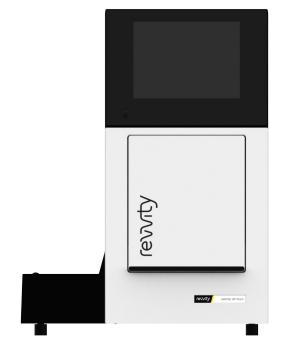# revvity

Compliance made easy: Navigating FDA 21CFR part 11 regulations

We are dedicated to meeting your needs in the dynamic pharmaceutical and biotechnology industries. To aid in your compliance planning, we provide enhanced security options with the LabChip® GXII Touch™ Protein Characterization System, encompassing access security, data security and verification, and a comprehensive set of audit logging functionality.

Security Features:

- Controlled instrument access limited to authorized users
- Configurable passwords with expiration dates
- Configurable inactivity timeout for added security
- Automated data security from generation
- Verification of file integrity
- Comprehensive audit logs for validation
- Configurable user access rights

Trusted by researchers worldwide, we understand the need for swift, compliant solutions. Experience a faster, easier way to meet FDA regulations with our offering.

For research use only. Not for use in diagnostic procedures.

Key Software Features of the LabChip GXII Touch Protein Characterization System.

Instrument Access Security

- Instrument access limited to authorized users only. Username plus password identify each user in the software.
- Passwords are fully configurable with syntax requirements and expiration dates.
- Configurable timeout for system inactivity requiring the user to re-enter their user ID and password.

Data Security & Verification

- Data automatically secured from the instant it is generated.
- Files pertinent to a specific protocol run are bundled at the end of the protocol to provide a unique "fingerprint" of the protocol run.
- Verification confirms that bundled files have not been tampered with.

Audit Trails & Log

- Full auditing facilities so protocol runs and parameter changes can be validated.
- Logon events, methods, and evaluation parameter changes are tracked.
- Bundled files provide an audit trail and allow for easy access to protocol information during an audit.

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