

# Biotage® Extrahera™ GLP Software

Manage. Secure. Network. Audit.



# Introducing Biotage® Extrahera™ GLP Software

Since its introduction in 2015, the Biotage® Extrahera™ has transformed automated sample preparation with its precision engineering, easy to use software and flexible formats for Supported Liquid Extraction (SLE), Solid Phase Extraction (SPE), Phospholipid Depletion (PLD) and Protein Precipitation (PPT). Now, with the new GLP software package, users can combine the utility of the system's advanced lab automation with the organizational features used under Good Laboratory Practices. Whether you operate in a GLP workspace, or you simply need to tidy up your lab's workflow, the Extrahera GLP software package has the tools you need to successfully organize your lab.



# Highlighted GLP Features



## Manage

- » Oversee system control and access with five distinct User Roles.
- » User roles designed to match lab personnel with their training and expertise.



## Secure

- » Maintain system and data security.
- » Incorporated password protection, timed sessions, and restricted USB port access.



## Network

- » Network integration allows for backup/restore or export of reports and audit trails to your local area network or LIMS system.
- » Receive email alerts for system pauses or errors and view your runs on your laptop using the remote viewing option.



## Audit

- » Automatically monitor all system operations with precision tracking.
- » Generate a clear audit trail documenting all activities, including user credentials and reasons for making any method changes.

# Manage

The user management system prevents unauthorized access through the use of usernames and associated alpha-numeric passwords, which must pass integrity checks and are time-sensitive. Because different levels of expertise demand different levels of access, the GLP software features five defined roles with various permission levels.

## Routine User

The Routine user role was developed for technicians responsible for day-to-day operation, maintenance, and general upkeep of Extrahera. Routine users can view and run methods, generate reports, and access remote viewing when logged into the system.

## Monitor User

Personnel such as lab supervisors, directors, and senior managers may require high-level oversight. The Monitor User role ensures they receive important email notifications from selected users & from remote viewing.

## QA/QC User

Quality officers are typically responsible for monitoring and documenting system training, maintenance, operation, and pipette head calibration. Accordingly, the QA/QC user can review methods and reports and can access remote viewing when logged into the system.





## Power User

Designed with the method development chemist in mind the Power User has access to all functions of the GLP platform except system administration and service. When locked, the Power User maintains direct and exclusive authorship of their methods, simultaneously maintaining method integrity, and preventing unauthorized actions.



## System Administrator

Don't let the tie fool you, this job is for anyone who knows their way around IT and networking protocols. From connecting to your local area network (LAN) or laboratory information management system (LIMS), to setting up user accounts and privileges, the System Admin is the primary gatekeeper for Extrahera. System Admins can easily control the flow of information without the distraction of operator-level permissions.

# Secure

Preventing unauthorized system access and data export is paramount for GLP compliance. With the Extrahera GLP software, we've introduced added security measures to protect your system. These include integrity-checked alphanumeric passwords, session timeouts, scheduled password expiration, and user-defined restriction of USB access.

Protect reports and audit trails by exporting them in a secure, non-recoverable, password-protected pdf format, or as txt files that your LIMS system can process directly for sample tracking and downstream data mining.



» Visual alerts for system or user notification



» Auditory alerts for system or user notification



- » Export reports/audit trails as an uneditable pdf
- » Optional auto delete feature after report export
- » Optional USB export restriction



- » User based alpha numeric password
- » Password expiration date
- » Minimum attempt lock out
- » Timed session lock out





# Network

With Extrahera GLP software, interfacing Extrahera to your LAN or LIMS brings enhanced functionality for sample management, downstream data mining, and remote viewing.

Upload your sample batch work list, receive email notifications, download reports remotely, and archive your audit trails easily



## Sample Batch Work List

- » Import/Export sample list
- » Track all sample information



## Email Notifications

- » Receive email if an error occurs
- » Stay alert with completed runs and pauses

## Remote Viewer

- » Watch runs from your desktop
- » Download run reports



## Export Reports

- » Export reports with secure pdf or txt format

## Export Audit Trails

- » Export all audit trails in pdf or txt format
- » Maintain system-wide backup of all audit trails





# Audit

With your automation workflow established, tracking and documenting time-sequenced changes to your methods, consumables, and general operational entries can be a difficult task. With Extrahera GLP audit trail management, we've included a master audit trail and made it easier for auditors to examine changes quickly and easily.

Using password-protected entry, all edits to a method generate entries in the Method Audit Trail. This includes a time-stamped revision complete with user ID, method ID, required user comment, and unobscured before and after record changes from authorized users. Additional audit trails include Data Administration for tracking solvents and consumables, System Administration, Maintenance, Operational and Service



```
...type enabled: Yes
...Extraction Media enabled: Yes
...Sample Plate enabled: Yes
...Port: Pipette Tips enabled: Yes
...Report: End of run comment enabled: No
*****
2019-12-28 20:32:14 simulated_serialnumber ** Log file appended **
User: [10002] [Power User] [dan.menasco@biotage.com] Peter Power
Method is changed
Change ID: EANIFFBCNAAA-10000-1577565133
Change reason: extraction media correction
DELETED: Extraction media: "ISOLUTE SLE+ 400 µL Columns"
ADDED: Extraction media: "ISOLUTE SLE+ 400 µL 96 Well Plate"
*****
...ted in
...Power
```

# Additional Features

Because everyone deserves new features, the following are now available for your Extrahera, even if you don't have the GLP software.

## Feature Details

Interested in the details? You can find this and more in our Extrahera user's manual which you can download from our website [www.biotage.com](http://www.biotage.com). If you don't find the information you are looking for, or have additional questions, please contact your Biotage account manager or sales representative.

**We're here to support you.**



Run Individual Samples



Processing of 48 x 3 mL SPE Cartridges



Visual Alarms



Pipette Pump Calibration Notifications



HYDRO DME+ (Dual Mode Extraction)



Volatile Solvent designation



Audible Alarms



QR and Barcoding (with purchase of reader)

## The Next Steps

As with all new products, there are questions that need answers. Below you'll find some commonly asked questions and corresponding answers. If you don't see your question here, please reach out to your Biotage account manager or sales representative.

### **Can I receive a demo the GLP Software only without the Extrahera?**

Don't have a lot of time to coordinate a demo for the Extrahera system? You can demo the software without the system. Once you contact your local Biotage account manager or sales representative, they can assist you with setting up the desktop version of Extrahera GLP software.

### **I want the Extrahera with the GLP Software! Now what?**

Great! We're looking forward to working with you. Now that you're ready to take the next step, simply contact your local Biotage regional office (see below) and request the GLP package (P/N 416990) with your Extrahera purchase (P/N 414001). Our staff will connect you with the appropriate personnel and get you and your team up and running. Need application support too? We have application chemists across the globe with a vast amount of experience.

### **I got the GLP Software! Now what happens?**

Congrats on your purchase! Here's what you can expect for the next steps: once you've taken shipment of your new Extrahera, your local Biotage representative will set up and install the GLP license on site, so that you can begin creating user profiles and organizing your sample prep workflow.

Be sure to visit our website where you can download Sample Batch Work Lists and additional information about the GLP package.

### **I already have an Extrahera and I want the GLP Software!**

So, you already have an Extrahera or two and want the GLP software? Not a problem, we just need to know which software version each of your Extrahera systems is currently using.

If your current SW is 1.4.0 to 1.5.5, you will need a minor upgrade (P/N: 416932SP), which our Service team will perform on-site. If your SW predates version 1.4.0, you will require our dual flow upgrade (P/N: 415039) before you can upgrade to the GLP.

### **I have more than one Extrahera, will they all need the GLP software?**

It's up to you (but we think more is better). You can install GLP licenses on as many systems as you like or on just a few. However, even if all systems are upgraded to the GLP software, please note that you won't be able to have one user ID that communicates between the systems. We know, it's a bummer, and we want that feature too! Watch this space!

### **I need to be 21 CFR 11 compliant. Will the new Extrahera GLP package offer this?**

Hmm, sadly no. This version of GLP software is not 21 CFR 11 compliant. But let us know if this is something you really, really want. Our software people are very talented, and we are always interested to hear about our customer's needs.



# Your Complete Partner for Effective Chemistry

Biotage is a worldwide supplier of instruments and accessories designed to facilitate the work of scientists in life sciences. With our deep knowledge of the industry, academic contacts and in-house R&D teams, we can deliver the best solutions to your challenges. We take great pride in our flexibility and ability to meet our customer's individual needs. With strong foundations in analytical, organic process, and biomolecule chemistry, we can offer the widest range of solutions available on the market.

## EUROPE

Main Office: +46 18 565900  
Toll Free: +800 18 565710  
Fax: +46 18 591922  
Order Tel: +46 18 565710  
Order Fax: +46 18 565705  
order@biotage.com  
Support Tel: +46 18 56 59 11  
Support Fax: + 46 18 56 57 11  
eu-1-pointsupport@biotage.com

## NORTH & LATIN AMERICA

Main Office: +1 704 654 4900  
Toll Free: +1 800 446 4752  
Fax: +1 704 654 4917  
Order Tel: +1 704 654 4900  
Order Fax: +1 434 296 8217  
ordermailbox@biotage.com  
Support Tel: +1 800 446 4752  
Outside US: +1 704 654 4900  
us-1-pointsupport@biotage.com

## JAPAN

Tel: +81 3 5627 3123  
Fax: +81 3 5627 3121  
jp\_order@biotage.com  
jp-1-pointsupport@biotage.com

## CHINA

Tel: +86 21 68162810  
Fax: +86 21 68162829  
cn\_order@biotage.com  
cn-1-pointsupport@biotage.com

## KOREA

Tel: +82 31 706 8500  
Fax: +82 31 706 8510  
korea\_info@biotage.com  
kr-1-pointsupport@biotage.com

## INDIA

Tel: +91 22 4005 3712  
india@biotage.com

Distributors in other regions  
are listed on [www.biotage.com](http://www.biotage.com)

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