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Nota di contenuto	Front cover -- Contents -- Notices -- Trademarks -- Preface -- Assumptions and other key points to consider -- The team that wrote this redbook -- Become a published author -- Comments welcome -- Qualification Plan -- Document approval -- Change history -- Part 1 Qualification Plan information -- Chapter 1. Introduction -- 1.1 Scope -- 1.2 Structure of the Qualification Package -- 1.3 Acceptance criteria -- 1.4 Roles and responsibilities -- 1.4.1 Management roles -- 1.4.2 Qualification and project team roles -- Chapter 2. Infrastructure description -- 2.1 Technical design documents -- 2.2 Infrastructure identification/Inventory list -- 2.3 Equipment Environmental requirements -- 2.4 Infrastructure (equipment) functional description -- Chapter 3. Installation qualification preparation -- 3.1 Validation team training -- 3.1.1 General Regulatory Training/21CFR11 basics -- 3.1.2 Good Documentation Practices training -- 3.1.3 Qualification Plan/Protocol training -- 3.1.4 Testing Procedures training -- 3.2 Validation Team training/Qualifications Records -- 3.3 Signature Log -- 3.4 Installation manuals and procedures -- Chapter 4. Risk assessment -- 4.1 Risk identification -- 4.2 Risk mitigation -- 4.3 Applying risk to the testing protocol -- Chapter 5. Testing protocol -- 5.1 Protocol contents -- 5.2 Roles and responsibilities -- 5.3 Infrastructure installation/Configuration verification -- 5.4 Environmental conditions verification -- 5.5 Documentation verification

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