FCS Express offers you the most complete set of Part 11 compliance tools to meet the needs of your regulated laboratory.

Section | Summary of Rule | Compliance Strategy
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11.10 | Controls for Closed Systems | FCS Express is designed to run as a closed system: it can only be accessed via the FCS Express user interface.
11.10(a) | Validation | De Novo Software has validated FCS Express. De Novo can assist your laboratory with preparation of a validation plan to meet your unique requirements.
11.10(b) | Record Generation and Copying | FCS Express stores its layout files and results in a format that is both human readable and machine-readable.
11.10(c) | Record Protection | Records are saved in an encrypted and locked format, with checksum measures in place to detect tampering. De Novo Software advises that you save your FCS Express files in a secure folder.
11.10(d) | Access Limitation | FCS Express contains security features that limit access to authorized individuals.
11.10(e) | Audit Trails | Audit trails are secure and time-stamped. They record the date and time of actions that modify any aspect of your analysis, along with the name of the person who made the change.
11.10(f) | Operational System Checks | This does not apply to FCS Express.
11.10(g) | Authority Checks | User credentials are required to access FCS Express. FCS Express also features a comprehensive set of permissions that you can set on an individual user basis.
11.10(h) | Device/Terminal Checks | FCS Express applies checks to determine if it has received a valid flow cytometry data file.
11.10(i) and (j) | Training and User Accountability | De Novo Software can assist your laboratory with preparation of a training plan so that your scientists understand how to use FCS Express as well as the implications of Part 11 on their work.
11.10(k) | System Document Control | De Novo Software follows change control and life cycle management procedures for document control.
11.30 | Controls for Open Systems | Does not apply to FCS Express, which is designed to operate as a Closed System.
11.100(a) and 11.200(b) | Uniqueness of Electronic Signatures | FCS Express ensures that all user IDs are unique; therefore, all electronic signatures are unique.
11.100(b) | Verification of Identity | You must verify the identity of your FCS Express users.
11.100(c) | Certification | You must certify with the FDA that you intend to use electronic signatures.
11.200(a)(1) and (a)(3) | Two-Component Signing | FCS Express requires entry of username and password to sign layout files and results.
11.200(a) | Signature Authenticity and Collaboration to Falsify | To gain access to FCS Express and to sign a layout file or result, users must have a valid username and password.
11.200(b) | Biometric Signatures | Not required for FCS Express which operates as a Closed System.
11.300(b) | Password Aging | FCS Express has a configurable password aging feature.
11.300(d) | Controls to Prevent Unauthorized Credential Use | FCS Express disables accounts after a configurable number of failed login attempts.

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