

# Process Validation

A Guide for Devicemakers

## Table of Contents

### Introduction

**Key Concepts: Regulatory Framework for Process Validation ..... 5**

When to Validate a Process ..... 8

How to Validate a Process ..... 11

**Regulatory Compliance and FDA Inspections ..... 15**

What to Expect During an Inspection ..... 15

QSIT Sampling Plans ..... 17

**Installation Qualification..... 19**

Setting a Maintenance Schedule ..... 19

FDA Warning Letters ..... 20

ISO Requirements..... 22

OSHA Standards ..... 23

IQ Checklists ..... 24

Total Productive Maintenance ..... 26

**Statistical Tools for Process Validation ..... 27**

The Process Model ..... 28

Statistical Process Control ..... 29

Process Capability Indices ..... 31

Process Performance Indices ..... 33

Valid Statistical Techniques ..... 33

Attribute Acceptance Sampling..... 33

**Operational Qualification ..... 35**

Design Transfer ..... 35

Setting Limits and Performing Challenge Tests..... 36

OQ Checklist..... 39

<b>Performance Qualification .....</b>	<b>41</b>
Process Monitoring and Revalidation.....	41
PQ Checklist.....	42
<b>The Process in Production .....</b>	<b>43</b>
Hazard Analysis and Critical Control Points .....	43
Risk Management.....	45
<b>Appendices.....</b>	<b>47</b>
A. 21 CFR Part 820 – Quality System Regulation	
B. FDA Medical Device Quality Systems Manual: A Small Entity Compliance Guide (This item is on the CD in the back of the report.)	
C. Global Harmonization Task Force Quality Management Systems – Process Validation Guidance	
D. FDA Compliance Program Guidance Manual, Program 7382.845: Inspection of Medical Device Manufacturers	
E. Quality System Inspection Technique (QSIT) manual	
F. 29 CFR Part 1910.212: General Requirements for All Machines	
G. 29 CFR Part 1910.147: The Control of Hazardous Energy (Lockout/Tagout)	