# 21 CFR Part 11 Compliance What Every Project Manager Needs to Know Related Reads and Resources

Here’s a detailed, **project manager’s checklist** for managing projects that must comply with **FDA 21 CFR Part 11**—perfect for life sciences, pharma, biotech, or med device environments. You can include this in your blog as a downloadable asset or as a section at the end of the article.

## ✅ Project Manager’s 21 CFR Part 11 Compliance Checklist

Use this checklist throughout the **project lifecycle** to ensure electronic systems meet 21 CFR Part 11 standards.

**🔍 1. Initiation & Planning Phase**

* Confirm if 21 CFR Part 11 applies to this project/system
* Identify impacted processes (e.g., document management, audit trails, electronic signatures)
* Include compliance and validation activities in the project scope
* Engage Regulatory, QA, and Validation SMEs early
* Conduct risk assessment related to electronic records and signatures
* Define validation strategy (e.g., IQ/OQ/PQ approach)
* Ensure vendor qualification is part of procurement process
* Review system requirements against 21 CFR Part 11 technical controls

**🛠 2. Execution Phase**

* Validate software installation and configuration (Installation Qualification – IQ)
* Test system functionality (Operational Qualification – OQ), especially:
	+ Electronic signature workflows
	+ Access control and user authentication
	+ Audit trail capture and review
	+ Data retention and retrieval
* Perform Performance Qualification (PQ) with real-world scenarios
* Document test cases, outcomes, and deviations in a traceable format
* Coordinate with vendor for any off-the-shelf validation packages
* Train end users on compliant system usage and security practices
* Ensure SOPs are updated to reflect system changes

**📊 3. Monitoring & Controlling Phase**

* Monitor validation test completion and issue resolution
* Track change controls through a compliant workflow
* Maintain configuration management and version control
* Conduct internal audits to verify compliance is being maintained
* Ensure all role-based access is active and appropriate
* Review audit trails and system logs periodically

**🧾 4. Closure & Transition**

* Validate that final system configuration matches documentation
* Archive validation documentation in a secure, retrievable format
* Finalize SOPs and training records
* Conduct handoff meeting with operations/support team
* Ensure backup, recovery, and disaster recovery plans are tested and documented
* Retain all compliance documentation for audit readiness

## 📁 Bonus: Supporting Documentation Checklist

**Project managers overseeing 21 CFR Part 11–compliant systems should ensure the following documentation is created, reviewed, and retained:**

* **✅ Validation Master Plan (VMP)**
* **✅ User Requirements Specification (URS)**
* **✅ Functional Specification (FS)**
* **✅ Design Specification (DS)**
* **✅ Risk Assessment Matrix**
* **✅ Installation Qualification (IQ) Protocol & Results**
* **✅ Operational Qualification (OQ) Protocol & Results**
* **✅ Performance Qualification (PQ) Protocol & Results**
* **✅ Test Scripts and Traceability Matrix**
* **✅ Training Records for All Roles**
* **✅ Standard Operating Procedures (SOPs)**
* **✅ Change Control Forms and Logs**
* **✅ Audit Trail Review Procedures & Logs**
* **✅ System Access Control Documentation**
* **✅ Backup and Disaster Recovery Plans**
* **✅ Final Validation Summary Report (VSR)**
* **✅ Vendor Qualification Documentation (if using third-party systems)**

## 📚 Related Reads for Project Managers

### 1. [FDA: Title 21 CFR Part 11 – Electronic Records; Electronic Signatures](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11)

Official source for the regulation itself.
Covers scope, implementation, and technical standards directly from the U.S. FDA.

### 2. [ISPE GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems](https://ispe.org/publications/guidance-documents/gamp-5)

Industry gold standard for computer system validation (CSV).
Outlines a lifecycle approach to system implementation and compliance aligned with FDA expectations.

### 3. [MasterControl Resource Center – 21 CFR Part 11 Explained](https://www.mastercontrol.com/quality/21-cfr-part-11/)

Simplifies complex Part 11 concepts for business leaders and PMs.
Includes whitepapers, FAQs, and compliance checklists for document control and e-signatures.

### 4. [Sparta Systems – TrackWise Digital and Compliance Enablement](https://www.spartasystems.com/products/trackwise-digital/)

Overview of a cloud-based EQMS platform designed to meet Part 11 requirements.
Helpful if your project includes quality systems implementation or upgrade.

### 5. [ValGenesis – Computer Systems Validation & Part 11 Strategy](https://www.valgenesis.com/)

Focuses on digital validation lifecycle management tools.
Ideal for understanding automation and traceability in validation-heavy environments.

### 6. [PDA Technical Report No. 80: Data Integrity Management System](https://www.pda.org/bookstore/product-detail/5349-data-integrity-management-system-tr-80)

Details how to maintain integrity of electronic records under Part 11.
Offers structured guidance for data governance and audit trail design.

### 7. [Lifescience Leader: Best Practices in FDA Compliance Projects](https://www.lifescienceleader.com/)

Features expert interviews, case studies, and technology trends.
Ideal for project managers leading initiatives across R&D, QA, and manufacturing.

### 8. [CSV Training: Computer System Validation – LinkedIn Learning Course](https://www.linkedin.com/learning/)

Look for **Computer System Validation (CSV) for FDA Compliance** or related topics.
Practical for project managers new to regulated systems or transitioning from non-GxP environments.

## 📚 Related Reads on ManagingProjectsTheAgileWay.com

1. [**Security Considerations for Infrastructure vs Application Projects**](https://www.managingprojectstheagileway.com/2468354_security-considerations-for-infrastructure-vs-application-projects) ***Explore how different project types approach security and compliance—key for understanding validation planning.***
2. [**The Project Manager’s Crucial Role in Project Risk Management**](https://www.managingprojectstheagileway.com/1759500_the-project-manager-s-crucial-role-in-project-risk-management) ***Learn how to proactively identify and mitigate regulatory and compliance risks in your project lifecycle.***
3. [**Driving Project Success: Lessons from Leading Agile Teams Across Regulated Environments**](https://www.managingprojectstheagileway.com/2248618_driving-project-success-lessons-from-leading-agile-teams-across-industr) ***A practical guide to leading Agile teams while navigating FDA requirements and documentation rigor.***
4. [**Top 12 KPIs Every Project Manager Should Track for Project Success**](https://www.managingprojectstheagileway.com/2482967_top-12-kpis-every-project-manager-should-track-for-project-success) ***Includes compliance-related metrics like documentation accuracy, defect leakage, and validation timelines.***

## 📘 Recommended External Resources

* [**FDA: 21 CFR Part 11 — Electronic Records; Electronic Signatures**](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11) ***Official regulatory text from the U.S. FDA.***
* [**ISPE GAMP 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems**](https://ispe.org/publications/guidance-documents/gamp-5) ***Industry best practices for system validation—essential for life sciences PMs.***
* [**PDA Technical Report No. 80: Data Integrity Management System**](https://www.pda.org/bookstore/product-detail/5349-data-integrity-management-system-tr-80) ***Guidance on how to manage data integrity across regulated systems.***
* [**Sparta Systems – TrackWise Digital**](https://www.spartasystems.com/trackwise/) ***Explore how EQMS platforms like TrackWise support 21 CFR Part 11 compliance.***
* [**MasterControl 21 CFR Part 11 Resource Center**](https://www.mastercontrol.com/quality/21-cfr-part-11/) ***Useful whitepapers, webinars, and FAQs on electronic records and validation.***
* [**ValGenesis – Validation Lifecycle Management System**](https://www.valgenesis.com/) ***A digital platform built for managing validation and Part 11 documentation.***