3.3.2 Network Qualification Plan

A network qualification plan describes a company's approach for qualifying IT infrastructure and networks. It is used as a source for project specific individual qualification project plans.

3.3.3 Risk Management Master Plan

A risk management master plan describes a company's approach for risk assessment and risk management, for example, to comply with 21 CFR Part 820 and the FDA's Part 11 Guidance: Scope and Applications. It is used as a source for project specific individual risk management project plans.

3.3.4 Security Master Plan

A security master plan describes a company's approach to ensure security and limited and authorized access to buildings, critical areas within buildings, e.g., data centers and to computers and data.

3.4 Written Procedures

Routine activities in regulated environments should follow written procedures. These are typically defined as standard operating procedures. Examples are:

3.4.1 Training for GxP, 21 CFR Part 11 and Computer Validation.
3.4.2 Risk Assessment used in GxP Environments.
3.4.3 Part 11 Scope and Controls.
3.4.4 Testing File Integrity of E-Mail Attachments.
3.4.5 Validation of Commercial Computer Systems.
3.4.6 Risk-Based Validation of Computer Systems.
3.4.7 Auditing Computer Systems.
3.4.8 Retention and Archiving of Electronic Records.
3.4.9 Change Control of Computer Systems.
3.4.10 Scanning of Paper Documents for FDA Compliant Archiving.
3.4.11 Assessment of Suppliers of Software and Computer Systems.

3.5 Checklists, Forms, Templates, Examples

Checklists, forms, templates and examples help implement individual projects effectively and consistently. Examples are:

3.5.1 Checklist/Gap Analysis: 21 CFR Part 11.
3.5.2 Checklist/Gap Analysis: Using Computers in FDA Regulated Environments.
3.5.3 Template/Examples: User Requirement Specifications for Chromatographic Data Systems.
3.5.4 Example: Project Schedule – 21 CFR Part 11.
3.5.5 21 CFR Part 11 Implementation - Step by Step.
3.5.6 Case Studies: 21 CFR Part 11 – Scope and Controls.
3.5.7 Template/Examples: Network Infrastructure and Computer System Identification.
3.5.8 Letter to the FDA about using Electronic Signatures.

3.6 Step by Step - Implementation

This document helps to integrate all requirements, procedures and documents into a single project. It is a step-by-step instruction guide and is hyperlinked to supporting documents such as regulations, training tools, master plans, procedures and forms. For more sophisticated projects, a simple word document can be replaced by more intelligent software.

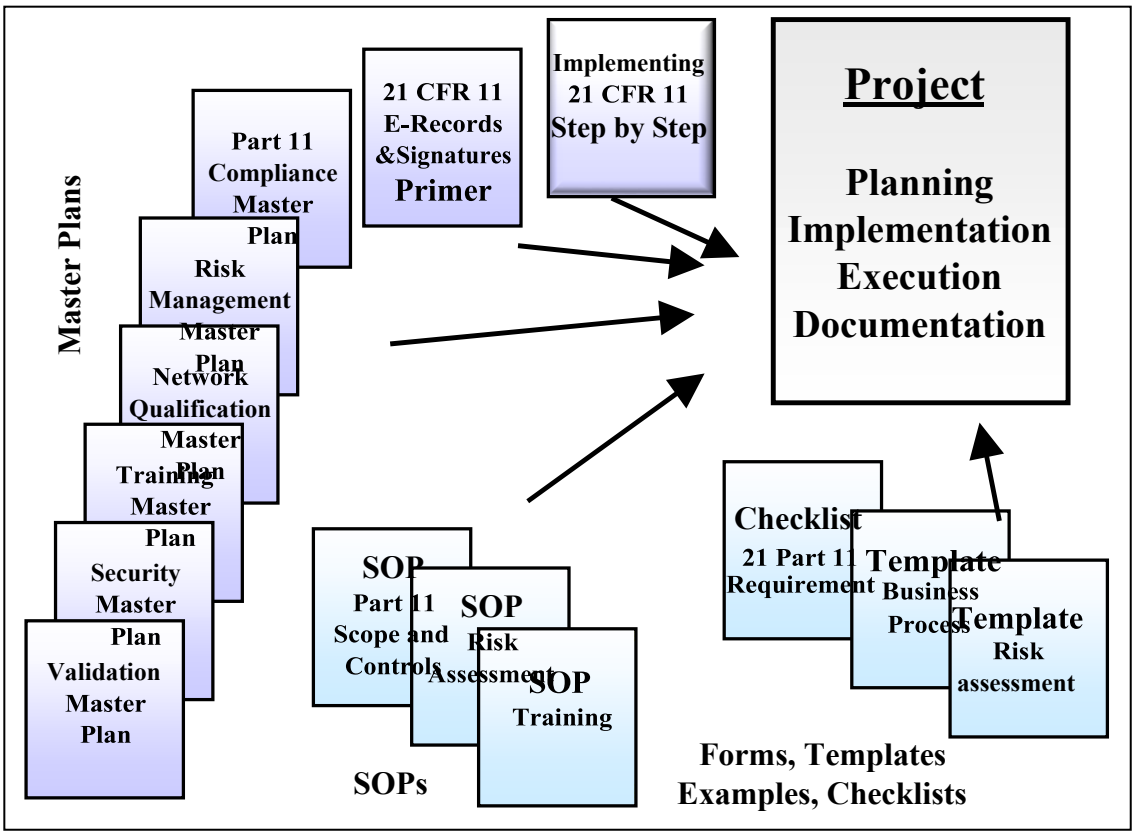

Figure 1: Cross functional documentation for Part 11

4. Project Team

Implementing 21 CFR Part 11 in an organization will affect different departments. It also requires strong management support to ensure ongoing resources and motivational support. Therefore a strong project team with a good project leader is important.

Project members should come from Operations (manufacturing, laboratories), IT, QA, Documentation and Regulatory Affairs. Members should be knowledgeable in particular business areas or about particular projects.

Project members should form and lead sub-teams within their area to discuss and agree on department specific Part 11 issues.

For each team member a back-up should be identified mitigating the risk of unavailability of core members. A list should be created and maintained with contact information of core members and back-ups.

4.1 Project Sponsor

The project sponsor should be a member of management. Responsibilities include ensuring ongoing funding of the projects.

4.2 Project Leader

The project leader owns the project. He/she should have good communication skills and experience in project management. Responsibilities include:

- Drafts and updates of project plans.
- Ensures ongoing progress of the project according to the project plan.
- Reports the progress of the plan to the project sponsor and management.
- Selects project team members together with functional supervisors of affected departments.
- Ensures necessary trainings of project team members.
- Leads the project team and team meetings.
- Resolves issues within the project team.

4.3 IT

IT plays an important role for Part 11 compliance. Responsibilities include:

- Advices and approves purchasing for computer hardware, operating systems software and network devices.
- Together with QA develops procedures for infrastructure qualification.
- Advices and approves purchasing of electronic record management systems.

- Develops and maintains security procedures.
- Administrates user IDs and encrypted passwords for authorized access to systems.
- Develops and delivers training related to security procedures and other IT related issues.
- Forms and leads the department's Part 11 project sub-team.

4.4 Quality Assurance

- Reviews procedures and other documents for compliance with internal standards and regulations.
- Develops training material and delivers training about regulations and internal standards.
- Audits computer systems for compliance with procedures.

4.5 Regulatory Affairs

- Communicates with regulatory agencies to get the most accurate information on regulations, guidelines and their interpretations.
- Updates the project team on regulations, guidelines and their interpretations.

4.6 Quality Control

- Ensures that all software and computer systems in the department are listed in the Part 11 system inventory list.
- Actively participates in the definition of Part 11 requirements for all software and computer systems in the department.
- Ensures that all systems are brought into Part 11 compliance according to the project schedules.
- Ensures that QA and IT are notified before purchase of new systems.
- Forms and leads the department's Part 11 project sub-team.

4.7 Manufacturing/Laboratories

- Ensures that all software and computer systems in the department are listed in the Part 11 system inventory list.
- Actively participates in the definition of Part 11 requirements for all software and computer systems in the department.
- Ensures that all systems are brought into Part 11 compliance according to the project schedules.
- Ensures that QA and IT are notified before purchase of new systems.
- Forms and leads the department's Part 11 project sub-team.