

## Elements To Consider - Computer Systems Validation Plan



**Allan Marinelli**

By

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Pre-Implementation Phase: System Requirement Specifications (User Requirement Specifications, Functional Specifications, and Design Specifications) Software Configuration Specifications Installation Qualification Package from the Vendor (Shrink Wrap or Wrapper Approach under the Test Environment) Installation Qualification Package from the Vendor (Shrink Wrap or Wrapper Approach under the Production Environment) Functional Risk Assessment (FRA) Operational Qualification Package from the Vendor (Shrink Wrap or Wrapper Approach under the Test Environment) Traceability Matrix Optional: Interim...

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