

21 CFR PART 11 TOOLS FOR CONFIDENT COMPLIANCE IN GxP LABORATORIES

Octet CFR software and our GxP Server enable data acquisition and data analysis in laboratories working under GMP, GLP, and 21 CFR Part 11 regulations. It also provides all necessary technical administrative features for compliance with FDA regulations. The table below provides a general guide to the features included in various versions of the software. The latest release, Version 9, is available for use on Octet QK, QK^e, RED, RED96, QK384, RED384, HTX and the new Octet K2 system. For more information or for upgrade options, please contact your local sales representative or fill out our [software download request form](#).

Feature	Version 7.x	Version 8.x	Version 9.x
Pall ForteBio GxP Server			
Higher security measures: new login dialog and all critical actions logged such as add/inactivate users, groups and projects			✓
Added inactivate and activate user functions to replace the delete user function			✓
Use of BLItz and Octet systems on the same GxP server		✓	✓
Querying of the audit trail by project and experiment name		✓	✓
Print audit trail data in PDF format		✓	✓
Data Acquisition			
Experiment Wizard includes built in protocol templates for kinetics, quantitation and epitope binning			✓
Capture Antibody step type in Advanced Quantitation for easier conversion of ELISA to Octet assays			✓
Latest offering of all biosensor types			✓
All critical user actions are logged to the audit trail and the Settings Change history		✓	✓
High sensitivity kinetics rate option for QK ^e and QK384 instruments		✓	✓
Electronic signatures added to files acquired by 21CFR software to prevent modifications to data files		✓	✓
Visualization of all assay steps in advanced quantitation module		✓	✓
Regeneration steps in kinetics module, similar to quantitation		✓	✓
Multiple assay steps can be added at one time in "Step Data List" in kinetics for quick assay setup		✓	✓
All assay steps in multiple assays within an experiment can be displayed in a grid for better visualization		✓	✓
Quantitation Data Analysis			
Allow and log all modifications to standard concentration values, sample IDs and dilution factor(s) when quantitating selected step from kinetics experiments			✓
Edit cells in table, such as known concentration (standard wells), dilution factor, replicate group and sample ID			✓
Settings Change History dialog to view history of all changes and old vs. new values for settings parameters		✓	✓
All critical user actions logged to audit trail and Setting Change History		✓	✓
Locked exported Excel [®] report so data cannot be tampered		✓	✓
Additional information, including software name and version, export data and time added to Excel report		✓	✓
View and analyze all assay steps in advanced quantitation		✓	✓
View all graphs in either logarithmic or linear scale		✓	✓
Interactive data visualization of plate map, results table and trace data		✓	✓
Spacebar shortcut key to include/exclude data in results table	✓		✓
Quantitation of association step from kinetic experiments	✓	✓	✓
Import/export multiple external standard curves to quantitate new datasets	✓	✓	✓

Kinetics Data Analysis		
Edit cells, customize and sort results table		✓
Assign % K_{D1} and K_{D2} contribution to 2:1 model interaction		✓
Transfer reference sensor(s) and reference well(s) info from Data Acquisition to Data Analysis software		✓
Allow and log all modifications to standard concentration values, sample IDs and dilution factor(s) when quantitating selected step from kinetics experiments		✓
Settings Change History dialog to view history of all changes and old vs. new values for settings parameters	✓	✓
All critical user actions logged to the audit trail and Setting Change history	✓	✓
Locked exported Excel report so data cannot be tampered	✓	✓
Cursors to add report points to kinetics data	✓	✓
Two new cursors to add multiple report points to processed data	✓	✓
View all graphs in either logarithmic or linear scale	✓	✓
Additional information, including software name and version, export data and time added to Excel report	✓	✓
Spacebar shortcut key to include/exclude data in results table	✓	✓
Order Columns option enables reordering of columns from default order in saved report	✓	✓



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