

# Calibration Manager and 21 CFR Part 11 Electronic Signatures and Records

Migrating to 21 CFR Part 11 requirements has become a priority for many FDA regulated companies. This is no longer a concept for many of them, but rather tangible guidelines to be implemented into daily processes. This paper contains information on the ruling, as well as how Calibration Manager, the standard in calibration management software for FDA regulated software, meets the requirements of 21 CFR Part 11.

## OVERVIEW

Effective August 20, 1997, the Food and Drug Administration (FDA) issued 21 CFR Part 11, setting forth criteria under which the agency will accept, under certain circumstances, electronic records and electronic signatures as equivalent to paper records and handwritten signatures. Part 11 allows firms to take advantage of electronic technology, and to have electronic records considered equivalent to traditional paper records.

The use of electronic documents and signatures is voluntary. Part 11 does not mandate the use of electronic technology, but it does allow companies to take continued advantage of productivity gains inherent in new technologies, while remaining in compliance with FDA regulations.

Part 11 sets forth the conditions under which electronic records and electronic signatures will be considered equivalent to their traditional counterparts. Systems will need procedures and controls to ensure that electronic records are accurate and complete.

Such systems will need to be validated to ensure accuracy, reliability, and consistency, and they will need security checks and audit trails to verify that records are accurate and that changes are recorded. Electronic signatures are subject to additional requirements, to ensure that a signature can only be used by its genuine owner, and that the act of signing a document electronically is equivalent to a traditional handwritten signature.

## CALIBRATION MANAGER

Calibration Manager is a database application designed specifically to help meet the calibration record-keeping requirements of 21 CFR Parts 211 and 820. The features and functions of Calibration Manager that help ensure compliance with these two predicate rules will also simplify compliance with Part 11. These features include enforcing password expiration, tracking of all electronic signature activity, configuring the electronic signature settings to mandate use, and maintaining data integrity. In addition, Calibration Manager's Electronic Signature feature has been designed to help you meet the requirements set forth in Part 11.



## CALIBRATION MANAGER FEATURES THAT ADDRESS 21CFR PART 11 ER/ES

This section lists specific requirements from Part 11 and the Calibration Manager features that address those requirements. Please consult the full text of Part 11 for all requirements for compliance.

- *Part 11.10a - Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine. Such procedures and controls shall include the following: Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.*

We consider Calibration Manager 4.0 to be a closed system, due to the fact that all electronic records contained within the system are protected by a secure front-end. We offer Validation Protocol and SQA products to help validate our system. The Audit Trail captures creation, modification and deletion of all electronic records containing calibration data. Any calibration data record that has been first signed electronically and then modified has a specific 'status', indicating that a change was made to that record.

- *Part 11.10b - The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.*

Electronic form - All calibration data may be viewed through the Calibration Manager user interface. All signed calibration data records are visibly linked to their signatures by way of a predefined tab on the screen. Human readable - The product ships with predefined reports containing calibration data records and their corresponding electronic signature(s). Reports can also be exported to other formats.

- *Part 11.10c - Protection of records to enable their accurate and ready retrieval throughout the records retention period.*

Calibration Manager has a two-tiered security system, requiring the user to enter a valid User ID and Password in order to gain access into the system. In addition, users may be given access to only specific sets of records within the system. Records may be archived by an administrator. The



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architecture of the Calibration Manager data allows for records to be backed up on a regular basis. Blue Mountain provides an upgrade utility, as well as technical support, in order to migrate existing calibration data into the new version of Calibration Manager.

- *Part 11.10d - Limiting system access to authorized individuals.*

Calibration Manager requires a user to enter a valid User ID and Password in order to gain access into the system. Calibration Manager logs changes to user security records.

- *Part 11.10e - Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.*

Calibration Manager tracks the creation, modification and deletion of all calibration data contained within the system. All audit trail entries are linked to their parent calibration data record and can be viewed while viewing the parent record. Calibration Manager also tracks changes made to system and dataset settings. These settings include: general system-level security options, system-level user security accounts, system-level configuration options, general dataset-level security options, dataset-level user security accounts and dataset-level configuration options. Each entry into the audit trail includes the date and time of the event, the type of action taken (addition, modification, deletion), the identity of the user who took the action, and if a record was modified, the field(s) changed and the old and new value(s).

- *Part 11.10f - Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.*

Calibration Manager has two types of record validation settings: The administrator may select a specific number of signatures to be required before a record can be 'valid'. A status indicator will show if a record is not valid. The administrator may configure a field to be a 'required' field. If a field is required, the record cannot be saved until data is entered into that field.

- *Part 11.10g - Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.*



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Calibration Manager has a two-tiered security system, requiring the user to enter a valid User ID and Password in order to gain access into the system. In addition, users may be given access to only specific sets of records within the system. Within a certain set of records, a user may also be given specific operational rights (add record, edit record, delete record, electronically sign a record, etc.). Calibration Manager can be set up to time-out after a specified period of time, preventing an unauthorized user from accessing the system while a logged in user is away from his/her desk.

- *Part 11.10k - Use of appropriate controls over systems documentation including: (1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance. (2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.*

Any systems documentation provided to the user in electronic form cannot be changed by the user.

- *Part 11.50a/b - Signed electronic records shall contain information associated with the signing that clearly indicates all of the following: (1) The printed name of the signer; (2) The date and time when the signature was executed; and (3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature. The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).*

Within Calibration Manager, the electronic signature shall include the following items: User Name of person signing electronic record; Timestamp of when signature is completed (local time with time zone information); Reason for signature. The electronic signature information shall be viewable (by way of a tab on the form) from the associated Equipment History record. Calibration Manager will be shipped with one or more reports that include calibration data records and any associated electronic signatures. The user may also create custom reports containing calibration data and any associated electronic signatures.

- *Part 11.70 - Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.*



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The electronic signature will be unique to one Equipment History record and shall not be able to be copied to another Equipment History record. The electronic signature will be unchangeable once complete and cannot be deleted.

- *Part 11.100a - Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.*

The Calibration Manager security system ensures that, at a given time, each authorized user has a unique User ID/Password combination. A User ID may only be used one time if that user has electronically signed a record. If the user associated with a User ID that is associated with an electronic signature is removed from the system, their User ID cannot be reused or reassigned.

- *Part 11.200a - Electronic signatures that are not based upon biometrics shall: (1) Employ at least two distinct identification components such as an identification code and password. (i) When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual. (ii) When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all of the electronic signature components. (2) Be used only by their genuine owners; and (3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.*

The user shall be required to provide a valid User ID and password in order to complete the first electronic signature within a Calibration Manager session. The User ID and password shall only be valid if the user is logged in using the same User ID / password combination as they use to execute the electronic signature. The user shall be required to provide a valid password in order to complete any additional electronic signatures, once the first signature is successfully completed, within a Calibration Manager session. Calibration Manager may be configured to 'timeout' after a specified period of inactivity. A 'timeout' will lock the Calibration Manager system and end the session. Once the user unlocks the system, this begins a new session and will require their valid User ID and Password combination in order to complete the next electronic signature. An additional electronic signature within this new session will require that the user provide only their valid password.

Calibration Manager system security may be configured to require a user to change their password



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upon their first login. This will prevent a system administrator from knowing another user's password.

- *Part 11.300a - Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include: Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.*

The Calibration Manager security system ensures that each authorized user has a unique User ID/Password combination. A User ID may only be used one time. If the user associated with a User ID is removed from the system, their User ID cannot be reused or reassigned.

- *Part 11.300b - Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).*

The Calibration Manager security system allows the administrator to designate a 'password expiration' period (X days). If enabled, each user will be required to change his/her password every X days. If a user who has electronically signed a record is removed from the system, their electronic signature records will remain attached to their associated history records.

- *Part 11.300c - Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.*

Calibration Manager allows for a secure form of 'Backdoor Access'. If a system administrator is no longer available within an organization, Blue Mountain Quality Resources will oversee the addition of a new system administrator.

- *Part 11.300d - Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management. [11.3(d)]*

A valid User ID and Password combination are required in order to enter the Calibration Manager system. After a specified number of consecutive unsuccessful attempts to log in to a user account,



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the account will be locked. A user with adequate rights may unlock a user account. The account may automatically become unlocked after a fixed period of time. Once the account is locked, an email will be sent to one or more specified administrator(s) to notify them of the attempted break in.

### THE NEXT STEP

Blue Mountain is the pioneer in electronic signatures/electronic records for Part 11 compliance, as the first company to integrate this functionality into a calibration management software package. Blue Mountain has sold over 1,000 copies of Calibration Manager with Part 11 functionality - more than anyone in the industry. Version 4 is the third generation of Calibration Manager with ES/ER functionality.

Calibration Manager 4 was designed as a state-of-the-art software package, with the most sophisticated Part 11 functionality in the industry. Blue Mountain has worked with industry specialists on Part 11 functionality to ensure that it meets the requirements of the FDA. Some features include:

- Enforcing password expiration through the security options
- Tracking all electronic signature activity with the audit trail
- Configuring the electronic signatures/electronic records setting to mandate use
- Maintaining data integrity as Calibration Manager is a closed system

For more information about this feature or how Calibration Manager can improve operating efficiency, maintain requirements for FDA compliance, and maximize your return on investment, please contact us at 800-982-2388 or [www.coolblue.com](http://www.coolblue.com).

### ABOUT BLUE MOUNTAIN QUALITY RESOURCES, INC.

Blue Mountain Quality Resources is the Validated Leader in Calibration Management Software. With over 10 years of experience in FDA regulated markets, Blue Mountain offers a complete solution to calibration management needs, from set-up and installation to training and validation. Through our calibration productivity tools, Blue Mountain assists users in maintaining and monitoring the full cycle of calibration management. This allows companies to improve their operating efficiency, maintain requirements for FDA compliance, and maximize their return on investment.



## REFERENCES

- 21 CFR Part 11 – FDA
- Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures – GAMP Special Interest Group (21 CFR Part 11)
- Ken Chapman/Dynamic Drumbeat for Pharmaceuticals – Drumbeat Dimensions, Inc.

