BD FACSuite™ Software
21 CFR Part 11 Support

BD FACSuite™ software has many functions and options relevant to 21 CFR Part 11.

Section		Rule Summary	BD FACSuite Software
11.10	**Controls for closed systems**		
11.10(a)	Validation to ensure accurate, reliable, and intended performance, and the ability to discern altered/invalid records	System validation	IQ and OQ procedures will be available for the BD FACSVerse system.
11.10(b)	Generate valid copies in human-readable and electronic records suitable for inspection	Record generation for inspection	BD FACSuite software provides both electronic and human-readable formats (for example, reports, audit trails, user logs).
11.10(c)	Protect records, enabling their accurate retrieval	Record protection	BD FACSuite software stores crucial operational files, data files, and result information in an encrypted format within a hidden folder structure controlled by an indexing database.
11.10(d)	Limit system access to authorized individuals	System access limitation	BD FACSuite software requires all users to log in. Each user will have a defined role, including access privileges.
11.10(e)	Use audit trails to record date, time, operator, actions (for example, create, modify); changes shall not obscure previous information	Audit trails	BD FACSuite software provides the option to turn on audit trails for Worklist entries. Once turned on, audit trails cannot be turned off.
11.10(f)	Use of operational checks to enforce permitted steps and events	Operational checks	BD FACSuite software restricts what users can do based on their role and access privileges (Administrator and Operator).
11.10(g)	Use of authority checks to ensure system use, record signature, operation of computer system, or alter record	Authority checks	BD FACSuite software ensures that users have the proper authority to carry out particular functions based on their roles and access privileges. The software also has a tracking log to enable users to monitor system use.
11.10(h)	Check to determine validity of data input or operation	Data/operation validity checks	BD FACSuite software informs a user who attempts to put invalid information into a software field based on the design specifications and limitation of each input field. The software also prevents accidental or malicious alteration of the data in an exported file by attaching a checksum value to the file when it is exported. Before it can be imported, BD FACSuite software checks the value and prevents the import if the value has changed.
11.10(i)	Persons using ER/ES has proper training	User training	BD provides BD FACSuite/BD FACSVerse user training with certification. The organization is responsible for training on the Electronic Record/Electronic Signature SOP.
11.10(j)	Written policies holding individuals accountable for actions	User accountability	The user's organization is responsible.
11.10(k)	Controls over distribution and use of documentation of system and its maintenance. Also revision and change controls to maintain an audit trail that documents time-sequenced development and modification of systems documentation	System documentation control	BD follows the ECO process in documentation development.

11.30	**Controls for Open Systems**	Controls for open systems	Not applicable because the BD FACSuite/BD FACSVerse system is a closed system.

Section		Rule Summary	BD FACSuite Software
11.50	**Signature Manifestations**		
11.50(a)	Signed records to contain printed name of signer, date and time of signature, and meaning of signature (eg, review, approval)	Signature manifestations	BD FACSuite software enables printing of e-signatures and comments on all reports as required by the user/administrator. Reports include whether results pass/fail, have been reviewed, or were not approved. All electronic records within BD FACSuite software are time, date, and author stamped. Stamps cannot be changed on the final report.
11.50(b)	Same controls as for electronic records		

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Section		Rule Summary	BD FACSuite Software
11.70	**Signature/Record Linking**		
	Signature to be linked to record to ensure signature cannot be excised, copied or altered	Signature/record linking	BD FACSuite software provides e-signatures to link records with user signatures. Any modification of the record will automatically remove the e-signature.

Electronic Signatures			
11.100	**General Requirements**		
11.100(a)	Each signature is unique to one person and shall not be reused or reassigned.	General e-signature requirements	BD FACSuite software provides a unique name and password.
11.100(b)	Before organization establishes an electronic signature, it shall verify the identity of the individual.		The user's organization is responsible.
11.100(c)	Certify electronic signatures are equivalent to handwritten signatures and submit to FDA.		The user's organization is responsible.

11.200	**Electronic Signature Components and Controls**		
11.200(a)	Electronic signatures shall employ 2 distinct IDs (ID and Password), after first signing; subsequent signings only require a single ID during a continuous session.	Controls for e-signature	A BD FACSuite software e-signature consists of a unique username and password. BD FACSuite software requires both components at initial sign-in and then only one on subsequent signings in the same session.
11.200(b)	Electronic signatures using biometrics ensure they cannot be used by anyone else.		n/a

11.300	**Controls for Identification Codes/Passwords**		
11.300(a)	Maintain uniqueness of combined ID and Password for each individual	Uniquess of ID/password	BD FACSuite software provides a unique name and password.
11.300(b)	Ensure ID and Password are periodically checked, recalled, or revised	Password aging	BD FACSuite software enables the administrator to set a password expiration date.
11.300(c)	Deauthorize lost or missing ID and Password and issue new temporary/permanent replacement following all previous controls	Lost ID/password management	BD FACSuite software enables the administrator to manage user profiles, including user IDs and passwords.
11.300(d)	Safeguards to prevent unauthorized use and report any attempts of unauthorized attempted use	Prevention of unauthorized use of system	The administrator can configure BD FACSuite software to lock an account after a number of failed login attempts.
11.300(e)	Periodic testing of the generation of ID and Password procedure/device to ensure proper operation	Periodic testing of ID/password generation	The user's organization is responsible.

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