

Regulatory Challenges of Device Acceptance

Table of Contents

Introduction	
Sampling Plans.....	5
Warning Letters	7
Procedures for Acceptance	9
Acceptance Records.....	11
Data Types	15
Acceptance Status.....	17
Purchasing Flow – Know What's Happening Upstream	19
Urgent Use	27
In-Process Inspection	29
Conclusion	31
Appendix.....	33
A. Checklist for Acceptance Activities	