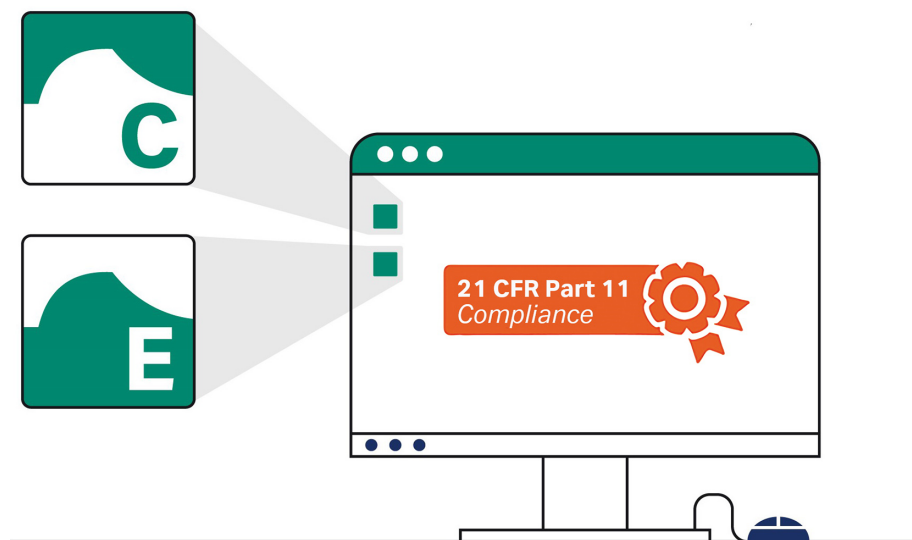


# Biacore™ Insight GxP

## User Manual



# Table of Contents

<b>1</b>	<b>Introduction .....</b>	<b>3</b>
1.1	About this manual .....	4
1.2	Important user information .....	6
<b>2</b>	<b>Overview of the GxP extension .....</b>	<b>8</b>
2.1	Scope of GxP compliance .....	9
2.2	User roles .....	10
2.3	Database recommendations .....	13
2.4	Regulated procedures .....	14
2.5	Signatures .....	18
2.6	Data integrity .....	19
<b>3</b>	<b>Operation .....</b>	<b>22</b>
3.1	Starting the GxP extension .....	23
3.2	Workspaces for GxP .....	25
3.3	Managing procedures .....	29
3.3.1	<i>Introduction</i> .....	30
3.3.2	<i>Procedure folders</i> .....	31
3.3.3	<i>Create new procedure</i> .....	32
3.3.4	<i>Revise existing procedure</i> .....	34
3.3.5	<i>Withdraw procedure</i> .....	35
3.3.6	<i>Revision history</i> .....	36
3.4	Running procedures .....	37
3.5	Evaluating regulated runs .....	39
3.6	Recovering methods from procedures .....	43
3.7	Viewing the audit trail .....	45
3.8	Signature settings .....	46
3.9	Applying signatures .....	48
3.10	Action history .....	50
3.11	Users workspace .....	51
<b>4</b>	<b>GxP compliance recommendations .....</b>	<b>52</b>
4.1	Operating system and database configuration .....	53
4.2	Data integrity .....	54
4.3	Assay development and validation .....	55
4.4	Standard Operating Procedures (SOPs) .....	56
	<b>Index .....</b>	<b>57</b>

# 1 Introduction

## About this chapter

This chapter gives an introduction to the *Biacore Insight GxP User Manual* and contains important user information.

## In this chapter

Section		See page
1.1	About this manual	4
1.2	Important user information	6

## 1.1 About this manual

### Purpose of this manual

This manual describes the software implementation of GxP support in Biacore™ software, and offers some guidance in establishing validated assays.

### Scope of this manual

GxP functionality is offered as an extension to the Biacore Insight software. The extension adds support for work in a GxP regulated environment. The software functionality is complemented by system qualification services which provide the necessary documentation for use of the system in regulated environments.

This manual describes how to use the software features added by the GxP extension. Refer to the documentation provided with your Biacore system for instructions on how to use other functionality in the system.

### Software versions

This manual covers the functionality of the GxP extension for Biacore Insight software version 6.0.

The GxP extension functionality does not apply to data imported into Biacore Insight Evaluation Software from other Biacore systems, and cannot be combined with the ***Biacore Intelligent Analysis™*** extension.

### Typographical conventions

Software items are identified in the text by ***bold italic*** text.

Hardware items are identified in the text by **bold** text.

Text that the user must either type exactly as shown in the manual, or that the software displays as a response (not a regular part of the graphic user interface), is shown by a monospaced typeface (for example, `Recipe Information`).

**Tip:**        *The text can include clickable hyperlinks to reference information.*

## Abbreviations and definitions

Abbreviation	Meaning
GxP	Collective abbreviation for GLP (Good Laboratory Practice), GCP (Good Clinical Practice) and GMP (Good Manufacturing Practice).
21 CFR Part 11	Code of Federal Regulations (21 CFR Part 11) Electronic Records; Electronic Signatures (US Food and Drug Administration).
ALCOA+	Extended framework of guidelines for establishing and maintaining data integrity for laboratory records (see <a href="#">Section 2.6 Data integrity, on page 19</a> ).
Control software	Software used to control the instrument (currently Biacore Insight Control Software).
Evaluation software	Software used to evaluate runs (currently Biacore Insight Evaluation Software).

## 1.2 Important user information

### Read this before operating the product



**All users must read the entire *Operating Instructions* before installing, operating, or maintaining the product.**

Always keep the *Operating Instructions* at hand when operating the product.

Do not install, operate, or perform maintenance on the product in any other way than described in the user documentation. If you do, you can be exposed or expose others to hazards that can lead to personal injury and you can cause damage to the equipment.

### Intended use of the product

The Biacore Insight GxP extension is intended for users who work in regulated environments and require controlled procedures for analysis and evaluation.

The Biacore Insight GxP extension is intended for research and development use only and shall not be used for diagnostic purposes.

### Disclaimer

Using the Biacore Insight GxP extension does not guarantee compliance with regulatory requirements. It is the user's responsibility to ensure that their analysis and evaluation procedures are validated and that the required documentation is maintained.

Cytiva cannot be held responsible for failure to conform to validation requirements.

### Prerequisites

In order to use the Biacore Insight GxP extension in accordance with the intended purpose, the following prerequisites must be met:

- The system should be installed according to the instructions in the *Installation* chapter of the *Operating Instructions*.
- A GxP role must be assigned to your user account (handled by the database administrator, see the *Biacore Insight Database Installation and Management Guide* for details).
- You should have a general understanding of the use of a personal computer running Microsoft Windows in the version supported by your product.
- You should be acquainted with the use of general laboratory equipment and with handling of biological materials.

- You should be acquainted with the use of your Biacore system that supports the Biacore Insight GxP extension.
- You must follow applicable laws and restrictions for working in a regulated environment.

A database administrator familiar with management of Microsoft SQL Server databases is required for installing and maintaining the database. Familiarity with database management is not required for operation of Biacore systems with the GxP extension.

## Additional documentation

This manual only describes the specific GxP-related features of the Biacore system. Features that are common to use in GxP and non-GxP contexts are described in the additional documentation provided with the system.

Documentation can be downloaded from [cytiva.com/biacore](https://www.cytiva.com/biacore).

# 2 Overview of the GxP extension

## About this chapter

This chapter provides an overview of the scope of GxP compliance and the way in which it is supported by the GxP extension.

## In this chapter

Section		See page
2.1	Scope of GxP compliance	9
2.2	User roles	10
2.3	Database recommendations	13
2.4	Regulated procedures	14
2.5	Signatures	18
2.6	Data integrity	19



## 2.1 Scope of GxP compliance

### Regulatory requirements

Regulatory authorities require pharmaceutical development and manufacturing companies to use quality assured equipment and to follow detailed and carefully documented analytical and manufacturing procedures. The purpose of this control effort is to ensure consistent and reliable quality in pharmaceutical products that reach the market. A prime mover is the United States Food and Drug Administration (FDA). Corresponding regulations in countries outside the United States often follow the lead of the FDA.

### 21 CFR Part 11

The FDA rule commonly referred to as 21 CFR Part 11 provides regulations for electronic documentation of computer-based analytical and manufacturing procedures, and aims to ensure that electronic records are complete and inviolate.

The GxP extension provides support for compliance with 21 CFR Part 11 regulations.

### Equipment qualification

Quality assurance of equipment (*equipment qualification*) aims to ensure that analytical and manufacturing equipment performs reliably according to the specifications of the manufacturer. Cytiva offers qualification services to provide the necessary documentation for equipment qualification.

## 2.2 User roles

### Introduction

Access to functions in the GxP extension is controlled by database roles, which provide a means for securing a robust GxP environment where opportunities for departure from prescribed procedures are minimized. The roles can be divided into two groups:

- *GxP roles*, which control access to functions and workspaces in the GxP extension
- *Data access roles*, which control permission to create, move, rename, and delete database objects such as methods, runs and evaluations

Users are granted role membership by the database administrator. Users of the GxP extension must be a member of at least one role from each group. More details are provided in the 29287249 *Biacore Insight Database Installation and Management Guide*.

Users with **GxPadministrator** role can view the role membership for users (see [Section 3.11 Users workspace, on page 51](#)).

### Software access restrictions

Users are authorized to use the GxP extension by being assigned a GxP role in the database. The following restrictions apply when the system software is started:

GxP role	Software authorization
No GxP role assigned	The user can only start the system software <i>without</i> the GxP extension.
GxP role assigned	The user can only start the system software <i>with</i> the GxP extension.

### GxP roles

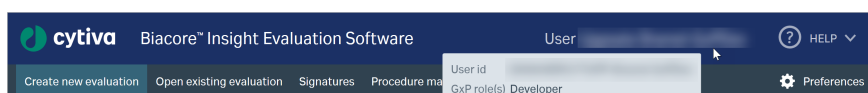
Essential features of the GxP roles are summarized in the table below. Users or user groups who are members of multiple roles have the combined permissions of the separate roles. For example, a user with only the **GxPadministrator** role is not permitted to run the instrument from the control software, but a user with both **GxPadministrator** and **GxPdeveloper** can run the instrument.

Access to the various workspaces in the control and evaluation software for the different user roles is specified in detail in [Section 3.2 Workspaces for GxP, on page 25](#).

Role	Permissions
<b>GxAdministrator</b> <b>or</b>	<p><b>GxAdministrators</b> are generally responsible for aspects of database management that require an understanding of the content of methods, runs, and evaluations.</p> <p><b>GxAdministrators</b> can be part of a team that includes the database administrator, responsible for database maintenance.</p> <p><b>GxAdministrators</b> are responsible for <b>Signature settings</b> (see <a href="#">Section 3.8 Signature settings, on page 46</a>).</p> <p><b>GxAdministrators</b> are not permitted to establish a connection with a Biacore instrument and can therefore not perform any runs. The role gives permission to open existing runs and methods in the control software, and evaluations in the evaluation software, but the role does not give permission to save any changes to them.</p> <p>The <b>GxAdministrator</b> role gives access to the <b>Users</b> workspace displaying user details (see <a href="#">Section 3.11 Users workspace, on page 51</a>).</p> <p><b>GxAdministrators</b> can get permission to sign regulated evaluations if needed.</p>
<b>GxPdeveloper</b>	<p><b>GxPdevelopers</b> are generally responsible for developing and maintaining regulated procedures.</p> <p>They can use all functions, including performing and evaluating non-regulated runs and creating regulated procedures. They are however not permitted to access the <b>Users</b> workspace or the <b>Signature settings</b> workspace.</p> <p><b>GxPdevelopers</b> can run regulated procedures, with the same constraints as for <b>GxPusers</b>.</p>
<b>GxPuser</b>	<p><b>GxPusers</b> are generally responsible for performing and evaluating routine analyses using regulated procedures.</p> <p>They can only run and evaluate regulated procedures and run maintenance tools. No other access is permitted.</p>

Components of the software that are not available to the user currently logged in are hidden: for example, the **Users** workspace is only displayed for **GxAdministrators**.

To identify the current user's GxP roles, hold the mouse pointer over the **User** name in the top banner of the software.



## Data access roles

Permission to create, move, rename, and delete objects in the database is granted by the database administrator by membership in the data access roles, independently of GxP roles (see the *Biacore Insight Database Installation and Management Guide* for details). A user must have membership in at least one of these roles in order to start the software, regardless of GxP role status. The database roles and corresponding permissions are listed in the following table.

Database role name	Permissions
<b><i>BiacoreUsersCreate</i></b>	Create
<b><i>BiacoreUsersCreateMoveRename</i></b>	Create, Move, and Rename
<b><i>BiacoreUsersCreateMoveRenameDelete</i></b>	Create, Move, Rename, and Delete

Data access roles are combined with GxP roles to establish a user structure that supports the required level of data integrity and traceability. For example, permission to delete database objects can be restricted to **GxP administrators**, while GxP users can be prevented from moving, renaming and deleting objects.

**Note:** *Permissions granted by data access roles can be overridden by restrictions in the software itself. For example, a user with **Delete** permission can delete non-regulated runs, but regulated procedures cannot be deleted by any user.*

## 2.3 Database recommendations

### Choice of database

Storing GxP data in a local database is strongly discouraged. A network database provides centralized storage with higher security and better support for backup and logging.

### Data compartmentalization

For installations where both GxP and non-GxP work is performed, it is recommended that separate databases are used for the two kinds of work. This has a number of advantages over a single database with mixed GxP and non-GxP content:

- User management is simplified by avoiding the requirement for separate GxP and non-GxP logins for the same physical user (the same user can choose the environment by selecting the appropriate database at login).
- Confusion that can arise from mixed database content is avoided.
- A database that contains only GxP content is more easily reviewed, audited, and archived.

## 2.4 Regulated procedures

### Introduction

Methods for runs and evaluation are prepared for GxP use by creation of *regulated procedures*. A regulated procedure contains one immobilization or analysis method and (optionally) one evaluation method. Including an evaluation method for analysis runs is strongly recommended. Running a procedure creates a *regulated run*, and opening a regulated run in the evaluation software automatically applies the evaluation method contained in the procedure. Evaluation items are not created automatically if the procedure does not contain an evaluation method. Additional evaluation items can be created, and are logged in the audit trail (see [Section 3.7 Viewing the audit trail, on page 45](#)).

Critical parameters and settings are locked in regulated procedures. A user with **GxPdeveloper** role defines the values for locked settings and parameters during method development. Once the procedure has been created, the locked settings and parameters cannot be changed, regardless of the role of the user running the procedure.

Procedures are stored in a protected area of the database that can only be accessed from the **Procedure management** and **Procedure start** workspaces (see [Section 3.2 Workspaces for GxP, on page 25](#)). Procedures cannot be listed in other workspaces or discovered by search functions.

**Note:** *Methods are included in procedures as separate copies of the original methods and are not identified by method names. Methods can be recovered from procedures (see [Section 3.6 Recovering methods from procedures, on page 43](#)), but do not retain any link to the original named methods.*

### Developing procedures

Procedures are developed and created by users with **GxPdeveloper** role. A regulated procedure contains the settings for analysis and evaluation methods that were current when the procedure was created. Subsequent editing of the settings in the original methods does not affect the settings contained in the procedure.

Procedure settings are changed by creating a new revision of the procedure, which supersedes the previous revision. Procedures cannot be renamed or removed from the database.

Procedures become active when the following conditions are fulfilled:

- The effective date has passed.
- The approval signature is applied (if signatures are used).

Only one revision of a procedure can be active at any one time.

Locked parameters and settings

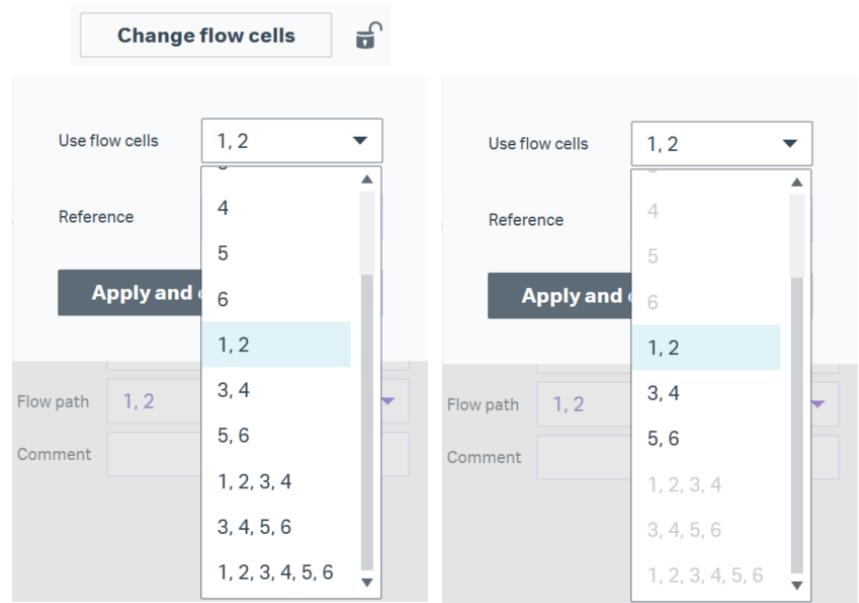
When the Biacore Insight GxP extension is active, some parameters and settings are highlighted in purple in various workspaces. These parameters and settings are locked when the method is included in a procedure:

Method status and user role	Meaning of purple highlight
During method development ( <i>GxPdevelopers</i> only)	The parameter or setting can be changed during method development, but will be locked when the method is included in a procedure.
In a regulated procedure ( <i>GxPdevelopers</i> and <i>GxPusers</i> )	The parameter or setting is locked.

Unlocking flow cell usage

For Biacore 1 series, the procedure developer can choose to keep the flow cell selection unlocked in the **Method definition** step of immobilization methods and analysis methods. This makes it possible to change flow cells when running the procedure, but the number of used flow cells must remain the same. For example, if flow cell pairs (1, 2) were used upon method development, then flow cell pairs (1, 2), (3, 4) and (5, 6) can be selected when running the procedure.


The two images below show the **Use flow cells** menu during method development (left-hand image), and in a regulated procedure (right-hand image):

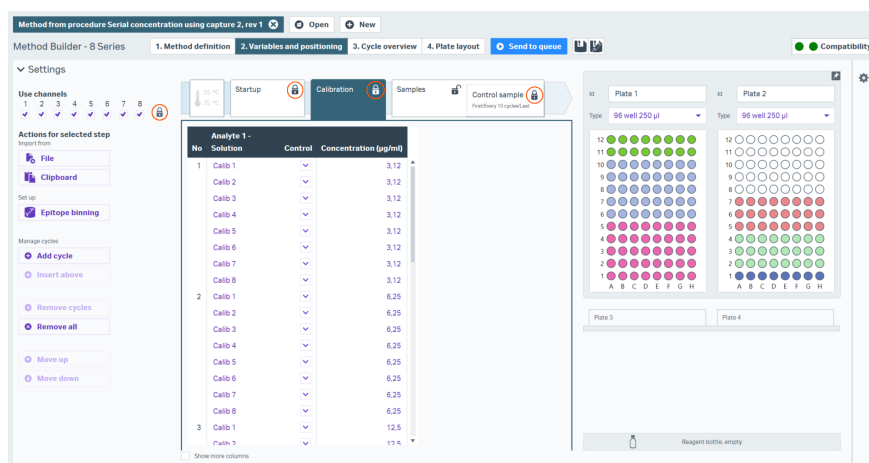


The **Reference** setting of analysis methods is automatically adjusted based on flow cell selection and cannot be changed upon procedure start. For Biacore 8 series, the flow cell selection of a procedure is always locked.

**Tip:** To unlock the flow cell selection of a regulated Biacore 1 series procedure saved in Biacore Insight 5.0 or earlier, revise the regulated procedure with a run method where the flow cell selection is unlocked.

## Locking variables and channel usage

By default, the channel usage (Biacore 8 series) and sample table in the **Variables and positioning** step of analysis methods are not locked, so that the user can change the channel usage and sample details when the regulated procedure is run. The procedure developer can choose to lock these settings for selected steps in the method using the lock icon . This is typically used for example for solvent correction, surface conditioning, startup, and calibration steps, so that only the samples can be changed when the procedure is run.



**Note:** The whole sample table for a step is either locked or unlocked. It is not possible to lock individual rows in the sample table.

Channel usage (Biacore 8 series) and ligand names are always locked in immobilization methods in regulated procedures.

## Procedure revisions

Procedures can be revised to incorporate new or changed methods. A new revision of a procedure supersedes any previous revision. Procedure revisions that have been superseded cannot be used for new runs.

A full revision history is maintained in the database.



## Running procedures

A procedure can be run and the results evaluated by any user with **GxPdeveloper** or **GxPuser** role. The restrictions regarding locked parameters and settings apply regardless of the role of the user. Runs derived from a procedure are referred to as *regulated runs*.

## Evaluating regulated runs

The evaluation method included in a procedure is applied automatically when results from the procedure are opened in the evaluation software. Item settings for evaluation items created by the procedure cannot be changed. Changes such as excluding or including points and setting curve markers are recorded in the audit trail. New items can be created freely: creation and removal of such items is recorded in the audit trail, but changes made to new items are not recorded.

Runs from procedures that do not include an evaluation method will be opened with no predefined evaluation items and no locked settings. Items can be added and addition or deletion of items is logged in the audit trail, but changes made to added items are not logged.

## 2.5 Signatures

### Introduction

With the GxP extension it is possible to apply signatures to Regulated procedures and Regulated evaluations. The GxP administrator manage the settings for the signatures (see [Section 3.8 Signature settings, on page 46](#)).

### Signature types

There are three different kinds of signatures applied in Biacore Insight software; create, review and approve. The create signature is automatically applied when a user creates a regulated procedure or regulated evaluation. It is possible to add one or two review signatures and they are optional. The last signature is always the approve signature.

The signature settings are applied independently to regulated procedures and regulated evaluations. The available settings are the same for procedures and evaluations. Each chosen signature can be renamed to suite local routines.

## 2.6 Data integrity

### Introduction

The GxP extension supports maintenance of data integrity following the guidelines for laboratory records known by the acronym ALCOA+:

Principle	Description
<b>Attributable</b>	Records who performed an action and when.
<b>Legible</b>	Readable throughout the entire lifecycle of the record.
<b>Contemporaneous</b>	Documented at the time of the activity.
<b>Original</b>	The original data is stored in the database.
<b>Accurate</b>	All editing of the record is documented.  <b>Note:</b> <i>"Accurate" in this context refers to accuracy of the documentation, not to accuracy of the experimental results.</i>
Complete	Data records are complete.
Consistent	Sequential elements of the analysis are date- and time-stamped in the expected sequence.
Enduring	Deletion of records can be prevented.
Available	Records can be accessed for review, inspection or audit during the lifetime of the record.

### Integrity of database objects

All original data for procedures, regulated runs, and regulated evaluations is stored in the database in read-only mode and cannot be overwritten. The integrity of procedures, regulated runs and regulated evaluations in the database is maintained as described below.

Item	Integrity measures
Procedures	Regulated procedures contain the revision history of the procedure as well as a full copy of the run and evaluation methods included in the procedure, so that the methods can be recovered if necessary from the procedure. Changing the original method does not affect the settings in the procedure.

Item	Integrity measures
Runs	<p>Run data cannot be modified.</p> <p>Run objects are created in the database at the start of a run but are not finalized until the run is complete. Ongoing runs cannot be opened in other instances of the control software. If the results of an on-going run are opened in the evaluation software, a snapshot of the results up to and including the last completed cycle is opened. Evaluation of snapshots cannot be saved or exported.</p>
Evaluations	<p>Regulated evaluations are named by the user when they are first created (using <b>Create new evaluation</b>).</p> <p>Modification of existing regulated evaluations (using <b>Open existing evaluation</b>) creates new drafts or versions. All previous evaluation versions are accessible for review in <b>Version history</b>.</p> <p>The possibility to save a draft of the regulated evaluation is intended to be used while performing the evaluation. The evaluation is not sent for signature approval and the version comment can be changed. The status for the regulated evaluation is "Draft".</p> <p>If signatures are used, the signature process starts when the user saves a new version of the evaluation. It is not possible to create a new version of an evaluation that is waiting for approval, i.e., has the status <b>Pending signature</b>.</p>

## Audit trail

Operations performed in Biacore Insight Evaluation Software on results from a regulated procedure are logged in an audit trail. The audit trail includes comments explaining for example why the logged changes were made. See [Section 3.7 Viewing the audit trail, on page 45](#) for details.

## Backup

The database administrator is responsible for establishing backup routines for the database. The GxP extension does not include any specific backup functions.

## Data export

Regulated runs and evaluations can be exported for transfer to another database and to Cytiva for support purposes. Information relating to the procedure from which the runs and evaluations were derived is however not exported, and runs and evaluations imported to another database do not have regulated status in the target database.

Procedures themselves cannot be exported. Follow the steps below to transfer a procedure to another database.

Step	Action
1	Recover and save the methods from the procedure (see <a href="#">Section 3.6 Recovering methods from procedures, on page 43</a> ).
2	Export the recovered methods and import them to the target database.
3	Recreate the procedure in the target database.
	<b>Note:</b> <i>Any revision history for the procedure will be lost.</i>
<b>Note:</b>	<i>The user is responsible for providing secure management of files exported as spreadsheets, presentations, and PDF files from regulated evaluations.</i>

# 3 Operation

## About this chapter

This chapter describes how to use the features specific to the GxP extension. How to use other functions is described in the *Biacore 1 series User Manual, 29706293*, the *Biacore 8 series User Manual, 29287247*, and the *Biacore Insight Evaluation Software User Manual, 29287248*.

## In this chapter

Section	See page
3.1 Starting the GxP extension	23
3.2 Workspaces for GxP	25
3.3 Managing procedures	29
3.4 Running procedures	37
3.5 Evaluating regulated runs	39
3.6 Recovering methods from procedures	43
3.7 Viewing the audit trail	45
3.8 Signature settings	46
3.9 Applying signatures	48
3.10 Action history	50
3.11 Users workspace	51

## 3.1 Starting the GxP extension

### Requirements

The GxP extension is started together with the control or evaluation software.

The following requirements must be fulfilled in order to start the GxP extension:

- A valid license for the GxP extension must be available.
- The user logging in to the software must have an assigned GxP role in the database (see [Section 2.2 User roles, on page 10](#)).

**Note:** *Users with a GxP role can only start the software with the GxP extension selected. Users who are not assigned a GxP role are not permitted to start the software with the GxP extension selected.*


### Select the GxP extension

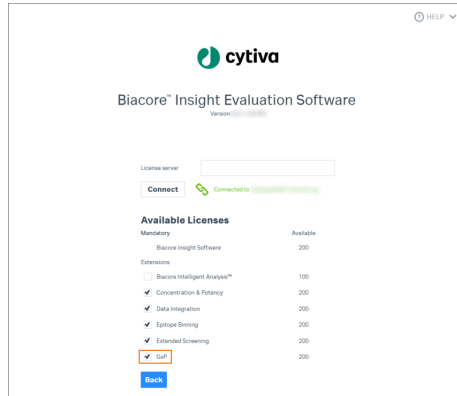
Follow the steps below to start the software with the GxP extension. The steps are the same for the control software and evaluation software.

Step	Action
1	Start the control or evaluation software.
2	If the <b>GxP</b> is listed under <b>Selected extensions</b> in the <b>Login</b> dialog, continue to log in to the software.

The screenshot shows the login interface of the Biacore Insight Evaluation Software. At the top, there is a 'HELP' button. Below it is the 'cytiva' logo. The main title is 'Biacore® Insight Evaluation Software'. There are three input fields: 'User id', 'Domain: DANMVER', and 'Password'. Below these fields are two links: 'Database' and 'Selected extensions'. The 'Selected extensions' link is active, showing a list of extensions: 'Concentration & Potency', 'Data Integration', 'Epitope Binning', 'Extended Screening', and 'GxP'. The 'GxP' extension is highlighted with a red box. At the bottom of the dialog are two buttons: 'Log In' and 'Cancel'.

Step	Action
------	--------

- |   |   |
|---|---|
| 3 | <p>If <b>GxP</b> is not listed in the <b>Login</b> dialog, click the pen icon  next to the <b>Selected extensions</b> list, then select the GxP extension. The number of available licenses for each extension is shown in the dialog.</p> |
|---|---|



- |   |   |
|---|---|
| 4 | Click <b>Close</b> to return to the <b>Login</b> dialog and log in to the software. |
|---|---|

**Note:** *If another instance of either control or evaluation software is running on the same computer, both the **User id** and the **Selected extensions** are locked to the settings used in the software that is already running.*

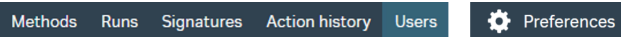
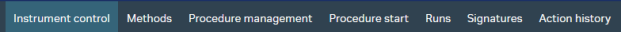


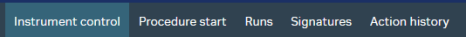
## 3.2 Workspaces for GxP

### Workspace availability

Workspaces available to users in GxP mode vary according to the GxP role assigned to the user. The tables in the subsequent sections summarize the available workspaces in Biacore Insight Control Software and Biacore Insight Evaluation Software according to the user's GxP role. Screenshots in the tables show the tabs as displayed in a newly opened instance of the software.


### Biacore Insight Control Software

Role	Workspace	Comments
<b>GxP-administrator</b>		
	<b>Methods</b>	Methods can be opened but not modified or saved.
	<b>Runs</b>	Runs can be opened.
	<b>Signatures</b>	Available actions depend on individual rights set in signature settings. See <a href="#">Section 3.8 Signature settings, on page 46</a> for more information.
	<b>Action history</b>	Full view access. Restrictions apply on items opened from <b>Action history</b> . See <a href="#">Section 3.10 Action history, on page 50</a> for more information.
	<b>Users</b>	See <a href="#">Section 3.11 Users workspace, on page 51</a> .
	<b>Preferences</b>	Instrument can be selected and signature settings changed. See <a href="#">Section 3.8 Signature settings, on page 46</a> .
<b>GxPdeveloper</b>		
	<b>Instrument control</b>	Full access.

Role	Workspace	Comments
	<b>Methods</b>	Full access.  Parameters and settings that are highlighted in purple will be locked in a regulated procedure.
	<b>Procedure management</b>	See <a href="#">Section 3.3 Managing procedures, on page 29</a> .
	<b>Procedure start</b>	See <a href="#">Section 3.4 Running procedures, on page 37</a> .
	<b>Runs</b>	Full access.
	<b>Signatures</b>	Available actions depend on individual rights set in signature settings. See <a href="#">Section 3.8 Signature settings, on page 46</a> for more information.
	<b>Action history</b>	Full access.  See <a href="#">Section 3.10 Action history, on page 50</a> for more information.
	<b>Preferences</b>	Instruments can be selected.
<b>GxPuser</b>		
	<b>Instrument control</b>	Restricted to <b>System setup</b> and <b>Maintenance</b> .
	<b>Procedure start</b>	Parameters and settings that are highlighted in purple are locked.  See <a href="#">Section 3.4 Running procedures, on page 37</a> .
	<b>Runs</b>	Restricted to regulated runs and maintenance runs.
	<b>Signatures</b>	Available actions depend on individual rights set in signature settings. See <a href="#">Section 3.8 Signature settings, on page 46</a> for more information.

Role	Workspace	Comments
	<b>Action history</b>	Full access. Restrictions apply on items opened from <b>Action history</b> . See <a href="#">Section 3.10 Action history, on page 50</a> for more information.
	<b>Preferences</b>	Instruments can be selected.

## Biacore Insight Evaluation Software

Role	Workspace	Comments
<b>GxP administrator</b>	Open existing evaluation Signatures Action history Users  Preferences	
	<b>Open existing evaluation</b>	Evaluations cannot be saved.
	<b>Signatures</b>	Available actions depend on individual rights set in signature settings. See <a href="#">Section 3.8 Signature settings, on page 46</a> .
	<b>Action history</b>	Full view access. Restrictions apply on items opened from <b>Action history</b> . See <a href="#">Section 3.10 Action history, on page 50</a> .
	<b>Users</b>	See <a href="#">Section 3.11 Users workspace, on page 51</a> .
	<b>Preferences</b>	See <a href="#">Section 3.8 Signature settings, on page 46</a> .
<b>GxP developer</b>	Create new evaluation Open existing evaluation Procedure management Signatures Action history	
	<b>Create new evaluation</b>	Full access. Parameters and settings that are highlighted in purple will be locked in a regulated procedure.

Role	Workspace	Comments
	<b>Open existing evaluation</b>	Full access.  Parameters and settings that are highlighted in purple in a regulated procedure are locked.
	<b>Procedure management</b>	See <a href="#">Section 3.3 Managing procedures, on page 29</a> .
	<b>Signatures</b>	Available actions depend on individual rights set in signature settings.  See <a href="#">Section 3.8 Signature settings, on page 46</a> .
	<b>Action history</b>	Full access.  See <a href="#">Section 3.10 Action history, on page 50</a> .
<b>GxPuser</b>	Create new evaluation   Open existing evaluation   Signatures   Action history	
	<b>Create new evaluation</b>	Restricted to regulated runs.
	<b>Open existing evaluation</b>	Restricted to regulated evaluations.
	<b>Signatures</b>	Available actions depend on individual rights set in signature settings.  See <a href="#">Section 3.8 Signature settings, on page 46</a> .
	<b>Action history</b>	Full view access.  Restrictions apply on items opened from <b>Action history</b> .  See <a href="#">Section 3.10 Action history, on page 50</a> .

## 3.3 Managing procedures

### In this section

Section		See page
3.3.1	Introduction	30
3.3.2	Procedure folders	31
3.3.3	Create new procedure	32
3.3.4	Revise existing procedure	34
3.3.5	Withdraw procedure	35
3.3.6	Revision history	36

## 3.3.1 Introduction

Analysis and evaluation methods are made available for running by users with **GxPuser** role by creation of *regulated procedures* (see [Section 2.4 Regulated procedures, on page 14](#)). Users with the **GxPdeveloper** role can create, revise and withdraw regulated procedures. **GxPdevelopers** can also run regulated procedures, with the same restrictions as **GxPusers**.

Procedures are managed from the **Procedure management** workspace in either the control software or the evaluation software.

The screenshot shows the 'Biacore™ Insight Evaluation Software' interface. The top navigation bar includes 'Create new evaluation', 'Open existing evaluation', 'Signatures', 'Procedure management' (active), and 'Action history'. A 'User' dropdown and 'HELP' icon are on the right. The left sidebar shows 'Procedures' and 'Signatures' tabs. The main content area displays a table of procedures:

Name	Revisions	Content	Status
Test 1	1	Analysis method Evaluation method	Pending sig
Sandwich using capture	2	Analysis method Evaluation method	Withdrawn
Parallel concentration using enhancement 2	1	Analysis method Evaluation method	Active
Parallel concentration using enhancement	1	Analysis method Evaluation method	Active
LMW single-cycle kinetics using GST Capture kit	1	Analysis method Evaluation method	Active
Fragment affinity screen	2	Analysis method Evaluation method	Active

A 'New' button is located at the bottom left of the table. The right sidebar shows 'Procedure details' for the selected procedure, including 'Path', 'Procedure description', and 'Revision comment'.

### 3.3.2 Procedure folders

Regulated procedures are stored in a protected area of the database that can only be accessed from the **Procedure management** (available to users with **GxPdeveloper** role), and **Procedure start** workspaces (available to users with **GxPdeveloper** or **GxPuser** roles).

Users with **GxPdeveloper** role can create new folders from the **Procedure management** workspace. Click  **Add folder** in the folder list panel of the workspace to create a new folder.

Procedures and procedure folders cannot be deleted, moved, or renamed.

### 3.3.3 Create new procedure

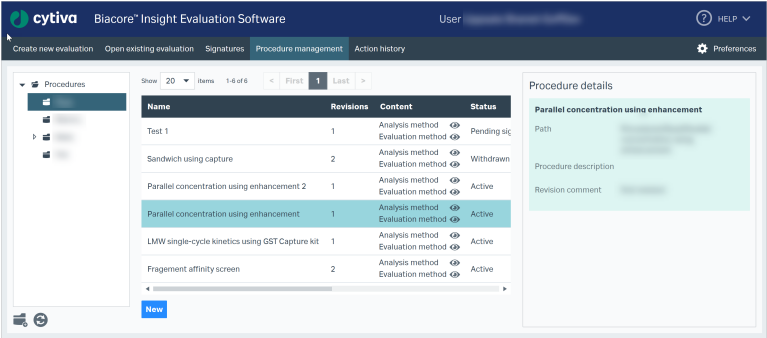
Regulated procedures are created by **GxPdevelopers**. Follow the steps below to create a new regulated procedure.

- Step

Action
- 1

Select the **Procedure management** workspace in either Biacore Insight software.
- 2

Select a folder where the procedure will be saved and click **New**.



**Note:**  
Select the folder where the procedure will be saved before clicking **New**.  
There is no subsequent opportunity to change this location.

- 3

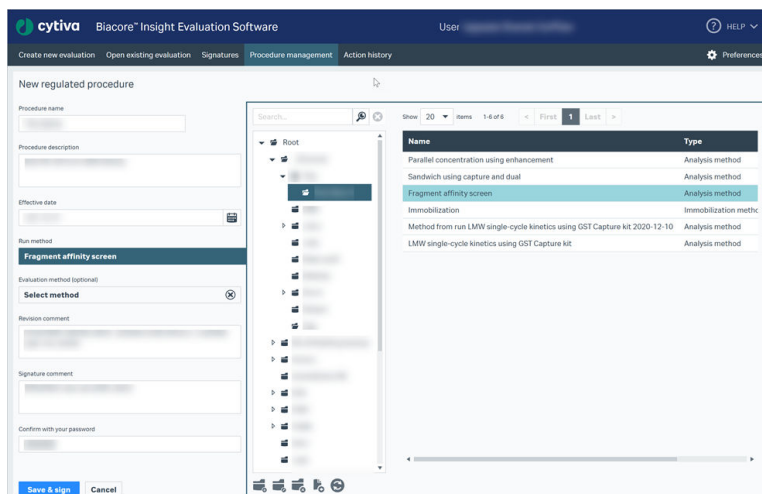
Enter a procedure name and optional procedure description.
- 4

Select an effective date (in the future) if required. The procedure will become available at local time 00:00 on that date in the time zone where it is created, and at 00:00 with offset in other time zones. If signatures are used, approval after the effective date activates the procedure instantly, and the effective date is changed to the time of the approval.  
  
With the default setting of the current date, the procedure will become available immediately in all time zones.



Step	Action
5	Use the browser list in the right-hand panel of the workspace to select <b>Run method</b> and <b>Evaluation method (optional)</b> . Including an evaluation method is strongly recommended for analysis runs.

- 5 Use the browser list in the right-hand panel of the workspace to select **Run method** and **Evaluation method (optional)**. Including an evaluation method is strongly recommended for analysis runs.



**Note:**

*This browser panel is used to select methods to include in the regulated procedure. It does not show the dedicated folder structure where the procedure will be saved.*

**Note:**

*Predefined methods cannot be included in regulated procedures.*

**Note:**

*It is not possible to include evaluation methods containing a **Biacore Intelligent Analysis** prediction model.*

- 6 Enter a revision comment and, if signatures are used, also enter a signature comment.
- 7 Enter your login password for authentication, then click **Save**, or if a signature is required, click **Save & sign**.

If signatures are used, the procedure must be accepted and signed before it becomes active. See [Section 3.9 Applying signatures, on page 48](#) for how to apply signatures. The procedure has the status Pending signatures until rejected or approved.


## 3.3.4 Revise existing procedure

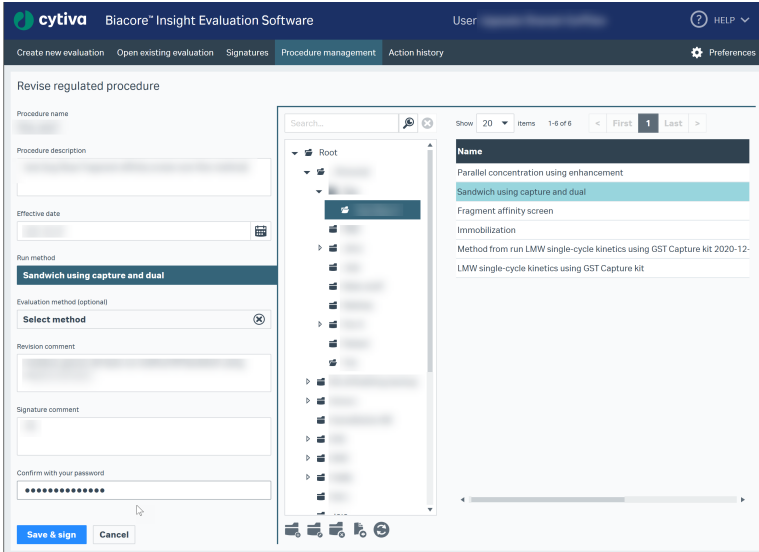
Procedures cannot be overwritten, but can be superseded by a later revision.

**Note:** *It is not possible to revise an existing procedure that has pending signatures.*

Follow the steps below to revise an existing regulated procedure.

Step	Action
------	--------

- |   |   |
|---|---|
| 1 | Select the <b>Procedure management</b> workspace.   |
| 2 | Click  <b>Revise procedure</b> in the <b>Action</b> column for the procedure you want to revise. |
| 3 | Make the required changes. The procedure name cannot be changed.  |



- |   |  |
|---|--|
| 4 | Select new methods as required, or keep the setting <b>[Method from last revision]</b> .   |
| 5 | Enter a revision comment and, if signatures are used, also enter a signature comment.  |
| 6 | Enter your login password for authentication, then click <b>Save</b> , or if a signature is required, click <b>Save &amp; sign</b> . |


If signatures are used, the procedure must be accepted and signed before it becomes active. See [Section 3.9 Applying signatures, on page 48](#) for how to apply signatures. The procedure has the status Pending signatures until rejected or approved.

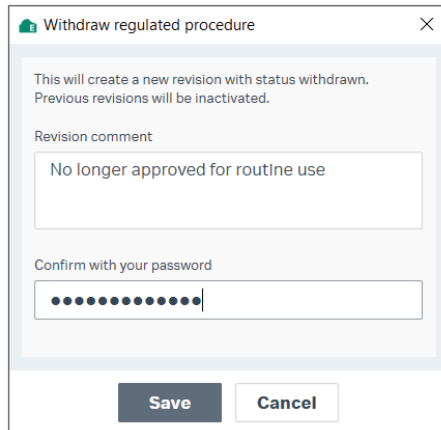
The revised procedure will supersede any previously active revision when the new revision becomes active.

### 3.3.5 Withdraw procedure

When a procedure is withdrawn, it is no longer available for use (but is still stored in the database for reference).

Follow the steps below to withdraw a procedure. Note that it is not possible to withdraw an existing procedure that has pending signatures.

Step	Action
1	Select the <b>Procedure management</b> workspace.
2	Click  <b>Withdraw procedure</b> in the <b>Action</b> column for the procedure you want to withdraw.
3	Enter a revision comment and your login password for authentication, then click <b>Save</b> .



The dialog box titled "Withdraw regulated procedure" contains the following elements:

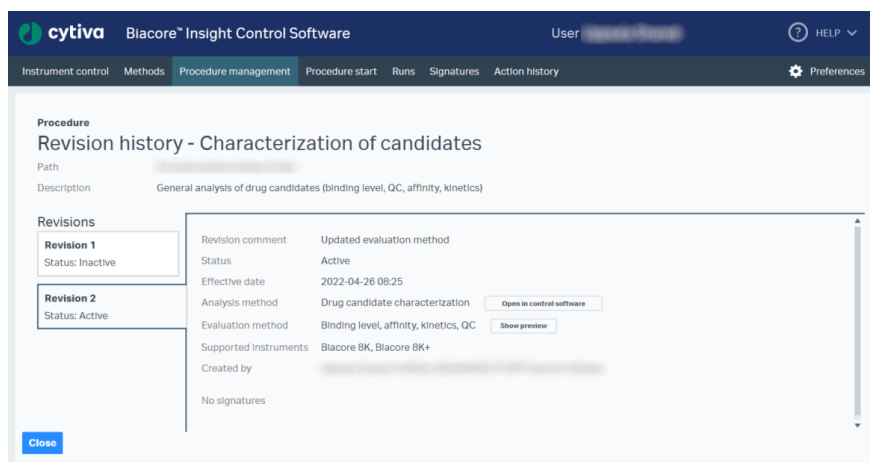
- A close button (X) in the top right corner.
- Instructional text: "This will create a new revision with status withdrawn. Previous revisions will be inactivated."
- A label "Revision comment" above a text input field containing the text "No longer approved for routine use".
- A label "Confirm with your password" above a password input field with masked characters (dots).
- Two buttons at the bottom: "Save" (highlighted in dark blue) and "Cancel" (white with a grey border).

A withdrawn procedure cannot be reactivated. However, you can create a new revision with the same settings.

## 3.3.6 Revision history

The **Revision history** in the **Procedure management** workspace lists the status of all revisions of the selected procedure since the first creation.

Click  **Show revision history** in the **Action** column to open the revision history.



The status is listed as one of the following:

Status	Description
<b>Active</b>	The procedure revision is currently active.
<b>Inactive</b>	The procedure revision has been replaced by a later revision.
<b>Withdrawn</b>	The procedure has been withdrawn.
<b>Pending signature</b>	The procedure revision is awaiting signatures.
<b>Pending date</b>	The procedure revision is set to become active on an effective date in the future.

**Note:** *Technically, withdrawing a procedure creates a new revision with status **Withdrawn**. The original revision is marked as inactive.*  
*For example, if revision 4 is withdrawn, the revision history will show revision 4 as **Inactive** and revision 5 as **Withdrawn**.*

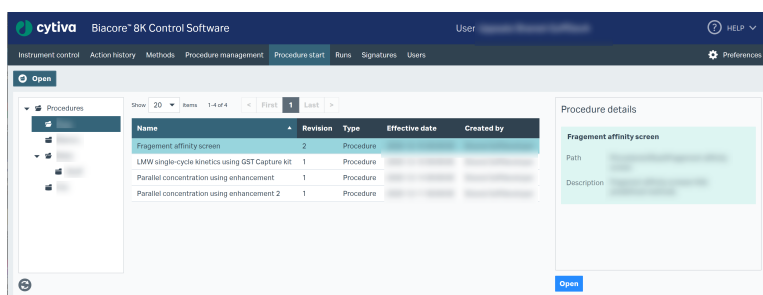
## 3.4 Running procedures

Procedures can be run by **GxPdevelopers** and **GxPusers**. The same restrictions apply regardless of the user's GxP role.

Follow the steps below to run a procedure.

Step	Action
------	--------

- |   |   |
|---|---|
| 1 | Open the <b>Procedure start</b> workspace in the control software. Only procedures are shown in this workspace. |
|---|---|



- |   |   |
|---|---|
| 2 | Select the procedure to run and click <b>Open</b> , or double-click on the procedure.   |
| 3 | The run method in the procedure will open at the first stage where user input is permitted. Parameters highlighted in purple cannot be changed (see <a href="#">Locked parameters and settings, on page 15</a> ).       |
| 4 | Provide input as required (for example, sample names) and send the method to the activity queue, as described in the <i>Biacore 1 series User Manual</i> , 29706293, or <i>Biacore 8 series User Manual</i> , 29287247. |
| 5 | In the activity queue, provide any required input and enter your login password for authentication.   |
| 6 | Start the run. The results of the run can be saved in any folder.   |

### Locking the software

For maximum security, the control software can be locked when the screen is unattended, to restrict access to the activity queue and ongoing runs. To lock the software, click the lock icon next to the user name in the top banner of the software window:



The whole window is grayed out when the software is locked.




To unlock the software, click anywhere in the window and enter the password in the dialog that appears. The software can only be unlocked by the current user.

**Note:** *Remember to lock all instances of the control software that are currently open. The lock applies separately to each instance.*

## 3.5 Evaluating regulated runs

### Creating a regulated evaluation

Follow the steps below to evaluate a regulated run.

Step	Action
1	Go to the <b>Create new evaluation</b> workspace in Biacore Insight Evaluation Software and navigate to the folder where the run is stored.  For <b>GxPusers</b> , only regulated runs are displayed. <b>GxPdevelopers</b> can access both regulated and non-regulated runs.
2	Select a regulated run and click <b>Open</b> or double-click on the run.
3	The evaluation method (if any) included in the procedure will be applied automatically. Items created by the evaluation method cannot be removed.  Parameters and settings created by the evaluation method are highlighted in purple and cannot be changed. This includes most settings that affect the content of an item. Points and curves can however be excluded locally or globally in locked items. Such changes are logged in the audit trail. Settings that affect the display only are generally not locked (for example, item panels can be hidden or displayed).
4	New items can be created freely by both <b>GxPusers</b> and <b>GxPdevelopers</b> . Settings in new items are not locked.  Creation of new items is logged in the audit trail, but the details within a new item are not logged.
5	Click  <b>Save and release a new evaluation version</b> , or if a signature is required, click  <b>Save and sign a new evaluation version</b> to save the evaluation. Alternatively, click  <b>Save draft evaluation</b> to save a draft (a preliminary version while performing the evaluation).
6	In the pop-up window, choose a location and name, and click <b>Save</b> .

Step	Action
------	--------

- |   |   |
|---|---|
| 7 | Complete the audit trail with a comment documenting for example why any changes were made and enter your login password for authentication. The dialog also provides a preview of the changes that will be logged in the audit trail. |
|---|---|

Save and release new version

Changes

Created evaluation: xxx "Regulated" gp/Reg/Procedure: 2017-05-15 15:10:15 procedure: "Regulated" gp/Reg/Procedure: xxxxxx

Added Item: 'Plot 2'

Added Item: 'Affinity 1'

Version comment

This is a new regulated evaluation

Confirm with your password

••••••••••

Save and release new version

Cancel

Save and sign new version

Changes

Created evaluation: xxx "Regulated" gp/Reg/Procedure: 2017-05-15 15:10:15 procedure: "Regulated" gp/Reg/Procedure: xxxxxx

Added Item: 'Affinity 1'

Version comment

This is a new regulated evaluation

Signature comment

I approve.

Confirm with your password

••••••••••

Save and sign new version

Cancel




If you selected **Save and sign a new evaluation version**, you are also prompted to enter a signature comment.



Step	Action
	If signatures are used, and you selected <b>Save and sign a new evaluation version</b> , the evaluation now has the status Pending signatures.

### Editing a regulated evaluation

Follow the steps below to edit a regulated evaluation.


Step	Action
1	Go to the <b>Open existing evaluation</b> workspace in the evaluation software. For <b>GxPusers</b> , only regulated evaluations are displayed. <b>GxPdevelopers</b> can access both regulated and non-regulated evaluations. For regulated evaluations, only the most recent version is displayed by default. See <a href="#">Accessing previous evaluation versions, on page 42</a> for how to access previous versions.
2	Select a regulated evaluation and click <b>Open</b> or double-click on the evaluation.
3	For items created by the evaluation method in the procedure (highlighted in purple), changes such as excluding and including points or curves and setting curve markers can be made. Such changes are logged in the audit trail.
4	New items can be created freely by both <b>GxPusers</b> and <b>GxPdevelopers</b> . Settings in new items are not locked.  Creation of new items is logged in the audit trail, but the details within a new item are not logged.
5	Click  <b>Save and release a new evaluation version</b> , or if a signature is required, click  <b>Save and sign a new evaluation version</b> to save the evaluation.  Alternatively, click  <b>Save draft evaluation</b> to save a draft (a preliminary version).  The evaluation will be saved as a new version in the same location and with the same name as the original.
6	Complete the audit trail with a comment documenting why the changes were made and enter your login password for authentication. The dialog also provides a preview of the changes that will be logged in the audit trail.  If you selected <b>Save and sign a new evaluation version</b> , you are also prompted to enter a signature comment.

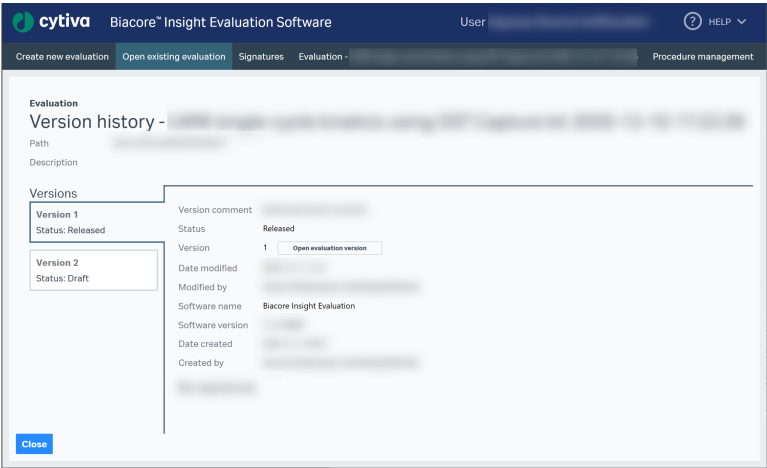
Step	Action
	If signatures are used, the evaluation will be available for review and has the status Pending signatures until rejected or approved.

### Accessing previous evaluation versions

By default, only the most recent version of a regulated evaluation is shown in the **Open existing evaluation** workspace. Older versions can be accessed and opened for examination, but changes made to older versions cannot be saved.

Follow the steps below to access older versions.

Step	Action
1	Go to the <b>Open existing evaluation</b> workspace and navigate to the required regulated evaluation.
2	Click  <b>View version history</b> .
3	Previous evaluation versions can be opened from the <b>Versions</b> list.



4	Click <b>Close</b> to return to the previous workspace.
---	---

## 3.6 Recovering methods from procedures

### Introduction

Immobilization, analysis, and evaluation methods can be recovered from procedure definitions and saved independently of the original method. Methods that are recovered from procedures represent the method as included in the procedure, regardless of any changes that may have been made to the original method.

Methods can only be recovered from procedures by users with **GxPdeveloper** role.

### Recovering an immobilization or analysis method

Follow the steps below to recover the run method from a procedure.

Step	Action
1	Open the <b>Procedure management</b> workspace and double-click on the procedure.
2	In the <b>Revision history</b> panel (see <a href="#">Section 3.3.6 Revision history, on page 36</a> ), select revision and click <b>Open in control software</b> .
3	The method will be opened in the control software, where it can be modified and saved as required. A method that is recovered from a procedure no longer has any connection to the procedure.

### Recovering an evaluation method

Follow the steps below to recover the evaluation method from a procedure.

Step	Action
1	Open the <b>Procedure management</b> workspace and double-click on the procedure.
2	In the <b>Revision history</b> panel (see <a href="#">Section 3.3.6 Revision history, on page 36</a> ), select revision and click <b>Show preview</b> .
3	The method will be opened as an <b>Evaluation method preview</b> in the evaluation software, where it can be saved under a new name. A method that is recovered from a procedure no longer has any connection to the procedure.

**Note:** *Changes cannot be made directly to the recovered method. To make changes:*

1. *Save the evaluation method with a new name.*
2. *Open a suitable non-regulated run using the saved evaluation method.*
3. *Make the necessary changes.*
4. *Create a new method from the evaluation session.*

## 3.7 Viewing the audit trail

### Audit trail content


The audit trail is a record of changes made by the user to regulated evaluations, including creation of new evaluation items and changes made to items created by the evaluation method. An entry is added to the audit trail each time the evaluation is saved (even if no tracked changes were made).



The audit trail only applies to regulated evaluations. Regulated runs cannot be edited and do not have an audit trail.

The audit trail is exported with the evaluation to spreadsheet, presentation or PDF file, to provide an external record of the evaluation history.

### Viewing the audit trail

Follow the steps below to view the audit trail.

Step	Action
1	Create a new or open an existing regulated evaluation.
2	Go to the <b>Home</b> workspace and select  <b>Show audit trail</b> in the <b>After evaluation</b> section.
3	The audit trail lists changes made to all previously saved versions of the evaluation. Changes that have been made in the current session but have not been saved are listed as <b>Unsaved</b> . Changes made and repeatedly saved as a draft are summarized in one row.

Audit trail					
Version	Status	Date	User	Changes	Version comment
1	Released	2022-06-29 11:15:13		Created evaluation: run 'EC50' analysis at 37C 2022-06-29 11:11:39; procedure 'EC50' analysis at 37C revision 1 Excluded sensorgram: item 'Evaluation - EC50'; sensorgram 'Ch 1, Fc 2, Cycle 5' Excluded sensorgram: item 'QC - Baseline'; sensorgram 'Ch 1, Fc 2, Cycle 5' Excluded sensorgram: item 'QC - Baseline'; sensorgram 'Ch 1, Fc 2, Cycle 5' Added item: 'Plot 1' Added item: 'Sensorgram 1'	New evaluation
	Unsaved	2022-06-29 11:25:35		Excluded sensorgram: item 'Evaluation - EC50'; sensorgram 'Ch 1, Fc 2, Cycle 14' Excluded sensorgram: item 'Evaluation - PLA'; sensorgram 'Ch 1, Fc 2, Cycles 5, 14' Excluded sensorgram: item 'QC - Baseline'; sensorgram 'Ch 1, Fc 2, Cycle 14' Excluded sensorgram: item 'QC - Sensorgram'; sensorgram 'Ch 1, Fc 2, Cycles 5, 14'	
<div>Close</div>					

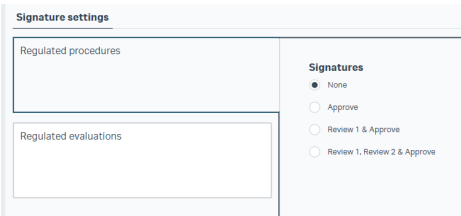
## 3.8 Signature settings

The Signature settings are managed by a user with the **GxPAdministrator** role, which is the only user role who has access to the workspace. The workspace is found under **Preferences** in the upper right corner in both Biacore Insight Control Software and Biacore Insight Evaluation Software.



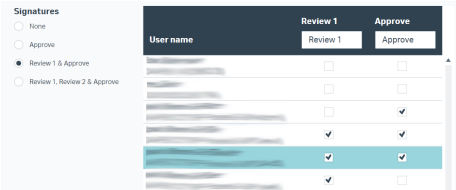
Settings can be applied to regulated procedures and regulated evaluation separately. The same settings are available for regulated procedures as for regulated evaluations. Follow the steps below to change the signature settings.

Step	Action
1	Select the <b>Preferences</b> workspace in either the control or evaluation software.
2	Select the <b>Signature settings</b> tab if there are several tab options.
3	Select to view either the settings for <b>Regulated procedures</b> or <b>Regulated evaluations</b> .

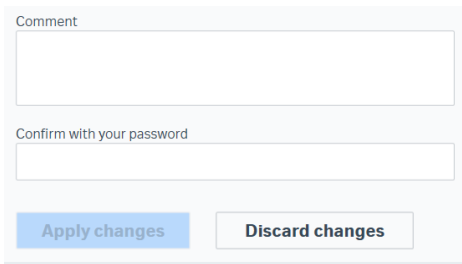


**Note:**  
Only users with a **GxPdeveloper** role can sign regulated procedures.

- |   |   |
|---|---|
| 4 | Select numbers of signatures to apply.  |
| 5 | Rename each signature if desired. Different signatures cannot have the same name. |



Step	Action
6	<p>Select users allowed to perform each signature.</p> <p>It is the responsibility of the <b>GxP administrator</b> to only select users that have access to relevant workspaces. At least one user for each chosen signature needs to be selected.</p> <p><b>Note:</b></p> <p><i>Users that have logged in to the database at least once is appearing in the list.</i></p>
7	<p>Perform step 3-6 for both regulated procedures and regulated evaluations.</p>
8	<p>When all settings are adjusted, enter a comment in the lower left corner. It is recommended to specify changes in the comment, as changes in the settings are not automatically logged. The comment will be found in the <b>Details</b> column in the <b>Action history</b>.</p>



The screenshot shows a web form for signature settings. It has a light gray background. At the top, there is a label 'Comment' above a large white text input box. Below this is another label 'Confirm with your password' above a smaller white text input box. At the bottom, there are two buttons: a blue button with white text 'Apply changes' and a white button with gray text 'Discard changes'.

9	<p>Type in your password and press <b>Apply changes</b>.</p> <p>The traceability for when and by whom the signature settings have been changed is found in the <b>Action history</b>. Filter for <b>Signature settings</b> in the drop-down menu for column <b>Type</b> (category <b>Other</b>).</p>
---	--

## 3.9 Applying signatures

The **Signatures** workspace lists all regulated procedures and regulated evaluations with status **Pending signatures**. Items that can be signed by the current user are listed in the tab **For me to sign**, while the tab **For others to sign** lists all other items with pending signatures.

The following restrictions apply:

- The creator of an item is not permitted to apply **Review** or **Approve** signatures to that item.
- It is not possible to apply multiple signatures of the same type to an item.
- It is not possible to apply an **Approve** signature if there is a pending **Review** signature.

**Note:** *In **Signature settings** it is possible to grant signature rights to many users. In such cases, items listed in the tab **For me to sign** can also be signed by other users.*

Follow the steps below to sign a regulated procedure or a regulated evaluation.

Step	Action
------	--------

- |   |  |
|---|--|
| 1 | Select the <b>Signatures</b> workspace.                              |
| 2 | Select a procedure or evaluation in the list <b>For me to sign</b> . |

- |   |  |
|---|--|
| 3 | Open the revision or version history, and the methods or evaluations included. |
|---|--|

**Note:**

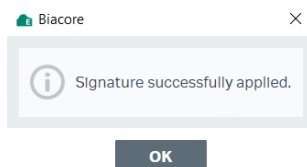
*Access to the revision history is limited to **GxPdeveloper**. Therefore, only users with **GxPdeveloper** role can sign regulated procedures.*

- |   |  |
|---|--|
| 4 | Review the information to make sure that it meets all your requirements. |
|---|--|



Step	Action
------	--------

- |   |   |
|---|---|
| 5 | Select <b>Accept</b> or <b>Reject</b> , write a comment, fill in your password, and click <b>Sign</b> . |
|---|---|



## 3.10 Action history

The **Action history** is a log of actions performed in the database, showing who performed which action and when.

The workspace is found in both Biacore Insight Control Software and Biacore Insight Evaluation Software, and is available for all users.

The information is shown in chronological order and cannot be altered, only sorted and filtered.



Date	User	Performed action	Type	Name	Instrument id	Chip id	Details	Actions
2022-04-11 16:19:21	Administrator (Administrator)	Create	Change solutions	N/A	17012	2022-04-11 16:07:45	Status: Running	Open
2022-04-11 16:09:34	Administrator (Administrator)	Log in	N/A	N/A	N/A	N/A	Software: Control	N/A

Actions that are always included in the log are; create, import, move, remove, rename, and update.

When the GxP extension is activated, the following are also logged:


- Log in/out
- Regulated procedures
- Regulated runs
- Regulated evaluations
- Signature
- Signature settings
- Export of database objects
- User defined action

Information will be added to the **Action history** continuously.

### Add user defined action

User defined actions can be added to the log as required, for example to document when new running buffer has been provided or when a Biacore system is relocated. Follow the steps below to add an action.

#### Step Action

- 1 Click the plus icon  to add a user defined action.
- 2 Select Instrument and/or chip from the list if applicable.
- 3 Type a comment describing the action.
- 4 Type your password.
- 5 Click **Save**.

## 3.11 Users workspace

The **Users** workspace displays GxP roles and database permissions for users and user groups authorized to use the system software. The **Users** workspace is only available to users with **GxP administrator** role.

Instrument control   Activity history   Methods   Procedure management   Procedure start   Runs <b>Users</b>								
User	User or group id	GxP role Administrator	GxP role Developer	GxP role User	Permission Delete	Permission Move and Rename	Permission Create	Created
	G4CTH252E\BiacoreEditorialAccessUsers					✓	✓	14/08/2018 12:42:24
	G4CTH252E\BiacoreFullAccessUsers	✓	✓		✓	✓	✓	14/08/2018 12:42:24
	G4CTH252E\BiacoreLimitedAccessUsers			✓			✓	14/08/2018 12:42:24

GxP roles and database permissions are managed by the database administrator (see the *Biacore Insight Database Installation and Management Guide*). Changes to roles and permissions cannot be made from the **Users** workspace.

**Note:** *If GxP roles and database permissions are assigned to Windows user groups, the **Users** workspace will display the settings for the group. Group members are not shown.*

# 4 GxP compliance recommendations

## About this chapter

This chapter offers some practical guidelines for working in GxP environments, and considers some aspects that are not directly regulated through the functionality of the GxP extension.

Compliance in operation of the GxP extension is based on the guiding principle that all validated runs are performed from regulated procedures. While compliance can in principle be established through strict SOPs for runs based on non-regulated methods, this approach makes unnecessarily heavy demands on construction and validation of SOPs and is not recommended.

## In this chapter

Section	See page
4.1      Operating system and database configuration	53
4.2      Data integrity	54
4.3      Assay development and validation	55
4.4      Standard Operating Procedures (SOPs)	56

## 4.1 Operating system and database configuration

While GxP extension supports work in a regulated environment, it does not in itself provide security for experimental results and proprietary information. It is the responsibility of the IT staff to make sure that the operating system settings provide a proper user management system and adequate security in accordance with site policies, both for the Biacore Insight database and for the computers where Biacore Insight Control Software and Biacore Insight Evaluation Software are installed. Details of security options and requirements can vary according to the site requirements and the operating system version, and are outside the scope of this User Manual.

The database administrator is responsible for assigning GxP roles to users or user groups and for assigning permissions to create, delete, move and rename objects in the database. User groups are created and maintained in the operating system: if GxP roles are assigned to groups in the database, it is important that the division of responsibility between IT and database administrator is clearly defined.

System clocks need to be correctly set on all computers that access the Biacore Insight database, to ensure correct time-stamping of database objects and coordination of procedure activation times. Time stamps are created as local time on the computer where the stamped operation is performed, and displayed with an offset to local time in a different time zone (for example, a run performed at 11:00 AM EST will be shown as 8:00 AM PST).

## 4.2 Data integrity

The following features ensure that important data is not lost from the database:

- Saving regulated runs, evaluations and procedures with the original object name creates a new version. Regulated objects are never overwritten.
- A procedure holds a copy of the run and evaluation methods included in the procedure, as they were at the time the procedure was created. Later changes or even deletion of the methods from the database do not affect the procedure. The methods can always be recovered from the procedure and saved as non-regulated objects.
- Data access permissions are granted to users independently of their GxP role (see [Data access roles, on page 12](#)). Restricting access permissions helps to ensure data integrity and traceability, independently of user roles.
- All data records are stamped with the time and creator id. This data cannot be changed or manipulated.

## 4.3 Assay development and validation

Assay development is the responsibility of users with the **GxPdeveloper** role, who are authorized to work with non-regulated objects and to create procedures. The stages in assay development are summarized broadly below.

Stage	Description
1	Establish conditions and create a method as required for surface preparation. If possible, determine tolerance limits for variations in parameters such as pH, buffer and salt concentration, and so on.
2	Create a procedure for the surface preparation process. An evaluation method is normally not relevant for surface preparation procedures.
3	<p>Establish conditions and create a run method. Determine tolerance limits where appropriate for parameters like the analyte concentration, temperature, and concentration of buffer components.</p> <p>Consider keeping the flow cell selection unlocked (Biacore 1 series) to make it possible to use the same procedure for many sensor chip setups.</p> <p>Leave the sample table unlocked so that the procedure can be applied to different sample sets. If fixed control samples are used, place them in a separate (nested) step and lock the table for this step. Similarly, lock the assay steps for solvent correction, surface conditioning, startup cycles, and calibration steps where these are used.</p>
4	Run the assay with a realistic sample set and evaluate the results. When you are satisfied with the evaluation, create an evaluation method, including all essential components. In some cases it can be necessary to make adjustments to the analysis method and reiterate the evaluation.
	<p><b>Note:</b></p> <p><i>The default settings for <b>Export to PDF</b> have no items selected, and are locked in a regulated procedure. If you want to export the regulated evaluation to PDF, make sure that the settings are correct before saving the evaluation method.</i></p> <p><i>This does not apply to <b>Export to spreadsheet</b> and <b>Export to presentation</b>, where settings can be changed in a regulated evaluation.</i></p>
5	Create a procedure, including the approved run and evaluation methods. The procedure will be available for running by users with the <b>GxPuser</b> role.

A procedure in the context of the GxP extension can form part of a validated laboratory procedure, although the GxP support provided by the extension is not in itself sufficient to ensure validation. Validation of laboratory procedures is entirely the responsibility of the system user, and generally requires documentation of Standard Operating Procedures (SOPs).

## 4.4 Standard Operating Procedures (SOPs)

SOPs that specify in full detail how an assay should be performed and documented are an essential feature of validated assays in a GxP environment. The use of procedures in the GxP extension contributes to the regulation of operating procedures, but cannot cover all aspects of GxP work. As a guiding principle, an SOP should give complete and unambiguous instructions for how an assay should be performed from start to finish, in such a way that a user with a minimum of prior knowledge can perform the assay correctly.

Preparation of SOPs for validated assays is the responsibility of the customer. Some aspects that should be considered are listed below.

- Include detailed instructions concerning preparation of buffers, reagents and samples. Calibration requirements for measuring equipment (e.g. balances, pipettes and pH meters) should be clearly stated and calibration procedures should be documented. Reagent specifications, including lot numbers where appropriate, should be documented for each assay.
- Procedures for surface preparation and analysis are normally separate. State clearly which surface preparation procedure should be used for a given analysis procedure.
- Depending on the performance demands of the assay, instrument preparation routines can be included in the SOP, for example cleaning and priming the flow system, docking the sensor chip, allowing a minimum stabilization time in standby mode after docking the sensor chip, and so on.
- The SOP can include instructions for where the results of an assay should be saved. Including more detailed instructions in the SOP will help to reduce potential difficulties in finding the data.
- The SOP should specify any archiving requirements. Export settings are saved in the evaluation method, but the GxP extension software does not place any restriction on where exported files should be saved.
- In order to ensure that the Biacore system is maintained correctly, procedures to be followed on completion of an assay should be included in the SOP. The recommended procedure is to leave the instrument in standby mode with distilled water or buffer for up to the maximum period, and to shut down the system for longer periods.
- Regular cleaning and maintenance of the instrument is important for best performance, and should be specified in a separate SOP.



# Index

## Numerics

21 CFR Part 11, 5, 9

## A

Abbreviations, 5  
 Action history, 50  
 ALCOA+, 5, 19  
 Analysis methods, 43  
     recover from procedures, 43  
 Assay development for GxP, 55  
 Audit trail, 20, 45  
     export, 45  
     viewing, 45  
 Audit trail content, 45

## B

Backup procedures, 20

## C

Channel usage, 16  
 Compliance recommendations, 52  
 Control software workspaces, 25  
 Create new procedure, 32

## D

Data access permissions, 12, 51  
 Data export, 20  
 Data integrity, 19  
 Database recommendations, 13  
 Database roles, 10  
 Developing assays for GxP, 55  
 Developing procedures, 14

## E

Equipment qualification, 9  
 Evaluating regulated runs, 17, 39  
 Evaluation methods, 43  
     recover from procedures, 43  
 Evaluation software workspaces, 27

## G

GxP extension features, 22  
 GxP roles, 10, 51  
 GxP administrator role, 11  
 GxP developer role, 11  
 GxP user role, 11

## I

Immobilization methods, 43  
     recover from procedures, 43  
 Important user information, 6

## L

Lock software, 37  
 Locked settings, 16  
     channel usage, 16  
     in immobilization methods, 16  
     sample table, 16

## M

Managing procedures, 30  
 Methods, 14, 43  
     for regulated procedures, 14  
     recover from procedures, 43

## O

Operating system configuration, 53

## P

Prerequisites, 6  
 Procedure folders, 31  
 Procedure management workspace, 30  
 Procedure revision history, 36  
 Procedure revisions, 16  
 Purple highlight in software, 15

**R**

Recommendations for GxP compliance, 52

Recover methods from procedures, 43

Regulated evaluations, 17, 20, 39, 41, 42

- access previous versions, 42
- create new, 39
- edit existing, 41
- integrity, 20
- versions, 41

Regulated procedures, 14, 15, 19, 30–32, 34–37

- create new, 32
- folders, 31
- integrity, 19
- locked settings, 15
- manage, 30
- revise, 34
- revision history, 36
- run, 37
- status, 36
- withdraw, 35

Regulated runs, 20, 39

- evaluate, 39
- integrity, 20

Regulatory requirements, 6, 9

Revise existing procedure, 34

**S**

Sample table, 16

Scope of GxP compliance, 9

Signature, 46

Signatures, 46, 48

- applying, 48
- settings, 46

Software access restrictions, 10

Software versions, 4

SOPs, 56

Standard Operating Procedures, 56

Starting the GxP extension , 23

- procedure, 23
- requirements, 23

**T**

Typographical conventions, 4

**U**

Unlock software, 37

User define action, 50

User Manual scope, 4

User roles, 10

Users workspace, 51

**V**

View audit trail, 45

**W**

Withdraw procedure, 35

Page intentionally left blank



**Give feedback on this document**

Visit [cytiva.com/techdocfeedback](https://cytiva.com/techdocfeedback) or  
scan the QR code.



## cytiva.com/biacore

Cytiva and the Drop logo are trademarks of Life Sciences IP Holdings Corporation or an affiliate doing business as Cytiva.

Biacore, and Biacore Intelligent Analysis are trademarks of Global Life Sciences Solutions USA LLC or an affiliate doing business as Cytiva.

Microsoft, SQL Server, and Windows are trademarks of the Microsoft group of companies.

Any other third-party trademarks are the property of their respective owners.

© 2020–2024 Cytiva

For local office contact information, visit [cytiva.com/contact](https://cytiva.com/contact)

29312548 AD V:20 08/2024