Biacore™ Insight GxP Extension and qualification services

LABEL-FREE INTERACTION ANALYSIS

Laboratories involved in pharmaceutical drug development and manufacturing need to comply with GxP (GLP/GCP/GMP) regulations. Scientists also need to validate and maintain any computer-controlled analytical systems used for GxP applications. Cytiva offers comprehensive support for interaction analysis in a regulated environment. Products and services that can be used in combination with Biacore™ 1 series and Biacore™ 8 series are:

- **Biacore™ Insight GxP Extension:** a software extension that enables operation in compliance with current GxP regulations and is specifically designed with a high level of built-in support for 21 CFR Part 11 compliance.
- **Biacore™ Insight Software Validation Support File**, including a self-assessment questionnaire, a system assessment checklist and a description of the GxP data integrity risk assessment process.
- **Change Control Notification (CCN):** is a subscription service allowing users to be notified of system changes, giving increased process robustness in regulated environments.
- **Cytiva's OptiRun™ Qualification Service:** ensures that systems are kept in a qualified state throughout their lifetime.

The products and services are described in detail below.

Biacore™ Insight GxP Extension

Biacore™ Insight GxP Extension is a software add-on enabling the use of Biacore™ 1 series and Biacore™ 8 series systems in regulated applications (Fig1). Biacore™ Insight GxP Extension facilitates compliance with worldwide regulatory expectations. The software is designed and developed using an ISO certified development model coupled with a strict quality management system (QMS) to ensure adequate verification. Security features and technical controls support 21 CFR part 11 compliance.

Fig 1. Biacore™ Insight GxP Extension offers seamless transition into regulated environments.

Features in Biacore™ Insight GxP Extension include:

- **Data integrity:** access control using Windows® Active Directory®, raw data stored in a noneditable format and enforced version handling.
- **User authorization levels:** Separation of duties via the three GxP user roles - administrator, developer, and user — set access rights to software functions.
- **Strict control of electronic records:** grant individual users the right to create, move, rename, and delete
- **Regulated procedures for operational control:** critical method settings are locked for change. Enables analysis and evaluation settings to be locked together in routine assays.
- **Audit trail:** tracks modifications performed on data evaluations.
- **Version history:** complete version history (no overwrites).
- **Electronic signatures:** used for creation and approval of regulated procedures for run and evaluation of data, and for approval of results obtained on Biacore™ 1 series and Biacore™ 8 series.
- **Easy data export:** data may be exported to Microsoft® Excel® format, Microsoft® PowerPoint®, or PDF for further data management or report out.

Validated software with 21 CFR Part 11 technical controls

Protecting the security and integrity of electronic records is essential for compliance. This includes ensuring the reliability and trustworthiness of electronic records (ER) used to support critical decisions.

Software with enhanced data security

Data integrity is maintained through access control and enforced version handling. Data is stored in an SQL database allowing for use of the built-in tools for backup of data. Access rights in Biacore™ Insight GxP Extension are controlled through membership of the different user groups administrator, developer, and user, with different access restrictions based on their respective needs (Table 1).

Table 1. Data integrity is maintained through access control and user groups

	User role[1]		
Action	**Administrator**	**Developer**	**User**
See user privileges	Allowed	Denied	Denied
Signature settings	Allowed	Denied	Denied
Perform system setup and maintenance tools	Denied	Allowed	Allowed
Create procedures	Denied	Allowed	Denied
Run and evaluate a procedure	Denied	Allowed	Allowed
Operate outside the scope of a procedure	Denied	Allowed	Denied

[1] Administrator: nonoperative role that can browse and view data but not create new data. Can be used to separate generation and administration of data.
Developer: run and evaluate freely. Defines procedures in which parameters that can affect the data for a routine assay are locked for editing for both developers and users.
User: limited to the scope of procedures, system setup, and maintenance tools.

Method templates for routine use can be locked to enforce operational control into regulated procedures (Fig 2). Alteration of a regulated procedure requires creation of a new revision.

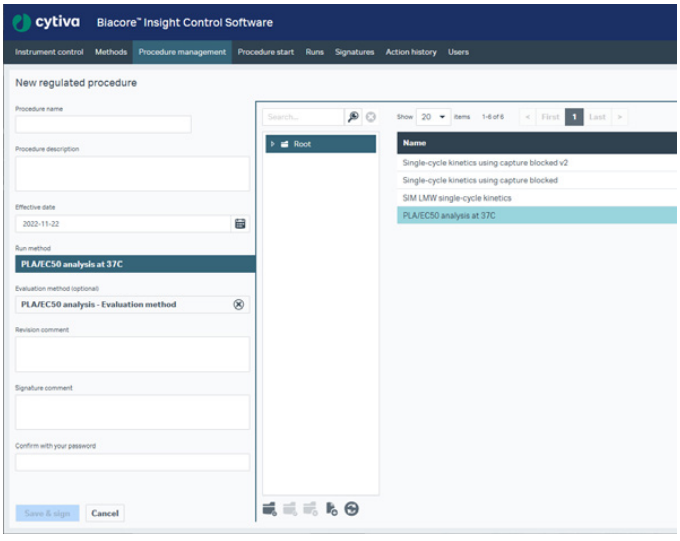

Fig 2. Procedures are used to couple analysis and evaluation methods together for operational control.

Method and audit trails for data traceability

A complete version history is maintained for created procedures and evaluations, covering user identity, date and time of creation, status, signatures and comment for publication. The version history is stored as an integral part of the published procedure or evaluation (Fig 3).

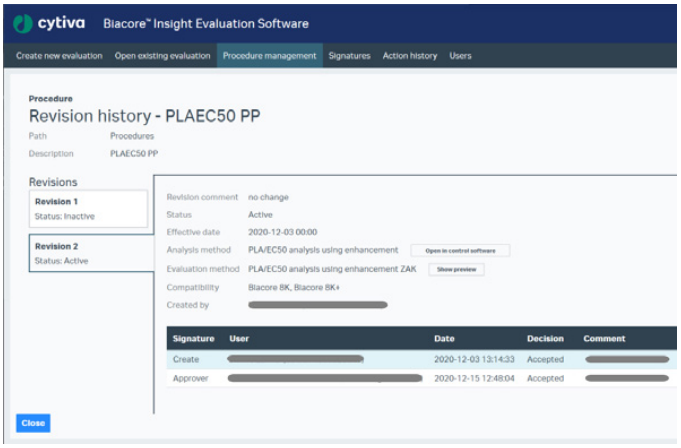

Fig 3. The complete revision and version history for procedures and evaluations, respectively is available.

Evaluations derived from regulated procedures are annotated with an ***Audit trail*** — recording all changes made to the contents (Fig 4). These are operator-independent, computer-generated, and time-stamped records for tracking entries that are made during evaluation.

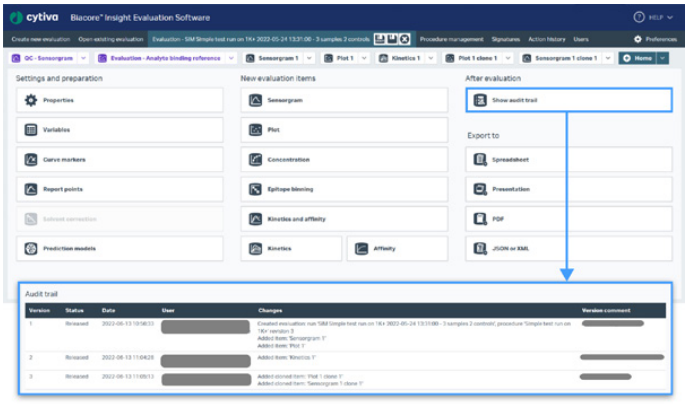

Fig 4. ***Audit trail*** is stored as an integral part of regulated evaluations.

Electronic signatures

Support for electronic signatures is included and can be used for the following key steps:

- Creation signature when saving
- Review signature (one or two)
- Approval signature

Signatures are stored with the procedure and evaluations respectively and will be available whenever you open an electronic record or perform an export or printout of the records.

Validation support documents

Biacore™ Insight GxP Extension includes Biacore™ Insight GxP User Manual and Validation Support File to save time during validation procedures. The comprehensive Validation Support package includes:

- Biacore™ Insight GxP User Manual — describes the implementation of GxP support in Biacore™ 1 series and Biacore™ 8 series using Biacore™ Insight GxP Extension and offers guidance for establishing validated assays.
- Biacore™ Insight Software Validation Support File including a self-assessment questionnaire, a system assessment checklist and a description of the GxP data integrity risk assessment process.

Together the two items above gives an overview of software development life cycle management according to Cytiva Quality Management System and provide important information for processes that use Biacore™ Insight Software. For more details, please visit cytiva.com/rsf

Change Control Notifications

The possibility to subscribe to Change Control Notifications (CCN), is offered as a complimentary service to customers working in a regulated environment. CCN service is a quality process to ensure that users are informed of all changes to Biacore™ systems and consumables that have an increased likelihood of affecting results from the handling of the instrument and software. The use of CCN allows users to be notified of system changes, giving increased process robustness in regulated environments. Subscribe at cytiva.com

OptiRun™ Qualification Service

Equipment qualification is the overall process of ensuring that a system performs according to specifications agreed by the user and vendor. Comprehensive compliance support saves time during system qualification. Biacore™ 1 series and Biacore™ 8 series SPR systems may be supplemented with OptiRun™ Qualification Service meeting worldwide regulatory requirements to ensure that the systems are kept in a qualified state throughout their lifetime (Fig 5).

Biacore™ qualification services include:

- Instrument qualification (IQ/OQ[1])
- Requalification (RQ)
- Change control procedures (CCP[2])

[1] The operational qualification (OQ) and requalification (RQ) procedures includes initial performance qualification (IPQ), a test that verifies that the system functions according to its operational specifications under conditions similar to those used by the user. The IPQ enables regular assessment and verification of the system's performance with an independent test kit developed specifically to meet qualification standards.

[2] Change control procedures are performed when needed at hardware and software changes.

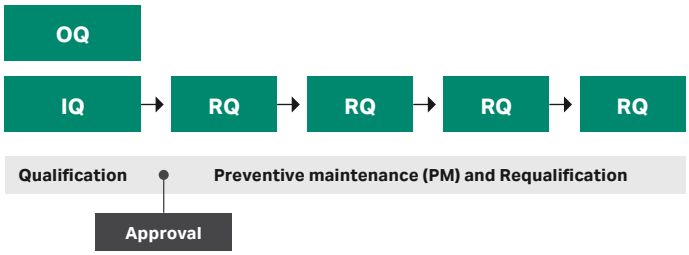

Fig 5. The regular qualification, monitoring, and maintenance process in the laboratory.

Equipment qualification is performed by qualified personnel when the system is installed in its selected operating environment. In addition, to keep the system in a qualified state, a requalification service (RQ) is also provided. This ensures correct function and maintenance from installation and throughout the system's entire lifetime.

Summary

All personnel within a company working in a setting which needs to follow regulatory requirements are responsible for assuring quality. Quality needs to be built into the study and cannot be added for the final report alone. Cytiva has over three decades of experience in development of software and systems for label-free interaction analysis and has taken many steps to support regulated companies to comply with regulatory requirements. The comprehensive package of tools and services provide:

- **Support for 21 CFR part 11 compliance**: Biacore™ Insight GxP Extension with its technical controls has been specifically designed to meet requirements for data integrity and traceability. An extensive validation support package is provided to give good support in complying with 21CFR part 11.
- **Equipment qualification:** OptiRun™ Qualification Service provide a comprehensive qualification support program that in combination with Change Control Notifications ensures efficient installation and operational qualification and provides tools to ensure that the processes are robust and the equipment kept in a qualified state.

Ordering information

Product	Product code
Biacore™ Insight GxP Extension	
Permanent Single License	29332212
Permanent 5 License Pack	29332213
Permanent 10 License Pack	29332214
Permanent 20 License Pack	29332215
1 year Single License	29332216
1 year 5 License Pack	29332217
1 year 10 License Pack	29332218
1 year 20 License Pack	29332219
IQOQ	
Binder IQOQ Biacore™ 1 series	29726521
E-Binder IQOQ Biacore™ 1 series	29726530
Binder IQOQ Biacore™ 8 series	29267090
E-Binder IQOQ Biacore™ 8 series	29389117
RQ	
Binder RQ Biacore™ 1 series	29726522
E-Binder RQ Biacore™ 1 series	29726531
Binder RQ Biacore™ 8 series	29267091
E-Binder RQ Biacore™ 8 series	29389118
RQ contract*	
Contract Addition RQ Biacore™ 1 series QM	29726535
Contract Addition RQ Biacore™ 8 series QM	29708701
CCP	
Binder CCP Biacore™ 1K to Biacore™ 1K+ Upgrade	29726525
E-Binder CCP Biacore™ 1K to Biacore™ 1K+ Upgrade	29726535

* Sold together with PM contract.

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