



21 CFR Part 11 ready module

For the Celigo image cytometer

The newly developed Celigo™ Express software works with the 21 CFR Part 11 ready module to simplify the data acquisition process by allowing researchers to use projects imported from Celigo Pro (v5.4) and quickly run them to collect sample data.

With a few clicks of the mouse, a scan can be run using Celigo Express:

- Select the project to run
- Click on "Start Scan"
- View your data



The screenshot illustrates the Celigo Express software interface with three key steps highlighted by red boxes and arrows:

- Select Project:** The 'Project' dropdown menu is open, showing a list of projects. The 'Select' button is highlighted.
- Start Scan:** The 'Start' button at the bottom of the interface is highlighted.
- View Data:** The 'Results' tab is selected, displaying a grid of wells. A specific well is highlighted, and a pop-up window shows the following data:

Well	Image	Results
Measurement		Value
Cell Count		42
Well Sampled (%)		100.00%
Concentration (cells/mL)		NaN

Celigo express with 21 CFR part 11 module

Celigo Express offers a 21 CFR Part 11 module that is compliant with the Code of Federal Regulations (CFR) Title 21 Part 11 – Electronic Records: Electronic Signatures published by the U. S. Food and Drug Administration (FDA). This module ensures that an organization’s use of electronic records and digital signatures in place of traditional paper-based documentation complies with current FDA regulations.

Key elements of the 21 CFR Part 11 module are:

- **Electronic Signatures** are captured during the counting and analysis workflow using e-Sign/e-Unsign buttons and include the name of an authorized user, the date/time when the signature was executed, and the meaning of the signature (i.e., indicating either Approval or Rejection of an action).
- **An Audit Trail** assures the integrity of an electronic record and continually monitors all users performing actions, the type of actions being performed, and the date/time associated with user actions.
- **User Roles** allows for specialized access control to the varying levels of Celigo Express functionality to specified groups. When creating a role, subsets of privileges can be selected to apply to users performing common or specialized tasks.
- **A Close-looped Database System** ensures the integrity of the data generated.

Understanding user role privileges

The Celigo Express 21 CFR Part 11 module allows for control of the following areas of role responsibility:

- **Data** – Controls whether users can create, delete, export/import, and approve/reject data during the counting and analysis workflow.
- **Settings** – Controls whether users can access the Projects screen functionality available under the Manage tab to allow them to update, delete, and import/export projects.
- **Users, Roles, or Audits** – Controls whether users can access the 21 CFR Part 11 module Users, Roles, or Audits options under the Manage tab to allow them to create, update, and delete Celigo Express users/roles, or monitor and export the audit trail automatically generated by the system after the module is enabled.

Privileges							
Data:	<input type="checkbox"/> Create	<input type="checkbox"/> Read	<input type="checkbox"/> Update	<input type="checkbox"/> Delete	<input type="checkbox"/> Export	<input type="checkbox"/> Import	<input type="checkbox"/> Approval
Settings:	<input type="checkbox"/> Create	<input type="checkbox"/> Read	<input type="checkbox"/> Update	<input type="checkbox"/> Delete	<input type="checkbox"/> Export	<input type="checkbox"/> Import	
Users:	<input type="checkbox"/> Create	<input type="checkbox"/> Read	<input type="checkbox"/> Update	<input type="checkbox"/> Delete			
Roles:	<input type="checkbox"/> Create	<input type="checkbox"/> Read	<input type="checkbox"/> Update	<input type="checkbox"/> Delete			
Audits:	<input type="checkbox"/> Read	<input type="checkbox"/> Export					

Celigo Express with the 21 CFR Part 11 ready module may be enabled for your instrument system at the time of purchase or implemented as an upgrade.

