Label-free interaction analysis

Biacore™ T200 GxP Package

For systems used in regulated applications, Biacore T200 GxP Package facilitates compliance with worldwide regulatory expectations by enabling GxP support and 21 CFR Part 11 compliance (Fig 1).

- Validated software provides security features and the technical controls required for 21 CFR Part 11 compliance
- Comprehensive compliance support saves time during validation

Features in Biacore T200 GxP Software include:

- **Data integrity:** access control and enforced version handling
- **User authorization levels:** administrator, developer and user levels set access rights to software functions
- **Published procedures for operational control:** enables assay run and evaluation settings to be locked together in routine assays
- **Audit trail:** tracks record modifications and maintains complete version histories for published procedures
- **Data can be exported** both manually and automatically in Microsoft® Excel® (XLS) format as well as Extended Markup Language (XML) format

The extensive validation support includes a system assessment report and recommendations of OS configuration for 21 CFR Part 11 compliance.

For full validation support including Equipment Qualification, Biacore T200 GxP Package should be supplemented with Biacore GxP Services to ensure that the system is kept in a validated state throughout its lifetime.

Fig 1. Biacore T200 GxP package offers seamless transition into regulated environments.

When regulatory compliance is required

Laboratories involved in pharmaceutical drug development and manufacturing must satisfy GxP (GLP/GCP/GMP) regulations. Computer-controlled analytical systems used in GxP applications must be validated and properly maintained. With the optional Biacore T200 GxP Package, Biacore T200 can be operated in compliance with current GxP regulations. It has been specifically designed with a high level of in-built GLP/GCP/GMP support for 21 CFR Part 11 compliance.

Validated software with 21 CFR Part 11 technical controls

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

The software has been developed using a development model to ensure adequate validation.

Software with enhanced data security

Data integrity is maintained through file access control and enforced version handling. Automatic backup facilities are provided as an additional safeguard against data loss. Access rights in Biacore T200 GxP Software are controlled through membership of the different user groups BIAadministrator, BIAdeveloper and BIAuser, with different access restrictions (Fig 2).

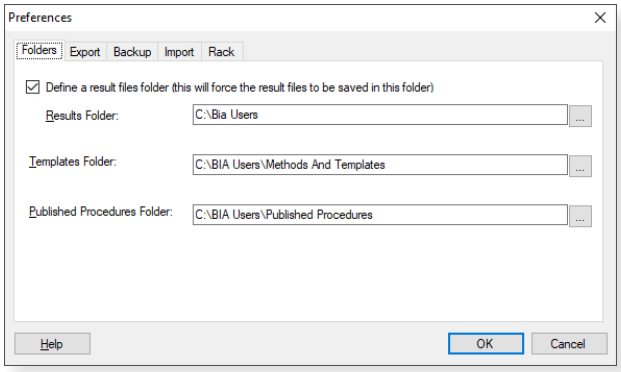

Fig 2. Data integrity is maintained through access control and user groups that determine access rights.

Method and wizard templates for routine use can be locked to enforce operational control into the analytical procedure (Fig 3). Alteration of a published procedure requires publication of a new version.

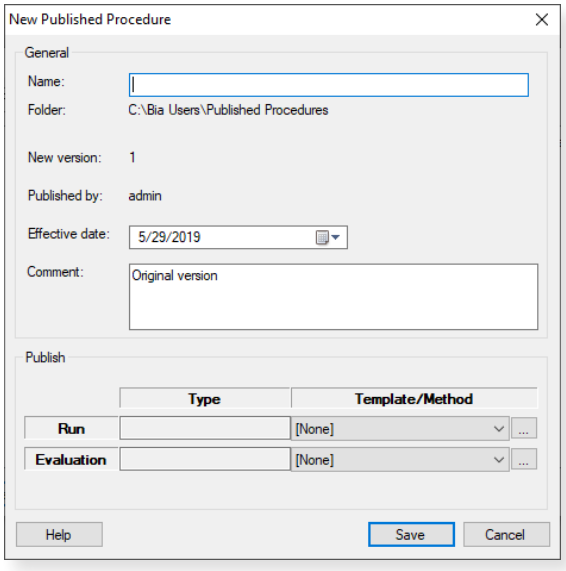

Fig 3. Method and wizard templates can be published for operational control.

Method and file audit trails for data traceability

A complete version history is maintained for published procedures, covering user identity, date and time of publication, status and comment for publication. The version history is stored as an integral part of the published procedure (Fig 4).

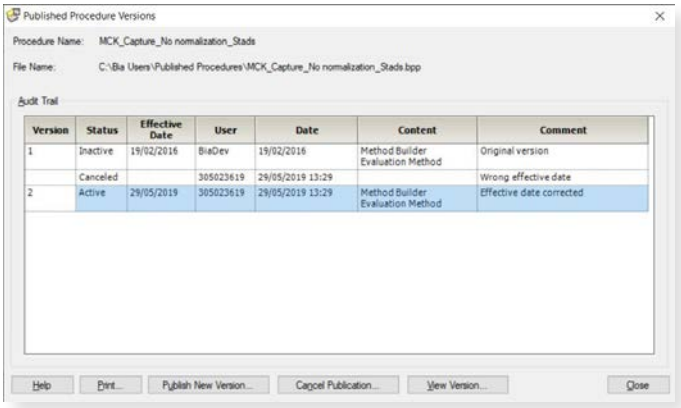

Fig 4. Version history for published procedures.

Result files and evaluation files derived from published procedures are annotated with an audit trail recording all changes made to the file contents (Fig 5). These are operator independent, computer-generated and time-stamped records for tracking entries that create, modify, or delete ER.

Fig 5. The audit trail is stored as an integral part of the file.

Sample import and data export options to facilitate data integration

Biacore T200 Software supports the import of sample and position information. With Biacore T200 GxP Package, automatic export of data in XML or XLS format is also supported. A postprocessing program can also be defined to transfer the results to a laboratory information management system (LIMS).

Validation support documents

In addition to the Biacore T200 GxP Software, Biacore T200 GxP Package includes Biacore T200 GxP Handbook and GxP Validation Support documentation to save time during validation procedures.

The comprehensive Validation Support package includes:

- Biacore T200 GxP Handbook – describes the implementation of GxP support in the Biacore T200 GxP Software and offers guidance for establishing validated assays using Biacore T200
- System assessment report – assesses how Biacore T200 GxP Software complies with 21 CFR Part 11
- Software conformance certificate – documents that the software was developed, tested, and design-validated according to a development model from GE Healthcare
- Hardware conformance certificate – documents that the instrument was developed, tested, and design-validated according to the quality procedures of GE Healthcare
- Recommendations of OS configuration for 21 CFR Part 11 compliance

Subscribe for change control notifications

A possibility to subscribe to change control notifications, CCN, is offered as a complimentary service to Biacore T200 GxP users (Fig 6).

CCN service is a quality process to ensure that users are informed of all changes to the system that have an increased likelihood to effect the result from or the handling of the product.

The use of CCN allows Biacore T200 GxP users to be notified of system changes, giving increased process robustness in regulated environments.

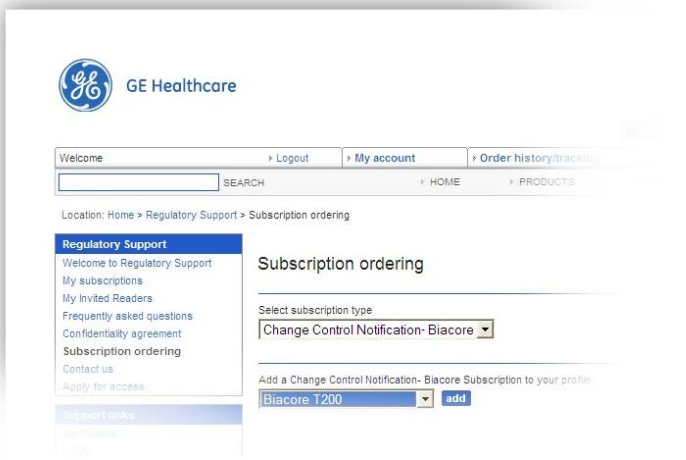

Fig 6. Subscriptions to change control notification are available online for Biacore T200 GxP users at gelifesciences.com/rsf

Full Qualification Services support for your Biacore T200

Equipment Qualification is the overall process of ensuring that a system performs according to specifications agreed by the user and vendor. Biacore T200 is supported by Equipment Qualification meeting worldwide regulatory requirements.

Biacore qualification services include:

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

[1] The OQ procedure includes Initial Performance Qualification (IPQ), a test tool that verifies that the system functions according to its operational specifications under conditions similar to those used by the customer. The IPQ enables regular assessment and verification of the system's performance with an independent test kit.

[2] Change Control Procedures are performed when needed at hardware and software changes.

Equipment qualification is performed by qualified GxP-trained personnel when the system is installed in its selected operating environment. In addition, to keep the system in a qualified state, a requalification (RQ) is also provided. This supports the ongoing qualification process and ensures correct function and maintenance throughout the system's entire lifetime. Together, GxP Extension package and Biacore qualification services have the control functionality needed to meet current GxP requirements. The systems and the comprehensive validation support program provide:

- Support for 21 CFR Part 11 compliance
- Equipment qualification (Fig 7)

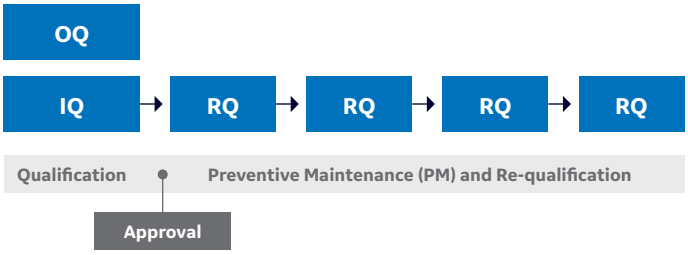

Fig 7. The regular qualification, monitoring, and maintenance process in the laboratory.

Technical specifications

Operating system: Windows® 7 Professional SP1, 64-bit or Windows 10 Professional, 64-bit.

Ordering information

Product	Product code
Biacore T200 GxP Package	28977954
Package includes Biacore T200 GxP Software, License Agreement with product key, and Biacore T200 GxP Handbook	
Validation support documentation System Assessment Report, Software Conformance Certificate, Hardware Conformance Certificate, and recommendation of OS configuration for 21 CFR Part 11 compliance	

Equipment not under service contract	Product code
IQOQ Biacore T200	29267094
Commissioning and Qualification Performance for IQ/OQ	28992654
RQ Biacore T200	29267095
Commissioning and Qualification Performance for RQ	28992654
IPQ kit type 2, CPL	22064005

Equipment under service contract	Product code
IQOQ Biacore T200	29267094
Contract addition - Commissioning and Qualification Performance for IQ/OQ	29328558
Contract addition - RQ document Biacore T200	29328255
Contract addition - IPQ kit type 2, CPL	29332371
Change Control Protocol Biacore	29267089
Commissioning and Qualification Performance for CCP	28992654

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