

CFR PART 11 – STEP BY STEP APPROACH

- Form a task force with members from the IT department, if existing, QA personnel and laboratory staff.
- Decide whether you intend to use electronic signatures. Report the decision to the FDA, for example: “This is to certify that "My Company" intends that all electronic signatures executed by our employees, agents or representatives, located anywhere in the world, are the legally binding equivalent of traditional handwritten signatures”.
- Create awareness for Part 11 among all employees, especially on the accountability of electronic signatures. For example, people should sign something like this: “I understand that electronic signatures are legally binding and have the same meaning as handwritten signatures”.
- Make an inventory of all computers in your organization or department that generate records required by a predicate rule or records that are used to demonstrate compliance with a predicate rule.
- Develop a master plan and SOP for risk assessment.
- Determine the risk category for each system.
- Define a priority schedule to bring all computer systems into Part 11 compliance.
- Develop a procedure on how to define Part 11 controls.
- Define Part 11 requirements for each system.
- Do a gap analysis to determine missing functionality and procedures for systems in 7. Develop an implementation plan to bring systems as identified in 7 into Part 11 compliance.
- Estimate costs for the systems as identified in 7 and for the whole project. Develop procedures for limited system access to authorized individuals. This should include a password policy.
- Develop procedures for implementing audit trails, to ensure data integrity and for long-term archiving with data retrieval throughout the entire retention period.
- Get management support and funding for the project.