Gyrolab® Software

Compliance with GxP requirements

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A majority of the world's leading biopharmaceutical companies, along with contract research organizations (CROs) and contract manufacturing organizations (CMOs) utilize Gyrolab immunoassay platforms in GLP and GMP environments.

Gyrolab systems include powerful, pre-installed software to allow the design, execution, and data analysis of automated immunoassays in a microfluidic, CD-based format.

All Gyrolab software programs and modules are designed for **21 CFR Part 11** compliance, ensuring straightforward assay development, validation, and transfer within regulated environments.
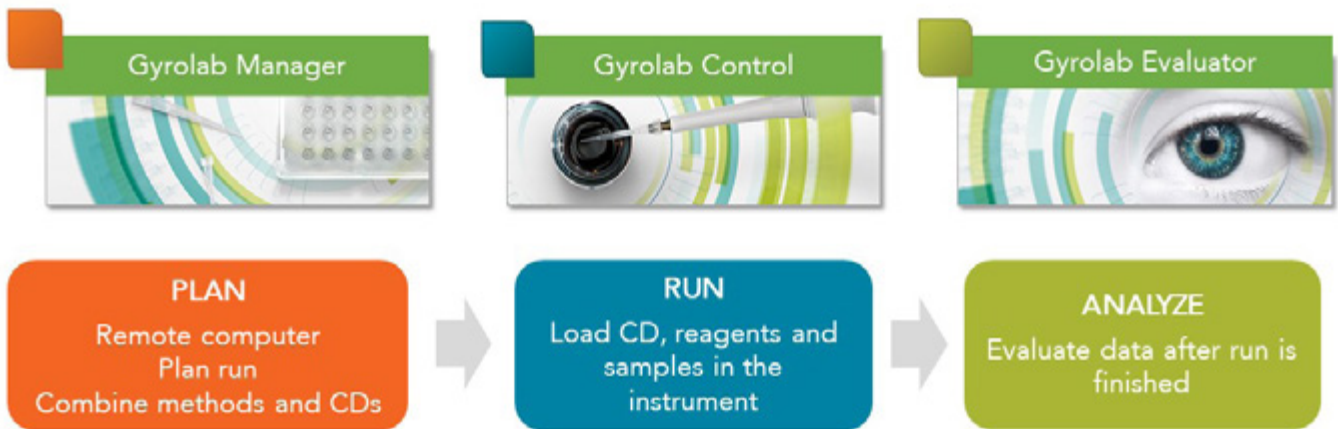
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Productivity at home, office, or lab

Gyrolab software suite is designed for optimum workflows.

Gyrolab® xPand and Gyrolab xPlore™ instruments are delivered with an easy to use, pre-installed software suite providing the functionality to design, run, execute, and analyze automated microfluidic immunoassays.

Gyrolab software is optimized for productivity in and out of the laboratory. Gyrolab Manager is used to plan and set up runs in the lab or remote, Gyrolab Control integrates and automates workflows, and Gyrolab Evaluator provides the power to analyze data and generate reports.

| Gyrolab Manager	Gyrolab Control	Gyrolab Evaluator
PLAN Remote computer Plan run Combine methods and CDs	**RUN** Load CD, reagents and samples in the instrument	**ANALYZE** Evaluate data after run is finished

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Gyrolab software modules provide expanded functionality

Gyrolab software modules add functionality onto the core software suite for additional application-specific analysis

Gyrolab Control Report

Automatic electronic generation of non-editable, 21 CFR Part 11 compliant, raw data reports to meet regulatory requirements.
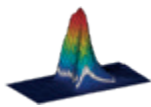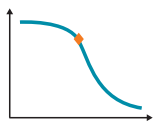

Gyrolab Viewer

Display and review on-column fluorescence for each datapoint.

Gyrolab ADA Software

Guides the development and validation of immunogenicity assays including ADA screening and confirmatory analysis.

Gyrolab Affinity Software

Facilitates the design and evaluation of in-solution affinity experiments.

Gyrolab LIMS Interface

Enables full integration of Gyrolab systems into a Laboratory Information Management System (LIMS) in compliance with GxP requirements.
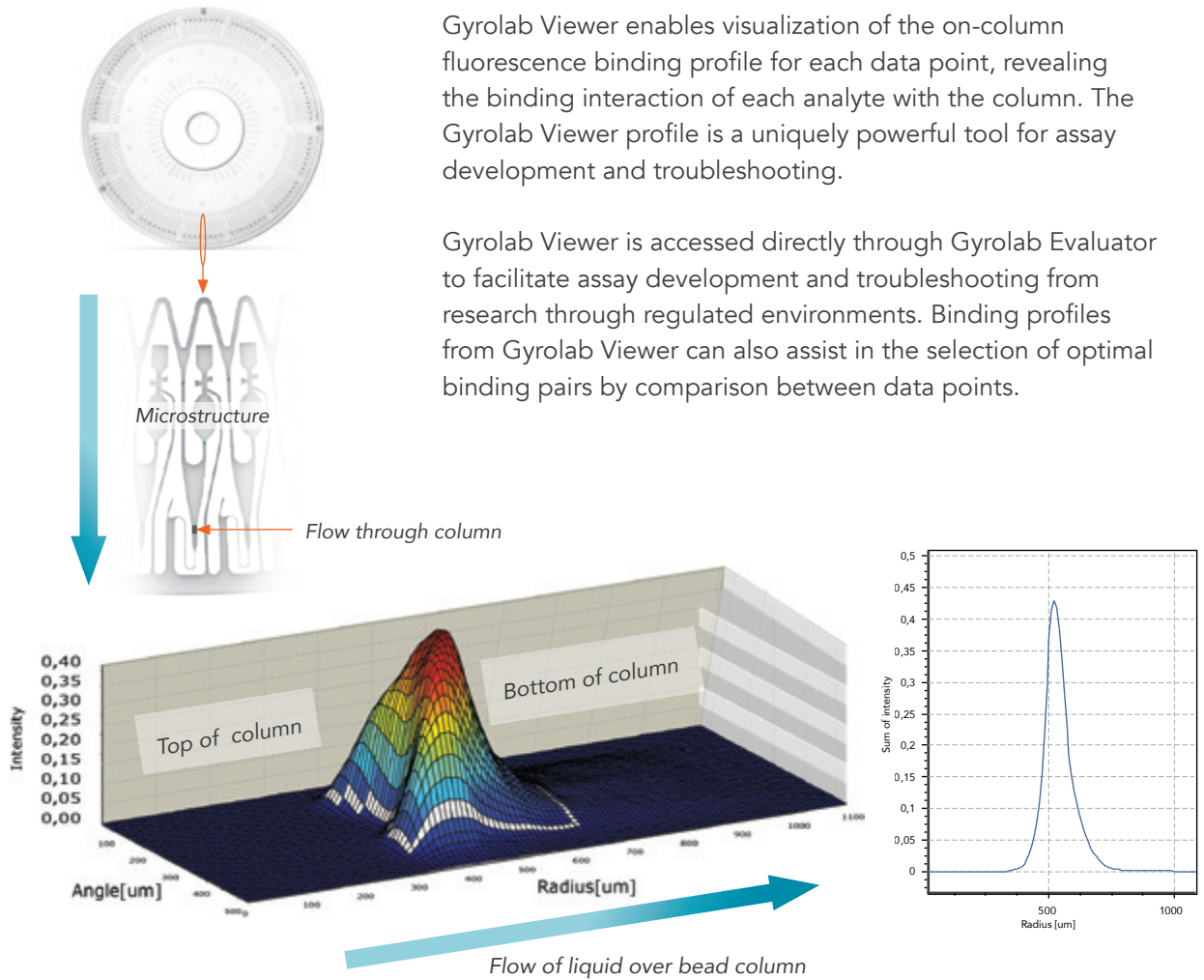
Gyrolab Control Report

An essential requirement of 21 CFR Part 11 is the generation of non-editable, raw data reports after each run. Gyrolab Control Report module automatically generates non-editable raw data reports after each run, in alignment with 21 CFR Part 11 compliance.

For users who use a LIMS system for data analysis, this module delivers reports that include run and experimental details in pdf format.

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Gyrolab Viewer

Microstructure

Flow through column

Gyrolab Viewer enables visualization of the on-column fluorescence binding profile for each data point, revealing the binding interaction of each analyte with the column. The Gyrolab Viewer profile is a uniquely powerful tool for assay development and troubleshooting.

Gyrolab Viewer is accessed directly through Gyrolab Evaluator to facilitate assay development and troubleshooting from research through regulated environments. Binding profiles from Gyrolab Viewer can also assist in the selection of optimal binding pairs by comparison between data points.

Flow of liquid over bead column

Gyrolab Viewer profiles facilitate assay development and QC data analysis

- Compare binding profiles
- Identify optimal binding pairs
- Investigate outliers
- Troubleshoot during development or routine analysis

## Viewer side by side comparison

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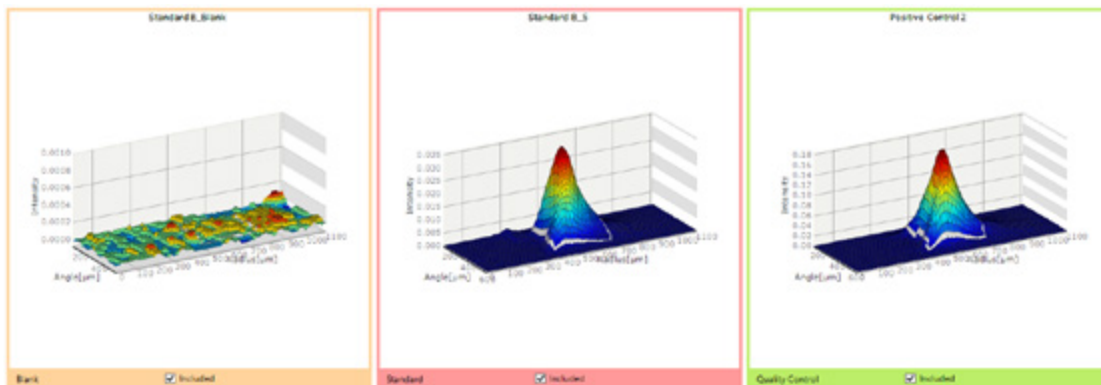
Gyrolab ADA Software

Assessment of anti-drug antibodies (ADAs) is a fundamental part of immunogenicity testing. Gyrolab ADA Software follows a standard ADA assay workflow of screening followed by confirmatory assays to provide time-efficient, drug-tolerant analysis of anti-drug antibodies (ADA) in serum samples.

The Gyrolab ADA Software module incorporates a cut point formula for automatic data evaluation, displaying data according to predefined acceptance and cut point criteria for clear visualization of results.

Gyrolab ADA Software guides confirmatory analysis by displaying results according to your acceptance criteria and confirmatory cut point. Samples falling outside of acceptance criteria are automatically highlighted.
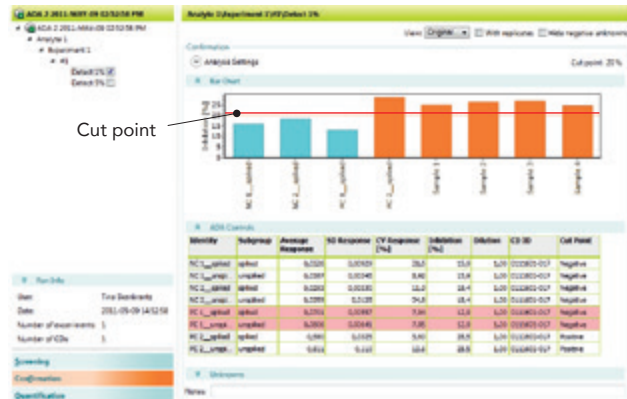
Gyrolab Affinity Software

Gyrolab Affinity Software module guides the design and evaluation of in-solution affinity experiments to determine K_D values for up to 14 interacting pairs.

- One interactant in a concentration series is mixed with the second interactant at a fixed concentration

- At equilibrium, the response of unbound 'fixed' interactant is measured with an automated Gyrolab Affinity analysis method

- The Affinity Evaluator Software generates affinity curves by plotting the response against the concentration of the variable interactant.

- The affinity curves are fitted according to the selected interaction model.

- Multiple curve analysis from one interaction pair is available with Gyrolab Evaluator v.3.6 and higher to obtain globally fitted parameters.

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Fully automated Gyrolab LIMS interface

Biopharmaceutical companies and contract research or contract manufacturing organizations (CRO/CMO) companies often require a Laboratory Information Management System (LIMS) interface for sample tracking and data storage. Gyrolab software provides several options for a LIMS interface.
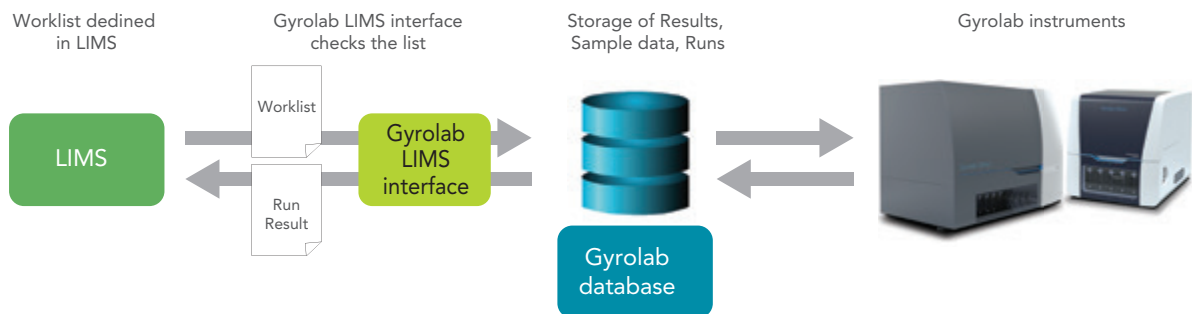
Worklist-mediated, manual Gyrolab run setup LIMS interface

- Information on samples to be processed during a Gyrolab run are provided to Gyrolab software by the LIMS

- Gyrolab software returns Run Results back to the LIMS

- User can automatically export Run Results with Gyrolab Result Exporter, maintaining data integrity in a secure process
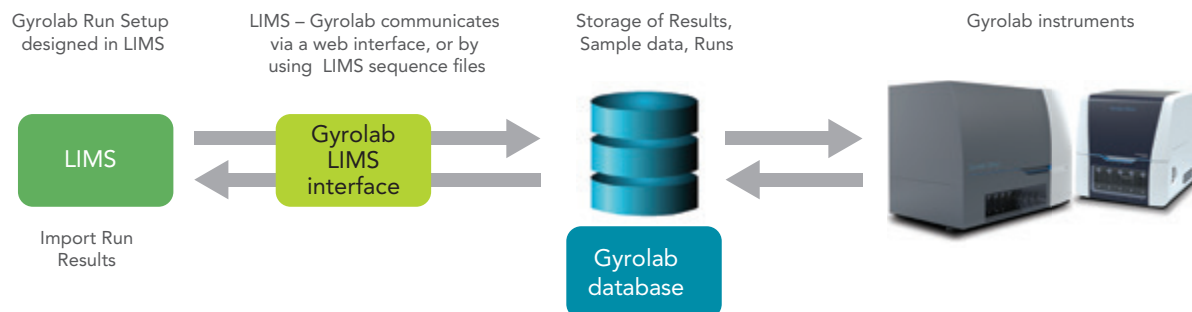
Fully automated LIMS interface

- LIMS communicates directly with Gyrolab software via a network Application Programming Interface (API) to set up a Run, and to later fetch the Run Results

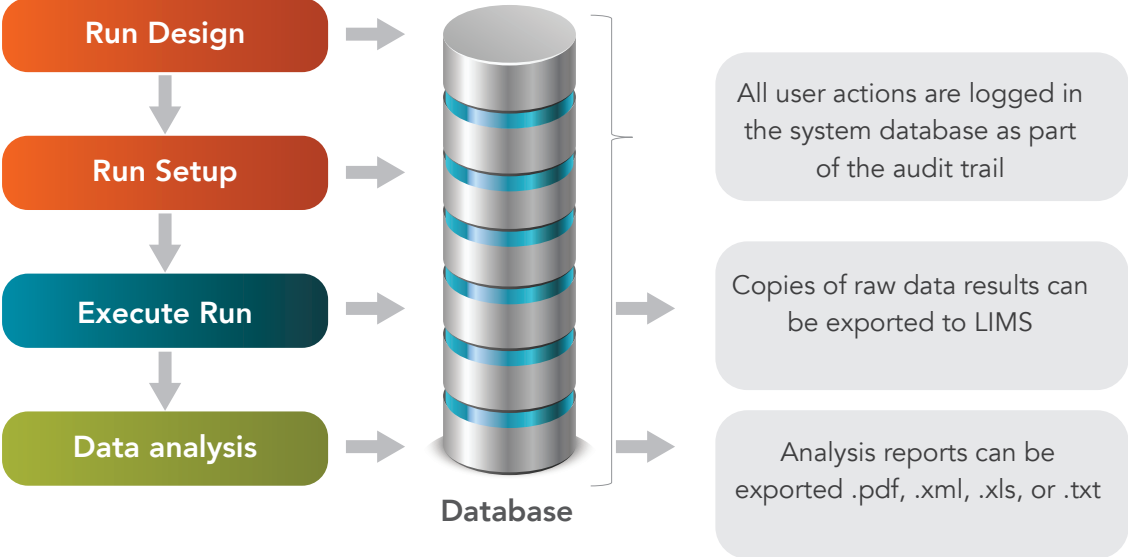- Gyrolab network API available with Gyrolab Control 8.1 or later

Worklist-mediated, manual Gyrolab run setup

| Worklist dedined in LIMS | Gyrolab LIMS interface checks the list | Storage of Results, Sample data, Runs | Gyrolab instruments |

Fully automated LIMS interface

| Gyrolab Run Setup designed in LIMS | LIMS – Gyrolab communicates via a web interface, or by using LIMS sequence files | Storage of Results, Sample data, Runs | Gyrolab instruments |

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Data storage and export meets 21 CFR Part 11 requirements

| Run Design |
| Run Setup |
| Execute Run |
| Data analysis |

Database

All user actions are logged in the system database as part of the audit trail

Copies of raw data results can be exported to LIMS

Analysis reports can be exported .pdf, .xml, .xls, or .txt

■ Gyrolab Manager

■ Gyrolab Control

■ Gyrolab Evaluator

- All data are stored in a persistent storage database
- Data cannot be added or modified without leaving a clear time-stamped trace in the audit trail
- Run design can be saved and reused.
- Sample information can be imported into the Gyrolab software

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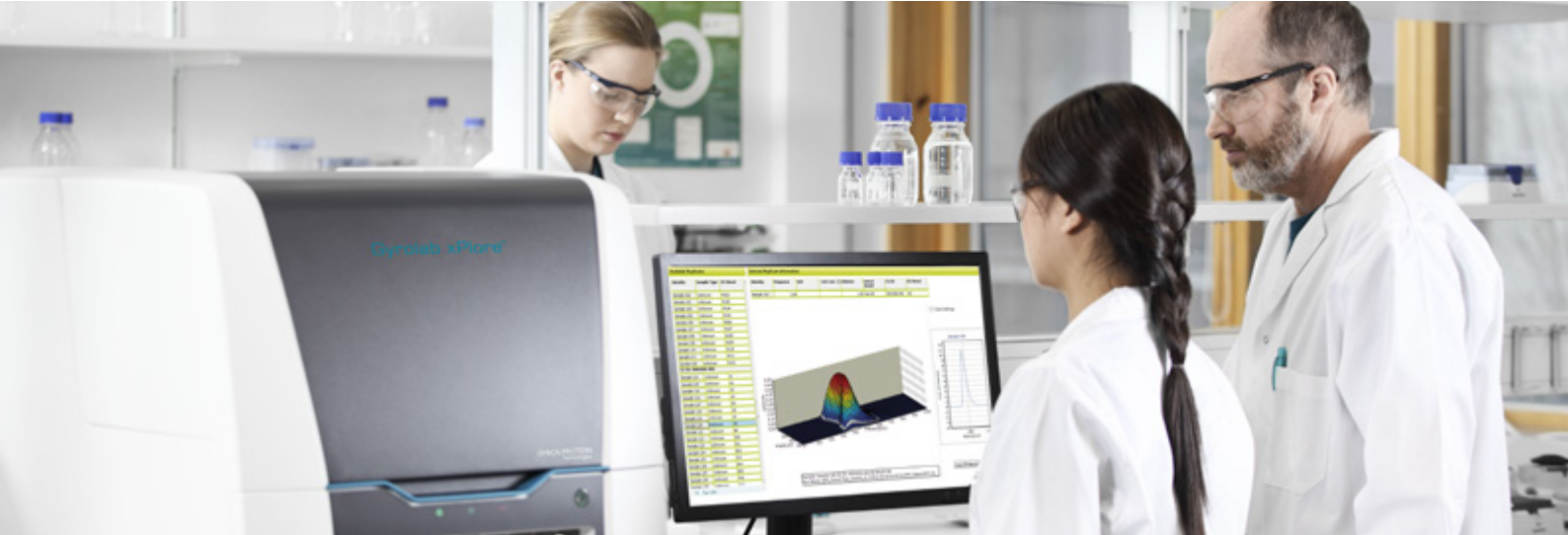
# Gyrolab software is designed with GxP and 21 CFR Part 11 compliance in mind

All software programs and modules are designed to meet 21 CFR Part 11 requirements, ensuring straightforward assay development and transfer within regulated environments.

Gyrolab software features in compliance with 21 CFR Part 11 include:

✓ Audit trail to log all changes and modifications

✓ User access levels and passwords with unique login ID and password

✓ Defined Gyrolab user roles and software privileges

✓ Administrator privileges to define custom-made user roles with unique privileges to control the level of user access

✓ Electronic signatures to sign off after evaluation of results in Gyrolab Evaluator

✓ Gyrolab Control Report with option to generate non-editable raw data reports after each run

Gyrolab systems in GxP environments are supported by the Gyrolab Service organization

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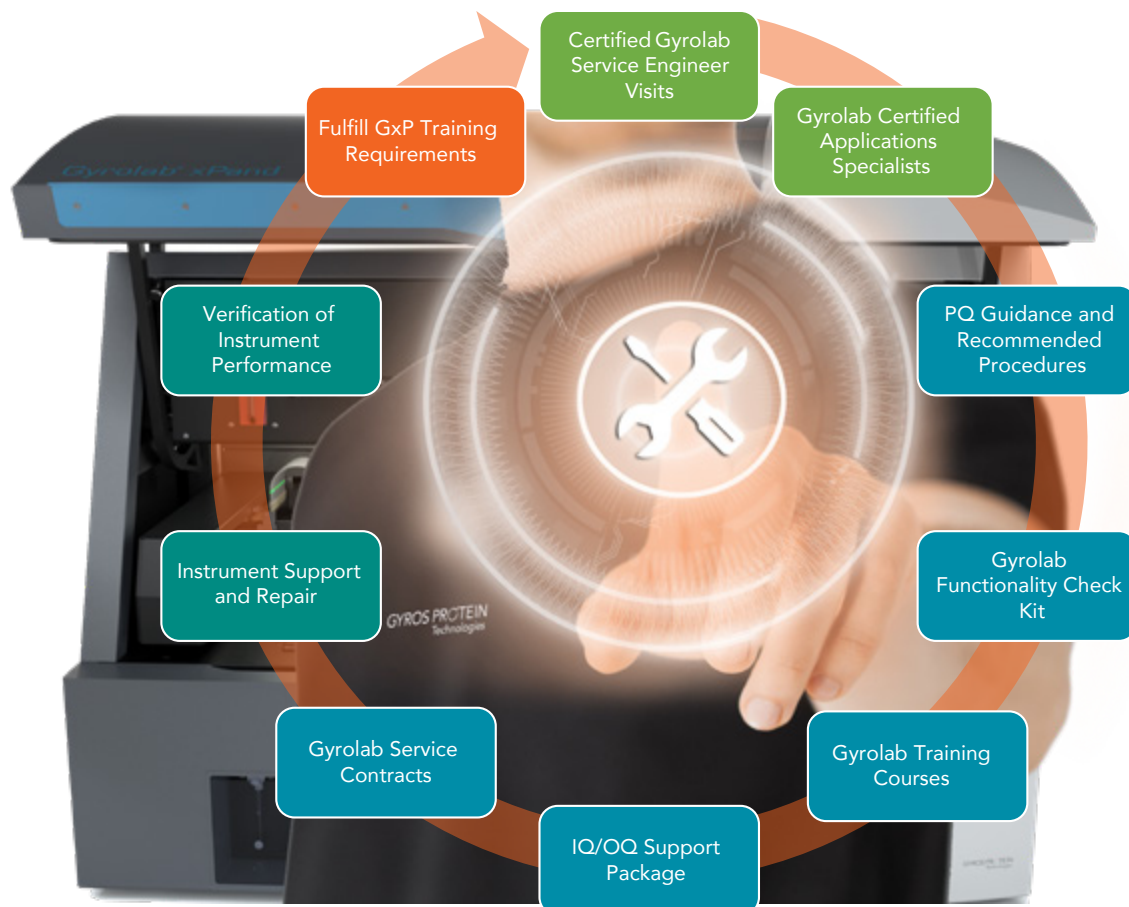
Gyrolab Software Validation and Simulator Package

Shorten software validation time

Validating new software releases can be time consuming, taking up valuable instrument time to run validations. Gyrolab Software Validation and Simulator Packages provide tools for speeding up validation processes.

Gyrolab Software Simulator Package

Gyrolab Software Simulator Package consists of a PC with a full installation of all Gyrolab software in a simulated instrument software environment. The simulator PC can be used to evaluate new Gyrolab software releases and prepare for software validation without having to upgrade the Gyrolab system in the lab. The PC with the simulator installation may also be used for formal validation of Gyrolab Evaluator and Gyrolab Manager.

Gyrolab Software Validation Package

Gyrolab Software Validation Package is a documentation package with requirements and test specifications to facilitate validation of the Gyrolab software packages: Gyrolab Control, Gyrolab Manager, and Gyrolab Evaluator.

Tools to speed up Gyrolab software validation:

✓ Evaluate new Gyrolab software releases with Gyrolab Software Simulator Package

✓ Prepare for software validation without having to upgrade the Gyrolab system PC

✓ Carry out testing of Gyrolab software outside the lab without occupying the instrument

✓ Create your validation plan using Gyrolab validation documentation with software requirements and test specification

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Product and ordering information

Prod. No	Product Name	Description
P0020520	Gyorlab xPand	Gyrolab xPand system including Gyrolab software programs; Gyrolab Manager, Gyrolab Control, Gryolab Evaluator, Gyrolab Viewer, Gyrolab ADA, Gyrolab Affininty, Gyrolab LIMS interface, and Gyrolab Control Report
P0020300	Gyrolab xPlore	Gyrolab xPlore system including Gyrolab software programs; Gyrolab Manager, Gyrolab Control, and Gyrolab Evaluator.
P0004955	Gyrolab User Licenses	Grants an unlimited number of Gyrolab software users.
P0005028	Gyrolab LIMS Interface	Software module to integrates Gyrolab system into a LIMS workflow.
P0020006	Gyrolab Control Report	Enables automatic generation of 21 CFR Part 11 compliant, non-editable, raw data report after each run.
P0020028	Gyrolab Viewer	Provides access to binding profiles of each data point directly from within Gyrolab Evaluator.
P0020025	Gyrolab ADA Software	Enables analysis of anti-drug antibodies using Gyrolab CDs. Supports ADA assay workflow through development and validation to screening and confirmatory analysis.
P0020413	Gyrolab Affinity Software	Enables Affinity software module from Gyrolab Evaluator.
P0020742	Gyrolab Software Simulator Package	Laptop computer with a full installation of all Gyrolab software in a simulated instrument software environment. Include Gyrolab User Licenses (P0004955).
P0020755	Gyrolab Software Validation Package	Documentation package with requirements and test specifications for Gyrolab Manager, Gyrolab Control, and Gyrolab Evaluator.
P0020523 P0020291	IQ/OQ validation support and PQ guidance	On-site installation and operational qualification performed by Gyrolab-certified service engineer. Includes documented procedures on how to perform performance qualification. P0020523 - Gyrolab xPand P0020291 - Gyrolab xPlore
P0020524	GOLD PLUS Service Contract, 1 year	P0020524 - Gyrolab xPand
P0020525 P0020307	GOLD Service Contract, 1 year	P0020525 - Gyrolab xPand P0020307 - Gyrolab xPlore
P0020526 P0020308	SILVER Service Contract, 1 year	P0020526 – Gyrolab xPand P0020308 – Gyrolab xPlore
P0004417	Basic Training Course	Introductory training course by Gyrolab-certified application specialist
P0005002	Gyrolab Functionality Check Kit	A confirmatory test of instrument performance

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