

**Finesse Whitepaper on 21 CFR Part 11 Compliance
as it relates to TruBio®**

The objective of Title 21 CFR Part 11 is to ensure that when electronic record keeping is instituted, it is maintained in a manner equivalent to written records. For process automation activities, GMP records are usually maintained for system engineering, operation, maintenance, and administration. When these records are maintained in an electronic format, adherence to 21 CFR Part 11 is required by FDA law.

21 CFR Part 11 has two parts: one dealing with electronic controls and the other with procedural controls. Electronic controls are required for any system maintaining electronic records; however, even the most stringent of electronic controls is not complete without procedural controls. Software controls can provide 21 CFR Part 11 capability, but Finesse maintains that it is the responsibility of the customer to enact the procedural controls which provide compliance.

Finesse maintains 21 CFR Part 11 capability through certain electronic controls within TruBio® as well as through the base platform of DeltaV. (For further information regarding DeltaV's compliance with 21 CFR Part 11, please refer to Emerson's whitepaper on the subject: "DeltaV Capabilities for Electronic Records Management," September 2004.)

In addition to the standard features supported by DeltaV, the following TruBio® items are capable of 21 CFR Part 11 compliance:

- Calibration records
- Vessel Save records
- Vessel Load records

The following paragraphs outline specific TruBio® functions that provide 21 CFR Part 11 capabilities.

21 CFR Part 11 Subpart B – Electronic Records

Section 11.10(a) Altered Records

This section requires that altered record may be recognizable as such.

All the record types named above are stored in an area that may be restricted to users through Windows security settings. Each report will be encrypted to protect against untraceable modifications to the file. TruBio® will not allow users to overwrite, delete or duplicate files.

Modified or renamed Vessel Save or Vessel Load files will not be able to be used.

The calibration report will contain the username and a time stamp indicating the date and time the report was logged. The user cannot edit, alter or delete the calibration report via the user interface.

11.10(b) Reproduction of Records

This section requires that records are able to be viewed in a readable format. All records listed above may be viewed within the TruBio® user interface, with appropriate security permissions.

Encrypted Vessel Save and Vessel Load files are decrypted and checked to confirm that the file has not been modified or renamed. Upon passing the decryption checks, the Vessel Save and Vessel Load records may be printed by exporting to a user specified filename in csv format. Encrypted Calibration Records may be printed by accessing the calibration print utility on the calibration form.

11.10(c) Protection of Records

This section specifies that records must be retained for a specific period of time. All records listed above are maintained, unless manually deleted by an administrator, for as long as the computer storage allows. Customer procedural controls must be in place to ensure timely backups of the data and secure offsite data storage is performed.

11.50 Signature Manifestations

This section requires that clear electronic signatures be made for all electronic records. Calibration records require that the user has the appropriate security access and a valid username and password is entered prior to writing the calibration data or the calibration record.

Included in the calibration record are the calibration values being applied, the calibration type, manufacturer name and serial number, the user name, an optional comment field to include the purpose of the calibration, and a date and time stamp of the individual performing the calibration.

11.70 Signature/Record Linking

This section requires that the electronic signature be linked to the correct username. The TruBio® calibration routine uses the user login name and password created through DeltaV security settings.