

---

## Master Plan

# Computer System Validation



**Revision 1.02  
December 2005**

This is an example of a Master Plan. It is a proposal and starting point only. The type and extent of documentation depends on the process environment. The proposed documentation should be adapted accordingly and should be based on individual risk assessments. There is no guarantee that this document will pass a regulatory inspection.


**Publication from  
[www.labcompliance.com](http://www.labcompliance.com)  
*Global on-line resource for validation and compliance***

*Copyright by Labcompliance. This document may only be saved and viewed or printed for personal use. Users may not transmit or duplicate this document in whole or in part, in any medium. Additional copies and licenses for department, site or corporate use can be ordered from [www.labcompliance.com/solutions](http://www.labcompliance.com/solutions).*

*While every effort has been made to ensure the accuracy of information contained in this document, Labcompliance accepts no responsibility for errors or omissions. No liability can be accepted in any way.*

Labcompliance offers books, master plans, complete Quality Packages with validation procedures, scripts and examples, SOPs, publications, training and presentation material, user club membership with more than 300 downloads and audio/web seminars. For more information and ordering, visit [www.labcompliance.com/solutions](http://www.labcompliance.com/solutions).

---

<b>Company Name:</b>	
----------------------	---

<b>Controls:</b>	
Superseded Document	N/A, new
Reason for Revision	N/A
Effective Date	December 1, 2005

<b>Signatures:</b>	
Author	<p>I indicate that I have authored or updated this Master Plan according to applicable business requirements and our company standards.</p> <p>Name: _____</p> <p>Signature: _____</p> <p>Date: _____</p>
Approver	<p>I indicate that I have reviewed this Master Plan, and find it meets all applicable business requirements and that it reflects the procedure described. I approve it for use.</p> <p>Name: _____</p> <p>Signature: _____</p> <p>Date: _____</p>
Reviewer	<p>I indicate that I have reviewed this Master Plan and find that it meets all applicable quality requirements and company standards. I approve it for use.</p> <p>Name: _____</p> <p>Signature: _____</p> <p>Date: _____</p>

## Table of Contents

<b>1. Introduction, Scope and Objectives of this Document</b> .....	<b>7</b>
1.1 Introduction .....	7
1.2 Scope.....	7
1.2.1 Enterprise Level .....	7
1.2.2 System Level .....	7
1.3 Objectives .....	8
<b>2. Policy</b> .....	<b>8</b>
<b>3. Related Documents and Activities</b> .....	<b>8</b>
3.1 Other Master Plans .....	8
3.1.1 Risk Management Master Plan (17.1).....	9
3.1.2 Network Qualification Master Plan (17.2) .....	9
3.1.3 21 CFR Part 11 Compliance Master Plan (17.3) .....	9
3.1.4 Security Master Plan (17.4) .....	9
3.1.5 Training Master Plan (17.5) .....	9
3.2 Procedures .....	10
3.3 Checklists, Forms, Templates, Examples .....	10
3.4 Validation Project Plans .....	11
<b>4. Responsibilities</b> .....	<b>11</b>
4.1 Validation Steering Committee .....	11
4.2 System Owner .....	12
4.3 Validation Project Team.....	12
4.4 IT Department.....	13
4.5 Quality Assurance.....	13
4.6 Regulatory Affairs .....	14
4.7 Operations (User Representatives).....	14
4.8 Documentation Department .....	14
4.9 Suppliers .....	14
4.10 Plant Maintenance .....	15
<b>5. Computer Systems to be Validated</b> .....	<b>15</b>
5.1 General Characteristics of Systems to be Validated .....	15
5.2 Examples .....	15