



# 21 CFR Part 11 Compliance

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

**Designed to maintain machine-readable metadata and human-readable reports, FCS Express has the following features to enhance your Part 11 compliance program:**

Section	Summary of Rule	Compliance Strategy
11.10	<b>Controls for Closed Systems</b>	<i>FCS Express</i> is designed to run as a closed system: it can only be accessed via the <i>FCS Express</i> user interface.
11.10(a)	<b>Validation</b>	De Novo Software has validated <i>FCS Express</i> . De Novo can assist your laboratory with preparation of a validation plan to meet your unique requirements.
11.10(b)	<b>Record Generation and Copying</b>	<i>FCS Express</i> stores its layout files and results in a format that is both human readable and machine-readable.
11.10(c)	<b>Record Protection</b>	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 <i>FCS Express</i> files in a secure folder.
11.10(d)	<b>Access Limitation</b>	<i>FCS Express</i> contains security features that limit access to authorized individuals.
11.10(e)	<b>Audit Trails</b>	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)	<b>Operational System Checks</b>	This does not apply to <i>FCS Express</i> .
11.10(g)	<b>Authority Checks</b>	User credentials are required to access <i>FCS Express</i> . <i>FCS Express</i> also features a comprehensive set of permissions that you can set on an individual user basis.
11.10(h)	<b>Device/Terminal Checks</b>	<i>FCS Express</i> applies checks to determine if it has received a valid flow cytometry data file.
11.10(i) and (j)	<b>Training and User Accountability</b>	De Novo Software can assist your laboratory with preparation of a training plan so that your scientists understand how to use <i>FCS Express</i> as well as the implications of Part 11 on their work.
11.10(k)	<b>System Document Control</b>	De Novo Software follows change control and life cycle management procedures for document control.
11.30	<b>Controls for Open Systems</b>	Does not apply to <i>FCS Express</i> , which is designed to operate as a Closed System.
11.100(a), 11.200(b)	<b>Uniqueness of Electronic Signatures</b>	<i>FCS Express</i> ensures that all user IDs are unique; therefore, all electronic signatures are unique.
11.100(b)	<b>Verification of Identity</b>	You must verify the identity of your <i>FCS Express</i> users.
11.100(c)	<b>Certification</b>	You must certify with the FDA that you intend to use electronic signatures.
11.200(a)(1)	<b>Two-Component Signing</b>	<i>FCS Express</i> requires entry of username and password to sign layout files and results.
11.200(a)(2) and (a)(3)	<b>Signature Authenticity and Collaboration to Falsify</b>	To gain access to <i>FCS Express</i> and to sign a layout file or result, users must have a valid username and password.
11.200(b)	<b>Biometric Signatures</b>	Not required for <i>FCS Express</i> which operates as a Closed System.
11.300(b)	<b>Password Aging</b>	<i>FCS Express</i> has a configurable password-aging feature.
11.300(d)	<b>Controls to Prevent Unauthorized Credential Use</b>	<i>FCS Express</i> disables accounts after a configurable number of failed login attempts.

For features, pricing and your FREE 30 day evaluation, visit:  
[www.denovosoftware.com](http://www.denovosoftware.com)

