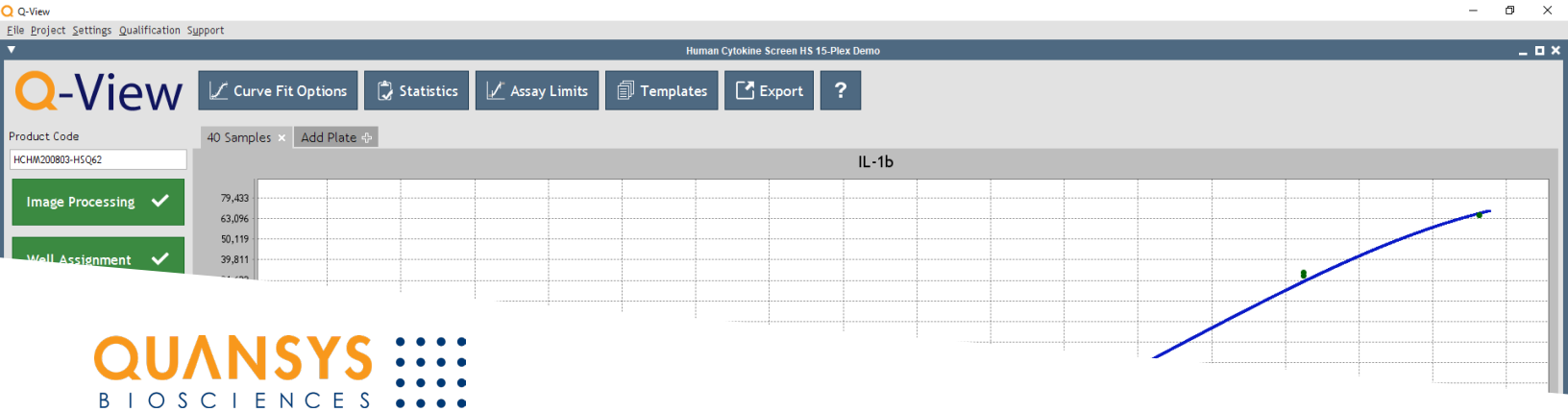


QUANSYS BIOSCIENCES

Q-View™ Software 21 CFR Part 11 Features

Overview

Q-View™ Software includes configurable features designed to help laboratories manage electronic records and electronic signatures in environments subject to 21 CFR Part 11. When enabled and used as part of a customer's validated system and quality procedures, these controls support user authentication, role-based access, audit trail visibility, data integrity, and electronic signature workflows.

Capabilities

User Accounts & Authentication

- When enabled, users must authenticate before accessing Q-View™ Software.
- Account types include Administrators and Users.
- Administrators have full access to software features; Users are limited by assigned roles.

Roles, Permissions & Password Policy

- User roles define permitted actions using a detailed permissions list.
- Password requirements can specify length and lowercase, uppercase, numeric, and special-character rules.
- Password expiration and failed-login lockout settings can be configured.

Record Traceability & Audit Support

- Project details record and display the project creator, the creation date and time, and the users who have accessed the project, including the date and time of each access.
- Project notes capture project-related information and cannot be modified or deleted after creation.
- Project history documents changes made throughout the lifetime of each plate report.
- The event log records application events with user, date, and time.

Electronic Signatures & Data Protection

- Electronic signatures can be required before exporting well assignment templates, curve fitting templates, and reports.
- Report-based electronic signatures are logged at the bottom of the report.
- Sensitive data is encrypted, and Q-View™ Software rejects modified or corrupted data.

Q-View™ Software and 21 CFR Part 11

Q-View™ Software provides configurable access control, audit trail, data integrity, and electronic signature features designed to support regulated laboratory workflows where electronic records and electronic signatures are used.

Implementation Notes

These software features are intended to support Part 11-related technical controls. Customers remain responsible for determining regulatory applicability, validating their intended use of Q-View™ Software, maintaining appropriate SOPs, training users, and operating the software within their quality system.

Configurable Permissions

Administrators can tailor user access by assigning specific permissions that reflect each user's responsibilities. Available permissions include:

Project, System & Imager Controls

- Create projects
- Manage imagers (focus, dark field, etc.)
- Perform imager qualification
- Perform IQ/OQ
- Open blot tools
- Technical support upload (projects and imager data)

Plate & Image Management

- Create new plates
- Rename plates
- Delete plates
- Enter product code
- Capture plate images
- Set image capture exposure times
- Import plate images
- Rename plate images
- Delete plate images
- Stack plate images
- Image options (invert, rotate, flip, etc.)
- Set and adjust plate overlay
- Export plate images

Well Assignment & Templates

- Assign well groups
- Assign well dilutions
- Open well assignment templates
- Create new well assignment templates
- Save well assignment templates

Data Analysis, Review & Reporting

- Adjust curve fit options (model, weighting, etc.)
- Adjust report statistics
- Adjust report assay limits
- Mask and unmask spots
- Export data analysis (curve fit images, reports, etc.)
- Submit reports for review
- Approve and reject reports
- View the data report tab
- Open data analysis templates
- Save data analysis templates
- Adjust user preferences

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Quansys is an ISO 9001:2015 and ISO 13485:2016 registered company and complies with GMP. Products are designed, developed, and manufactured according to the procedures outlined in our Quality Management System.

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