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:

- **A**ttributable – to **specific person** and his/her actions
- **L**egible – for **reviews, audits** or regulatory inspections
- **C**ontemporaneous – data is **recorded when created** and **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** – tool to support **legible** data for **ALCOA** principle
- **Installation qualification** (IQ) is an integral part of Clarity and tests **whether Clarity was properly installed**

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**
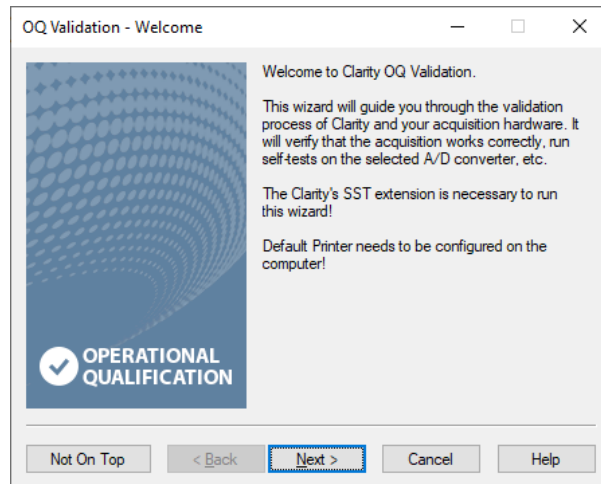
Audit trail

→ **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

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**

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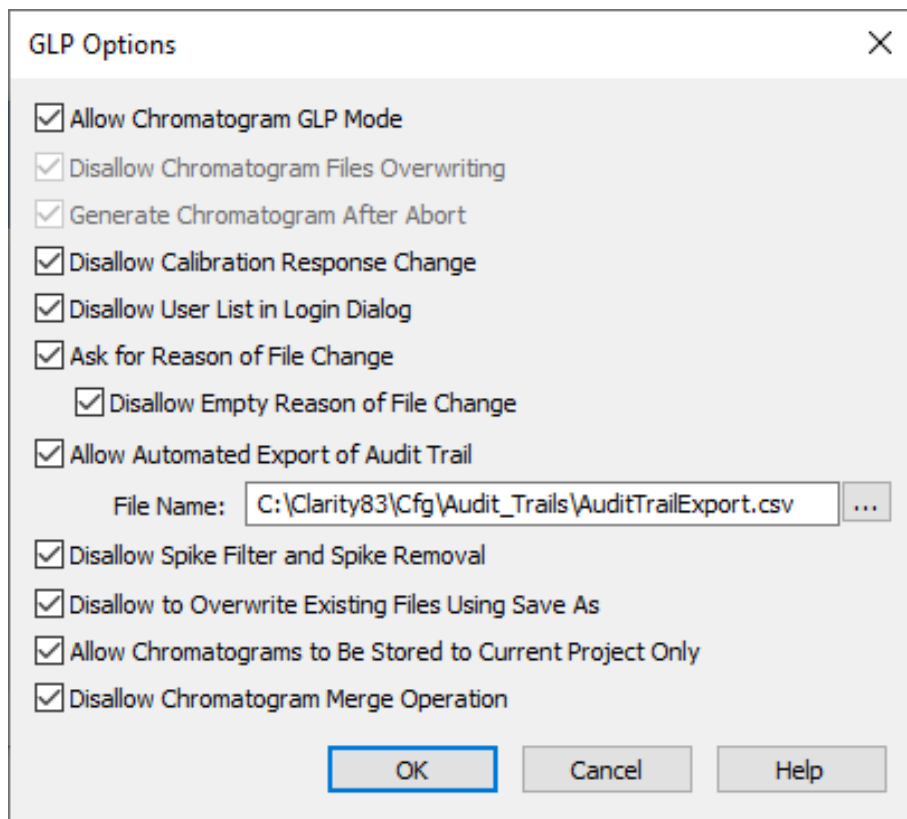
> These options enable Clarity to **fulfill requirements stated in related regulations** (CFR 21 - Part 11, EudraLex 4 – Annex 11 and so on)

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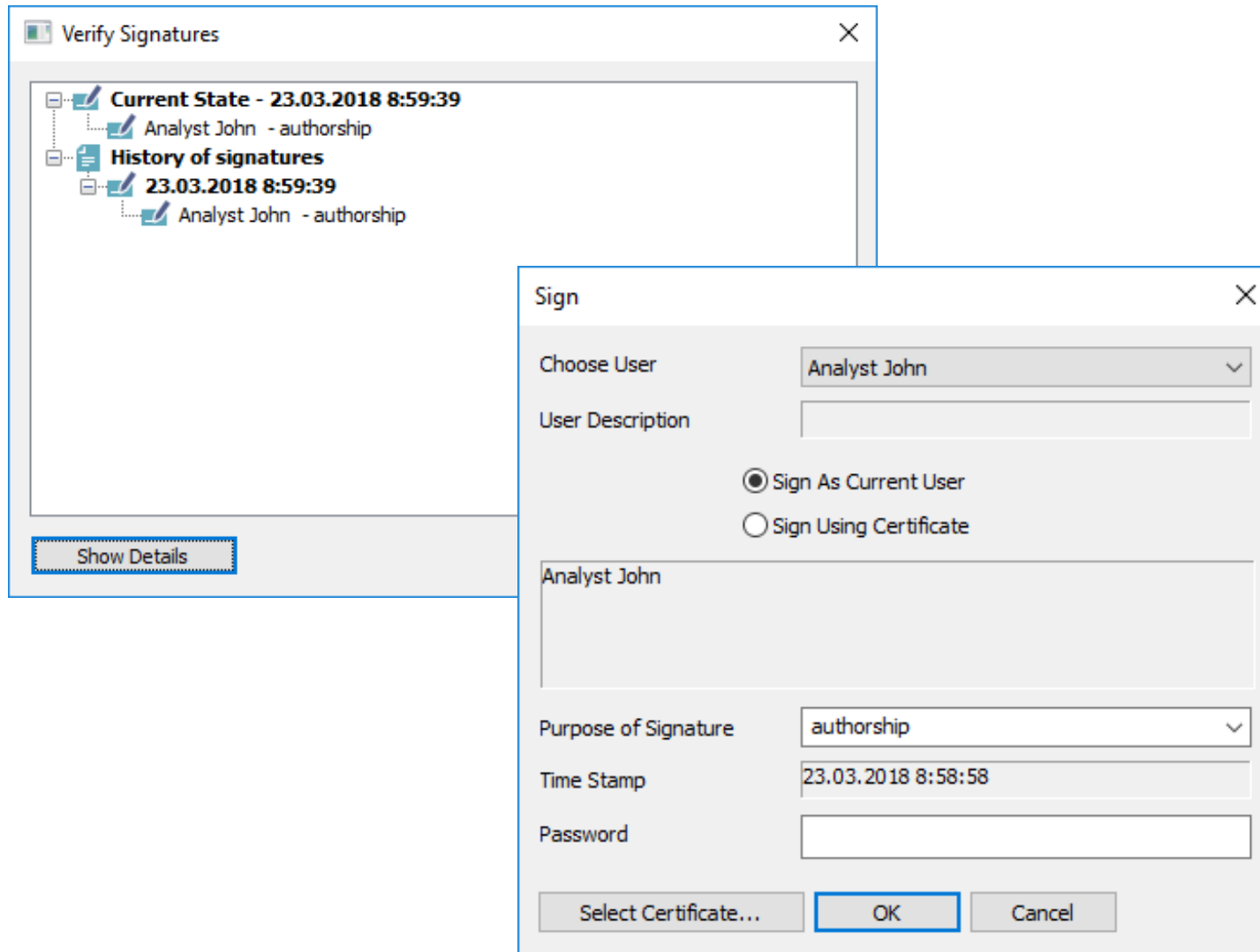
- Clarity supports signing of **chromatograms** using **certificates issued by various certification authorities**

- 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 Widows user account settings is required

→ Detailed **step-by-step** procedure how to set different Windows versions is in online manual

ℹ 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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