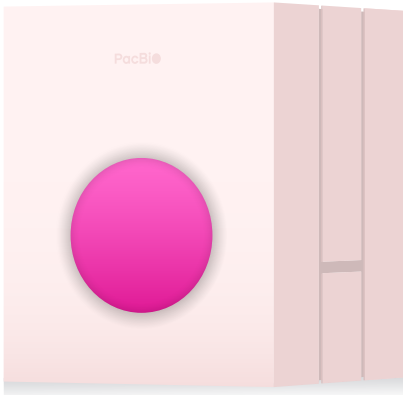


Electronic records and access controls on the Vega™ system + SMRT® Link

The United States Food and Drug Administration regulation 21 CFR Part 11 requires that electronic records and signatures are trustworthy, traceable, and attributable to individuals. Vega and SMRT Link provide the core technical controls needed to support these requirements, including user authentication, audit trails, and access management.

These capabilities are designed to help regulated labs implement compliant workflows. Final compliance depends on how the system is configured and used.



How PacBio® enables 21 CFR Part 11 compliance

User authentication with login mode	Traceability with audit trails
Login mode can be enabled per instrument to require users to log in with their SMRT Link username and a personal identification code (PIC). - Ensures actions are tied to a specific user - Extends user accountability to on-instrument activity - User management limited to admins	SMRT Link captures audit trails across both software and instrument activity. Each record includes: - Who performed the action - What action was performed - When the action occurred Audit trails are: - Tamper-evident - Accessible to admins - Exportable for inspection and documentation

PacBio provides	Customer is responsible for
- Authentication via login mode - Secure, timestamped audit trails - Attribution of actions to users - Configurable access controls - Audit log export	- Enabling and enforcing login mode - Defining password/access policies - Routine audit trail review - Standard operating procedures for audit review, deviations, and Corrective and Preventive Action and Standard Operating Procedure - System validation within their environment

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