards and adequately meets the requirements for the system documented within. You recommend approval of this document.
VP	Validation Plan