

# Principles of Equipment Qualification

A Guide for Drug and Device Manufacturers

## Table of Contents

### Introduction

<b>Official Requirements and Agency Expectations</b> .....	<b>5</b>
Legal Framework and Responsibilities.....	7
Who is Responsible for Qualification?.....	7
Qualification by Third Parties .....	7
Documentation of Qualification .....	8
Risk-based Approach .....	9
<b>Design Qualification</b> .....	<b>11</b>
Factory Acceptance Test/Site Acceptance Test (FAT/SAT).....	14
<b>Installation Qualification</b> .....	<b>15</b>
<b>Operational Qualification</b> .....	<b>17</b>
<b>Performance Qualification</b> .....	<b>19</b>
<b>Requalification</b> .....	<b>20</b>
Requalification After Major Changes.....	20
Periodic Review and Periodic Requalification .....	21
Contents and Execution .....	22
<b>Activities for Preparation of a Qualification</b> .....	<b>24</b>
Procurement Procedures .....	25
Project Start-up.....	26
Compilation of Requirements.....	27
Bidding Phase .....	27
Detail Planning.....	28
Design Qualification.....	28
Technical Acceptance Testing and Qualification.....	28

Handover .....	29
Responsibilities.....	29
Qualification Team .....	30
Risk Analysis .....	31
Risk Analysis in the Equipment Life Cycle.....	32
Evaluation of Risks .....	34
Execution of a Risk Analysis.....	35
<b>Qualification Documentation .....</b>	<b>37</b>
Content Requirements .....	39
Validation and Qualification Master Plan .....	40
Regulatory Requirements.....	41
Mandatory Contents of a QMP.....	42
Change Control .....	45
Structure of Qualification Documents .....	47
Qualification Test Protocols.....	48
Qualification Reports .....	49
Technical Documentation .....	50
<b>Appendices .....</b>	<b>52</b>
A. EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Annex 15: Qualification and Validation	
B. ICH Q9: Quality Risk Management	