



21 CFR Part 11 Compliance Checklist

If your company is planning to convert to an automated system for managing documents and business processes, make sure that the new system meets the needs outlined in the following 21 CFR Part 11 compliance checklist:

- ☐ **Authentic Electronic Records:** 21 CFR Part 11 requires an assurance of the authenticity of electronic records. To maintain compliance, system administrators need to have a system that includes functionality to delineate user permissions for every document vault in the system. The system must also be able to generate an audit trail for any captured document.
- ☐ **Multiple Password Authentication:** The potential for a signer to repudiate an approval must be minimized. An automated system meeting the requirements of the 21 CFR Part 11 checklist should require users to enter two passwords to approve any type of document collaboration, one password for login and another for approvals.
- ☐ **Computer System Validation:** The FDA requires that any electronic system used to manage compliance-oriented documents and processes must be validated. Implementation of an electronic system with a proven track record of performance and validation can drastically reduce the time and money a company devotes to its overall validation efforts. Depending on the company's internal corporate policies and risk evaluations, validation can be as simple or as thorough as the electronic system will allow.
- ☐ **Integrated Personnel Training:** According to 21 CFR Part 11, all users who have been approved to use the electronic system must be sufficiently trained to perform their assigned duties. A system that incorporates automated training capabilities can automatically trigger new training courses when an essential quality document is revised in order to ensure sustained organizational compliance with 21 CFR Part 11. A system with a proven training component should also be able to automate the follow-ups and escalations of past-due training tasks, create audit trails for all training information, and maintain employee training records.
- ☐ **Effective Change Control Management:** Document controls must provide revision controls, change controls, and time-based system modifications. In these regards, an organization's internal business processes and specific corporate protocols must be evaluated in order to determine what is needed to formulate an individualized 21 CFR Part 11 compliance checklist.

- **Electronic Signatures:** 21 CFR Part 11 compliance requirements also mandate that signed electronic records include the following data: name, date and time of signing, and meaning of signature. An effective electronic system should provide fields for all such required information to ensure 21 CFR Part 11 compliance as well as for supplementary information (if such fields are desired for use).
- **Interconnected Records/Signatures:** Electronic (and handwritten) signatures must be able to be linked to their corresponding electronic records. An established electronic system should easily be able to link every signature with a specified record.

MasterControl Solutions Meet the Criteria of the 21 CFR Part 11 Compliance Checklist

Within one year of 21 CFR Part 11 first going into effect, MasterControl introduced the industry's first document management software solution specifically designed to help life sciences organizations comply with the regulations delineated in 21 CFR Part 11. Now, more than 1,000 companies worldwide rely on MasterControl's integrated business process management solutions to achieve and sustain 21 CFR Part 11 compliance. Not only do MasterControl's solutions meet each of the components listed in the 21 CFR Part 11 compliance checklist above, but they also streamline and automate GxP processes and facilitate effective management of document control, change control, training management, audits, corrective/preventative action (CAPA), customer complaints, and other quality processes, all within a single Web-based application.

Specific Sections of 21 CFR Part 11 Addressed by MasterControl

Here are just a few examples of particular sections of the regulation that MasterControl can help you cross off your 21 CFR Part 11 compliance checklist:

- **Part 11 Section 11.10** - MasterControl software solutions ensure authenticity, integrity, and confidentiality of electronic records
- **Part 11 Section 11.10** - MasterControl minimizes the possibility of repudiation by signer
- **Part 11 Section 11.10 a** - The system can be fully validated according to the FDA's guidelines
- **Part 11 Section 11.10 i** - MasterControl facilitates proper training (and tracking of training) for system users
- **Part 11 Section 11.10 k** - MasterControl provides appropriate controls over system documentation including access to documentation for system operation and revision and change control procedures

- **Part 11 Section 11.50 a** - MasterControl ensures that electronically signed documents contain the name of the signer, time and date of the signing, and the meaning of signature
- **Part 11 Section 11.70** - MasterControl allows electronic signatures and handwritten signatures executed to electronic records to be linked to their respective electronic records

About MasterControl

MasterControl Inc. creates software solutions that enable life science and other regulated companies to deliver life-improving products to more people sooner. MasterControl's integrated solutions accelerate ROI and increase efficiencies by automating and securely managing critical business processes throughout the entire product lifecycle. More than 1,000 companies worldwide, ranging in size from five employees to tens of thousands, rely on MasterControl cloud solutions to automate processes for new product development, clinical, regulatory, quality management, supplier management, manufacturing and postmarket surveillance. MasterControl solutions are well-known for being scalable, easy to implement, easy to validate and easy to use. For more information, visit www.mastercontrol.com.

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