



REGULATED ENVIRONMENT IN REGARD TO CLARITY

P035/80C 01/2023



Legal boundaries for Regulated Environment

- ➔ **Regulated environment** is referred to in various legislations
- ➔ Clarity **end user organization** should be aware of legislation that is **applicable for it**
- ➔ Some of Related Guidelines
 - **Title 21, Part 11 – Code of Federal Regulations**
 - **EudraLex – Chapter 4, Annex 11**
 - **CFDA Pharmaceutical GMP, Appendix 2**
- ➔ ... and other **individual national** guidelines



How to achieve compliance?

- ➔ Follow the principle of **ALCOA** for all your data:
 - **Attributable** – to **specific person** and his/her actions
 - **Legible** – for **reviews, audits** or regulatory inspections
 - **Contemporaneous** – data is **recorded when created** and **timestamped**
 - **Original** – kept in the **same format as when created**
 - **Accurate** – 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 – tool to support legible data for ALCOA principle
- Installation qualification (IQ) is an integral part of Clarity and tests whether Clarity was properly installed

IQ

File Help

Installation Qualification Report

Date	23.04.2020, 13:44
Serial number of application	088-000888+38911/00
User Code	CW9PJKEJEFBKP7R
Version of application	Clarity version 8.3.0.127
Build date of application	10.04.2020, 01:51
Instruments	All
Extensions	SST; GPC; PDA; EA; CE; MS; NGA; DHA; GCxGC; MS-TOF
Controls	GC; LC; AS
Certification file	C:\Clarity83\bin\iq.chk
Checksum of cert. file	C7E8303812AD86C2
Date of cert. file	10.04.2020, 04:08
User	marekp
System	Microsoft Windows 10 Professional version 10.0 (Build 18362)
Acquisition and hardware devices	Key Rockey 4ND 088-00888+1073780735/000 id:2FE908DA Colbrick 1284 8890 <Unknown>

Core Files, Embedded Components: Passed (with warnings)

Files

[Show files list »](#)

3rd Party Packages

No external packages installed.

IQ

File Help

Installation Qualification Report

Date	20.04.2020, 09:58
Serial number of application	088-000888+38911/00
User Code	CW9PJKEJEFBKP7R
Version of application	Clarity version 8.3.0.127
Build date of application	10.04.2020, 01:51
Instruments	All
Extensions	SST; GPC; PDA; EA; CE; MS; NGA; DHA; GCxGC; MS-TOF
Controls	GC; LC; AS
Certification file	C:\Clarity83\bin\iq.chk
Checksum of cert. file	C7E8303812AD86C2
Date of cert. file	10.04.2020, 04:08
User	marekp
System	Microsoft Windows 10 Professional version 10.0 (Build 18362)
Acquisition and hardware devices	Key Rockey 4ND 088-00888+1073780735/000 id:2FE908DA DEMO Virtual detector <Unknown> Colbrick 1284 Virtual Digital Input Output Loop

Core Files, Embedded Components: Failed

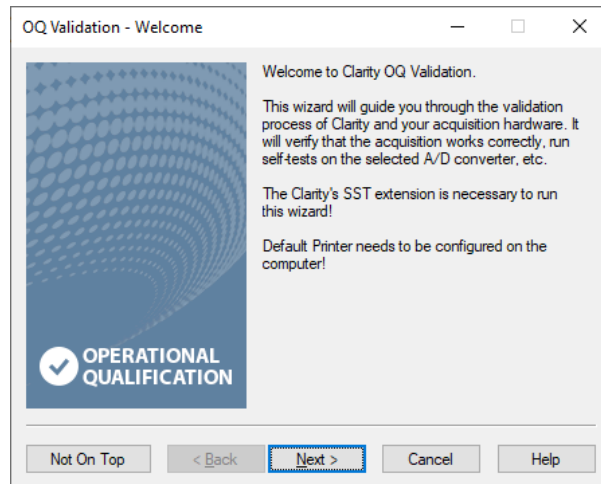
Files

[Hide files list <](#)

File	Path	Version	Size	File date	Status
advantecchf122sfc.rb	c:\clarity83\bin\utils\uni_drivers\advantec	-	36355	25.09.2015, 21:28	Failed: bad checksum
AdvionCMS.dll	C:\Clarity83\bin	6.4.14.1	487936	10.04.2020, 03:51	Passed
advioncommon.dll	c:\clarity83\bin	6.4.14.1	30208	10.04.2020, 03:51	Passed
adviondata.dll	c:\clarity83\bin	6.4.14.1	314304	10.04.2020, 03:51	Passed

Operational qualification

- OQ – tool to support **legible** data for **ALCOA** principle
 - **Operational qualification (OQ)** is an optional package for **testing Clarity's performance** and this package is used when **Clarity must be validated**





Audit trail

- ➔ **Audit Trail** – a tool to support **attributable** and **legible** data for **ALCOA** principle
- ➔ Audit Trail – system for **user activities tracking**
- ➔ In order to **track all actions or data modifications** made by all users from Clarity there are **built-in Audit Trails**
 - Audit Trails are **not modifiable**
 - Audit Trails can be **exported in various formats** for further processing



Audit trail

➔ Each Clarity file contains its **own Audit Trail** – chromatogram AT, method AT, sequence AT, calibration AT and AT for the whole station

OK	Time	Group	Severity	User Name	Instrument	Area	Description
85	09.04.2020 15:13:38	Calibration		Admin	Instrume...	Calibration Params.	C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal - Det. Signal 1 - Level [3]: Compound [ETHANOL];...
86	09.04.2020 15:13:38	Calibration		Admin	Instrume...	Calibration Params.	C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal - Det. Signal 1 - Level [3]: Compound [ETHANOL];...
87	09.04.2020 15:13:38	Calibration		Admin	Instrume...	Calibration Params.	C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal - Det. Signal 1 - Level [3]: Compound [ETHANOL];...
88	09.04.2020 15:13:38	Calibration		Admin	Instrume...	Calibration Params.	C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal - Det. Signal 1 - Level [2]: Compound [ETHANOL];...
89	09.04.2020 15:13:38	Calibration		Admin	Instrume...	Calibration Params.	C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal - Det. Signal 1 - Level [2]: Compound [ETHANOL];...
90	09.04.2020 15:13:38	Calibration		Admin	Instrume...	Calibration Params.	C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal - Det. Signal 1 - Level [2]: Compound [ETHANOL];...
91	09.04.2020 15:13:38	Calibration		Admin	Instrume...	Calibration Params.	C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal - Det. Signal 1 - Level [1]: Compound [ETHANOL];...
92	09.04.2020 15:13:38	Calibration		Admin	Instrume...	Calibration Params.	C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal - Det. Signal 1 - Level [1]: Compound [ETHANOL];...
93	09.04.2020 15:13:38	Calibration		Admin	Instrume...	Calibration Params.	C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal - Det. Signal 1 - Level [1]: Compound [ETHANOL];...
94	09.04.2020 15:13:38	Calibration		Admin	Instrume...	Calibration Params.	C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal - Det. Signal 1 - Compound [ETHANOL]; [Use IST...
95	09.04.2020 15:13:38	Calibration		Admin	Instrume...	Calibration Params.	C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal - Det. Signal 1 - Compound [ETHANOL]; [Used] ch...
96	09.04.2020 15:13:38	Print		Admin	Instrume...	Print Of Calibration	C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal - Print Of Calibration
97	09.04.2020 15:13:15	File		Admin	Instrume...	Files	Open File C:\Clarity83\DataFiles\Common\TC_CompoundsAll.sty
98	09.04.2020 15:13:15	File		Admin	Instrume...	Files	Open File C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal
99	09.04.2020 15:13:14	File		Admin	Instrume...	Files	Reload File C:\Clarity83\DataFiles\DEMO1\Demo1.met - #1; 05.04.2020 0:25:54
100	09.04.2020 15:13:14	Method		Admin	Instrume...	Method Change	C:\Clarity83\DataFiles\DEMO1\Demo1.met - Calculation: Integration Algorithm has been changed ...
101	09.04.2020 15:13:14	Info			System	Messages	Demo1.met does not match current instrument configuration. To use this method for acquisition, it...
102	09.04.2020 15:13:12	File		Admin	Instrume...	Files	Open File C:\Clarity83\DataFiles\DEMO1\Demo1.met - #1; 05.04.2020 0:25:54
103	09.04.2020 15:13:12	Method		Admin	Instrume...	Method Change	C:\Clarity83\DataFiles\DEMO1\Demo1.met - Calculation: Integration Algorithm has been changed ...
104	09.04.2020 15:13:12	File		Admin	Instrume...	Files	Open File C:\Clarity83\DataFiles\Projects\DEMO1.prj
105	09.04.2020 15:13:12	File		Admin	Instrume...	Files	Open File C:\Clarity83\Cfg\Admin.dsk
106	09.04.2020 15:12:46	File		Admin	Instrume...	Files	Save File C:\Clarity83\DataFiles\Projects\DEMO1.prj
107	09.04.2020 15:12:46	Acquisition		Admin	Instrume...	Acquisition and Sequence	No method sent - Ready to send method or start sequence: Instrument was aborted by user
108	09.04.2020 15:12:26	File		Admin	Instrume...	Files	Open File C:\Clarity83\DataFiles\Common\TC_CompoundsAll.sty
109	09.04.2020 15:12:26	File		Admin	Instrume...	Files	Open File C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal
110	09.04.2020 15:12:08	File		Admin	Instrume...	Files	Save File C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal
111	09.04.2020 15:12:08	Calibration		Admin	Instrume...	Calibration Params.	C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal - Det. Signal 1 - Compound [T-BUTANOL]; [Used] ...
112	09.04.2020 15:12:08	Calibration		Admin	Instrume...	Calibration Params.	C:\Clarity83\DataFiles\DEMO1\Calib\Ethanol.cal - Det. Signal 1 - Level [20]; Compound [ETHANOL];...



User accounts

- **User Accounts** – a tool to support **attributable** and **legible** data for **ALCOA** principle
- In order to allow **specific users to perform only specific actions**, there is a tool for setting Clarity users with **specific privileges**



User Accounts [Close]

User List

New Duplicate Delete

Admin
Jorge

Password Restrictions - Common for All

Min. Length 8 [chars.]
 LifeTime 90 [days]
 Expiration Warning 5 [days]
 Password Reuse 95 [days]
 Auto Lock 10 [min]

User Details for: Jorge

User

User Name: Jorge
Desktop File: Jorge
Description:

Other Users Can

Read & Write
 Read
 No Access

Access To

Instrument 1 Instrument 3
 Instrument 2 Instrument 4

User Info

Password: Submitted
Password Changed: 17. October 2022
Last Login:
Change Password...

User Access Rights

Open User Accounts
 Open Configuration
 Edit Method
 Edit Chromatogram
 Edit Calibration
 Projects
 Import Chromatogram
 Take Control of Locked Instrument

Edit Sequence
 Edit Report Style
 Select Method
 Open Audit Trail Settings
 Archive / Restore
 Post Run Settings
 Start Acquisition

Certificate

No certificates assigned to the selected user

Select Certificate... Clear Certificate

Certificate For Exporting To PDF

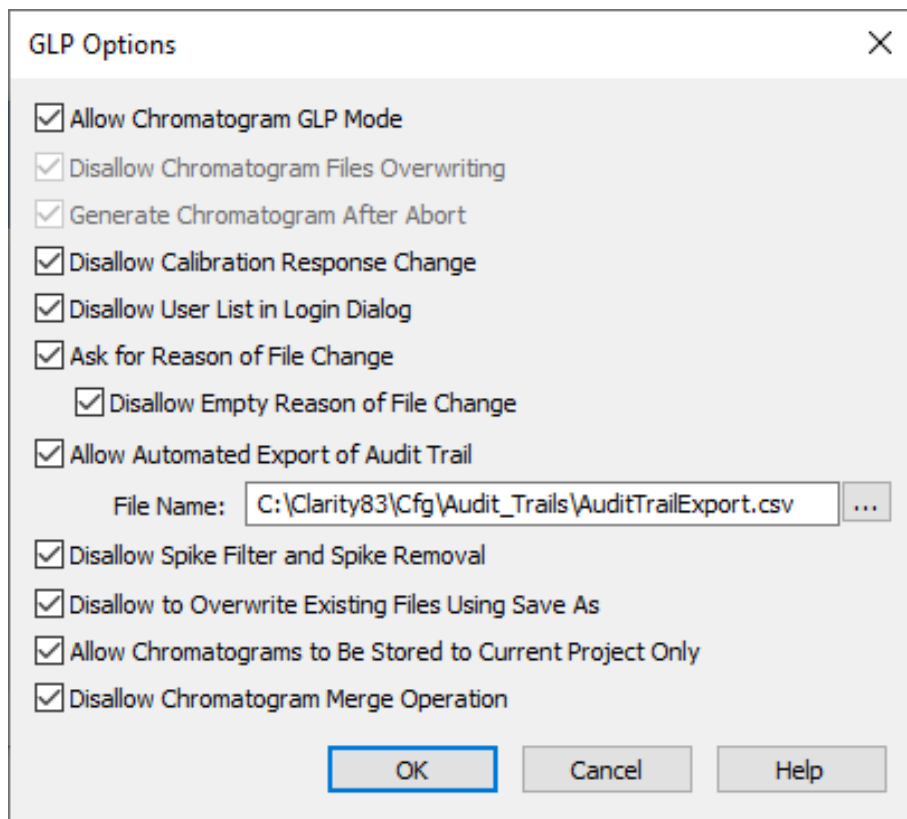
OK Cancel Help

→ Using the **User Accounts**, it is possible to assign different roles in Clarity, such as **analyst, Clarity administrator, reviewer, archivist** and so on



GLP options

- GLP Options – a tool to support **contemporaneous, original** and **accurate** data for **ALCOA** principle
- *GLP Options* represent a set of options which **all must be set if** Clarity is intended to be **deployed in regulated environment**

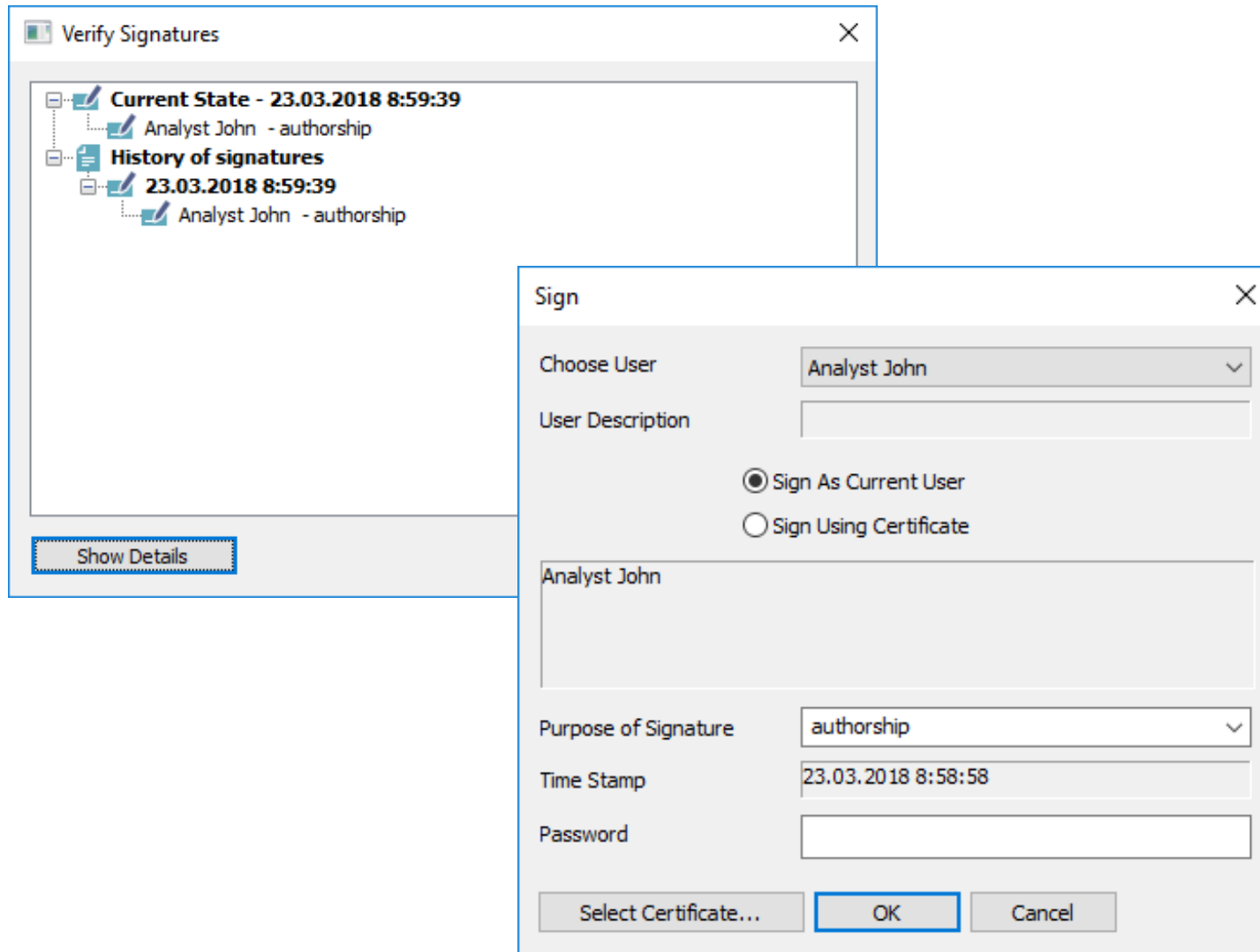


→ These options enable Clarity to **fulfill requirements stated in related regulations** (CFR 21 - Part 11, EudraLex 4 – Annex 11 and so on)



Electronic signatures

- **Electronic signatures** – a tool to support **attributable data** for **ALCOA** principle
- Electronic signatures allow to **sign chromatograms electronically** eliminating need of hand made signature on chromatogram printout
- Clarity supports signing of chromatograms using Clarity user accounts credentials (login and respective password)



→ Clarity supports signing of **chromatograms** using **certificates issued by various certification authorities**

→ Clarity also supports signing of **PDF printouts** using **respective certificates** issued for this purpose by various certification authorities



Data protection

- Data protection - data deletion or data alternation must be prohibited
- Proper Windows user account settings is required
- Detailed **step-by-step** procedure how to set different Windows versions is in online manual

 [M132 – Clarity in Regulated Environment](#)



Documentation

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



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



...THANK YOU FOR YOUR TIME



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