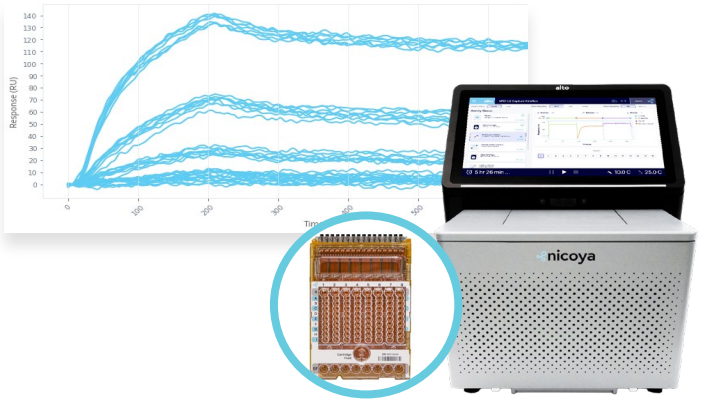
Alto GxP Suite™

Streamline development, enhance compliance

Introduction

Characterization of biomolecular interactions is an essential part of the drug discovery pipeline from initial characterization in R&D to biomanufacturing quality control. Nicoya's Alto® Digital Surface Plasmon Resonance™ (SPR) system offers unmatched ease of use along with excellent precision and accuracy for measurement of binding kinetics parameters and biomolecule quantitation. With its GxP suite, Alto can support the affinity measurement needs of pharmaceutical drugs through all stages of the development process.



Alto GxP software expansion

The features in Alto's GxP software expansion are specifically designed to support compliance with the FDA's 21 CFR part 11 guidelines around electronic records.

Access controls and data integrity

All experimental data generated on Alto, both on the instrument and in the user portal, are protected through user access controls. Administrators may add password expiry rules and configure lockout conditions in the event of unsuccessful login attempts. Raw Alto data is saved on the instrument in an edit-protected format and can be recovered post-experiment, regardless of modifications made during analysis.

Access to software functionalities is further protected through different user roles which have their own access rules and privileges (table 1). User roles may be assigned by an administrator.

Actions	Administrator	Scientist	Technician
See & edit user privileges	✓	X	X
See and edit authentication and E-signature settings	✓	X	X
Access and download audit trails	✓	X	X
Access and download data backups	✓	X	X
Override privileges	✓	X	X
Create methods	✓	✓	X
View and analyze results	✓	✓	X
Apply E-signatures	✓	✓	X
System diagnostics	✓	✓	✓
Run methods	✓	✓	✓

Table 1. User roles and corresponding feature access

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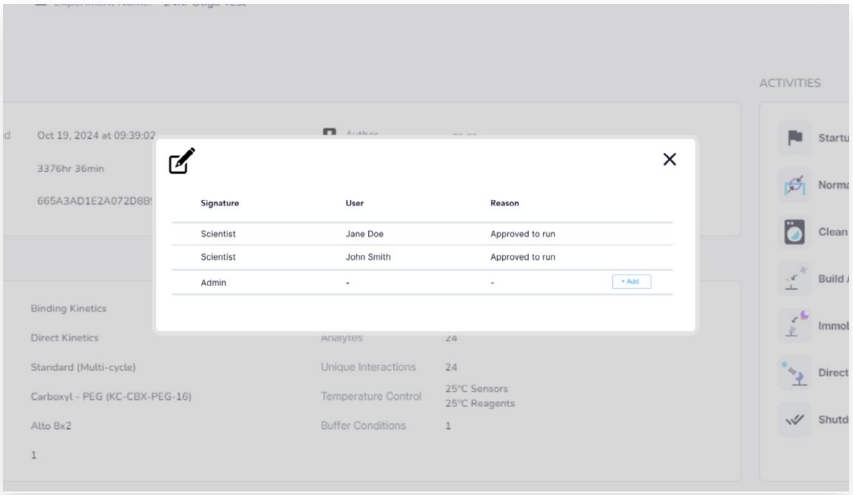
Electronic signatures

Alto's GxP software expansion supports up to three configurable signature levels and reasons which are used in key steps of assay design and analysis:

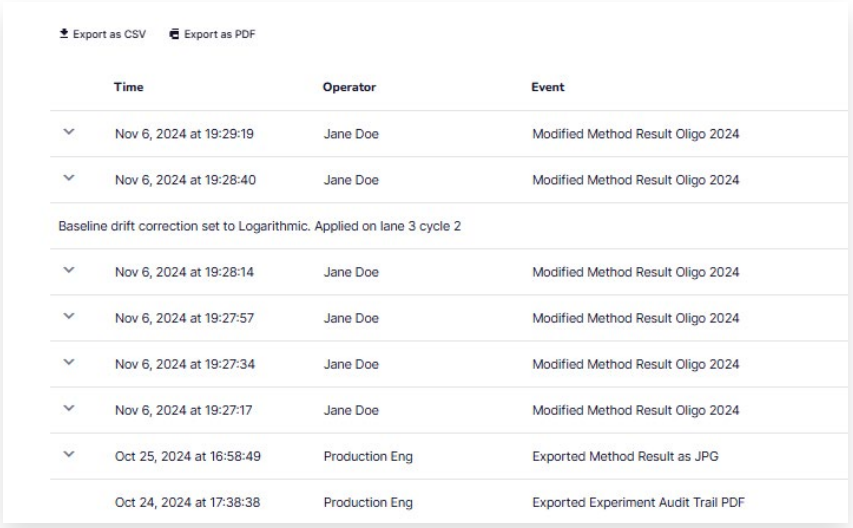
- Methods need to be signed by all required parties prior to being run on the device.
- Once signatures are applied, results are locked and further analysis modifications cannot be made.



Example of E-signatures being applied to analysis.

Audit trails

A full history of modifications made to each method and results file is recorded in its audit trail, with the corresponding timestamp and user for each action. An audit trail is also maintained for system events, including logins, power cycles, diagnostics and calibration tests, software updates and more.



Example of method result audit trail.

Alto qualification services

Instrument qualification ensures that the device performs according to specifications. This can include preventive maintenance, installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ). The following services are available for users who wish to qualify their Alto instrument(s):

- **Qualification kit:** contains all required instructions and documentation required for users to perform IQ, OQ and PQ on their own.
- **Qualification service:** a trained Nicoya representative will travel to your site and perform IQ (if required due to instrument relocation), preventive maintenance and OQ.

Summary

Maintaining traceability and quality is paramount in regulated therapeutics development and manufacturing environments. Through its GxP suite, Alto offers key features to support 21 CFR part 11 compliance, including enhanced data security and access controls, electronic signatures, audit trails, user role control and more. Nicoya's rigorous qualification processes and tools also offer all the required documentation and materials to qualify Alto for operation. The GxP suite, combined with Alto's ease of use, high throughput, and excellent data quality for affinity analysis, makes Alto an ideal choice for use in biotherapeutics characterization.