

23.0331



Clarity™

ADVANCED CHROMATOGRAPHY SOFTWARE

REGULATED ENVIRONMENT

IN REGARD TO CLARITY

REGULATED ENVIRONMENT - LEGAL BOUNDARIES

- Referred to in various legislations
- Clarity end-user organization must be aware of legislation applicable for it
- Example of related guidelines
 - Title 21, Part 11 – Code of Federal Regulations (21 CFR Part 11)
 - EudraLex – Chapter 4, Annex 11
 - CFDA Pharmaceutical GMP, Appendix 2
 - ...other individual national guidelines



ACHIEVING COMPLIENCE

- ▶ Follow the principle of **ALCOA** for all your data:
 - **A**ttributable – to a **specific person** and his/her actions
 - **L**egible – for **reviews, audits** or regulatory inspections
 - **C**ontemporaneous – record of **when** data was created, and data is **timestamped**
 - **O**riginal – kept in the **same** format as when created
 - **A**ccurate – records are correct and include **“whole truth”**



A compliance with the directives can be achieved **only by a combination** of the respective software capabilities, overall system settings and use of standard operational procedures as properly defined by the end user organization.

INSTALLATION QUALIFICATION - IQ

► Checks correct installation of Clarity

Files

[Show files list »](#)

3rd Party Packages

Agilent ICF:

⚠ Agilent ICF is present in your system. It is necessary to perform its validation separately [here](#). The result must be attached to this report.

Knauer ClarityChrom:

⚠ Knauer ClarityChrom is present in your system. It is necessary to perform its validation separately [here](#). The result must be attached to this report.

PerkinElmer NexION control module:

⚠ PerkinElmer NexION control module is present in your system. It is necessary to perform its validation separately [here](#). The result must be attached to this report.

Checked by: Signature:

Core Files, Embedded Components: Passed (with warnings)

File	Path	Version	Size	File date	Status
cswunivm.exe	c:\clarityinstallations\9.0.0.82\bin	9.0.0.82	725504	12.07.2023, 18:52	Warning: bad checksum
cswunivm.exe	c:\clarityinstallations\9.1.0.14\bin	9.1.0.14	725504	10.08.2023, 03:25	Passed

IQ

File Help

Installation Qualification Report

Date	23.10.2023, 13:18
Serial number of application
User Code
Version of application	Clarity version 9.0.0.82
Build date of application	12.07.2023, 18:42
Instruments	3
Extensions	SST; GPC; PDA; EA; CE; MS; NGA; DHA; GCxGC; MS-TOF
Controls	GC; LC; AS
Certification file	C:\Clarity\Bin\iq.chk
Checksum of cert. file	E69A2CD43B088B77
Date of cert. file	12.07.2023, 23:00
User	samuel
System	Microsoft Windows 11 Professional version 10.0 (Build 22621)
Acquisition and hardware devices	Key Rockey 4ND S5300 DemoSN DEMO

Core Files, Embedded Components: Failed

Files

[Hide files list «](#)

File	Path	Version	Size	File date	Status
advantecchf122scfc.rb	c:\clarity\bin\utils\uni_drivers\advantec	-	35747	23.10.2023, 13:17	Failed: bad checksum
AdvionCMS.dll	C:\Clarity\Bin	6.4.14.1	487936	10.03.2021, 17:42	Passed
AdvionCommon.dll	C:\Clarity\Bin	6.4.14.1	30208	12.07.2023, 22:46	Passed
AdvionData.dll	C:\Clarity\Bin	6.4.14.1	315392	12.07.2023, 22:46	Passed
AdvionObjects.dll	C:\Clarity\Bin	6.4.14.1	935424	12.07.2023, 22:46	Passed
agc1290.dll	c:\clarity\bin\hengpinggcms	1.0.7.1	516096	12.07.2023, 22:46	Passed
apix_sdk.dll	c:\clarity\bin\apixchrompbx2	2.8.0.1538	3526656	12.07.2023, 22:46	Passed
asi500pump.rb	c:\clarity\bin\utils\uni_drivers\asi	-	46586	12.07.2023, 18:34	Passed

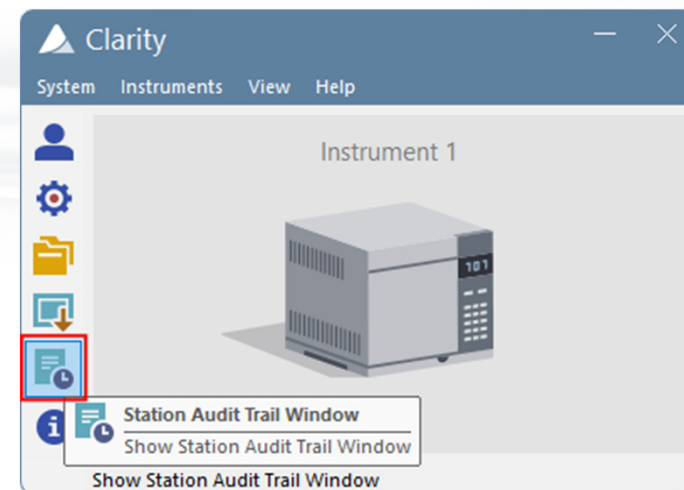
OPERATIONAL QUALIFICATION - OQ

- > Needed for Clarity validation – requires SST extension
- > Checks acquisition and data processing



AUDIT TRAIL

- Tool to support **attributable** and **legible** data
- Tracking user activities
- Tracking all actions and data modification
 - Audit trail is not modifiable
 - Audit trail can be exported in various formats
- Complete AT for the entire station
- Specific AT for each file



USER ACCOUNTS

- Tool to support **attributable** and **legible** data
- Limiting actions that can be done by specific user
- Set different roles

User Accounts

User List

New Duplicate Disable Delete

Adam
Frank
Steve (disabled)

Password Restrictions - Common for All

Min. Length 10 chars
 Lifetime 90 days
 Expiration Warning 5 days
 Password Reuse 150 days
 Login Attempts 3
 Auto Lock 10 min

User Details for: Adam

User

User Name Adam
Desktop File shared
Description Lab Admin

Access To

Instrument 1 Instrument 2 Instrument 3 Instrument 4

User Access Rights

Open User Accounts Edit Sequence
 Open Configuration Edit Report Style
 Edit Method Select Method
 Edit Chromatogram Open Audit Trail
 Edit Calibration Open Audit Trail Settings
 Projects Archive / Restore
 Import Chromatogram Post-run Options
 Take Control of Locked Instrument Start Acquisition

User Info

Password: Submitted
Password Changed: 14. May 2025
Last Login: Change Password...

Certificate

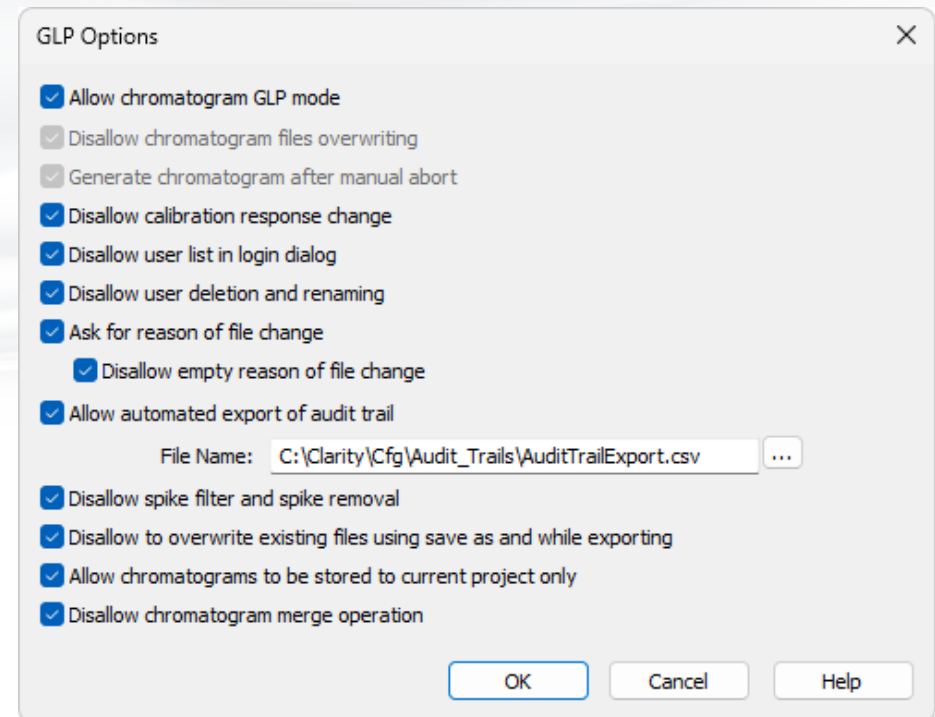
MyCertificate

Select Certificate... Clear Certificate

OK Cancel Help

GLP OPTIONS

- Tool to support **contemporaneous, original** and **accurate** data
- Set of options to ensure compliance
 - All MUST* be enabled in regulated environment



ELECTRONIC SIGNATURES

- Tool to support **attributable** and **legible** data
- Enables signing chromatograms electronically
 - No need for manual signature of printouts
 - Using Clarity user accounts
 - Using various certificates

Sign

Choose User: Samuel

User Description:

Sign As Current User
 Sign Using Certificate

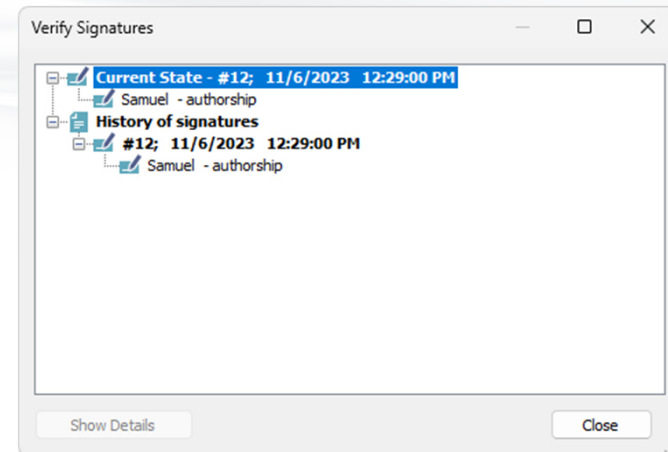
Samuel

Purpose of Signature: authorship

Time Stamp: 11/6/2023 12:27:54 PM

Password:

Select Certificate... OK Cancel



DATA PROTECTION

- Data deletion and alteration must be prohibited
- Proper Windows user accounts required
- Step-by-step setup procedure in M132 manual

i M132 – Regulated Environment - <https://www.dataapex.com/downloads/26163/view>

DOCUMENTATION

- Manual **M132** – Clarity in Regulated Environment
- Datasheet **D021** – Declaration of Software Validation
- Datasheet **D019** - Clarity 21 CFR Part 11 tools

i Above documentation is available for download at www.dataapex.com

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THANK YOU FOR YOUR ATTENTION