DATA SHEET

# TMI-Orion

# Qlever Software

## Pharmaceutical industry
## Medical sector

**Editing of secured validation and qualification reports for pharmaceutical industry and medical sector.**

Qlever is a software solution for the acquisition, analysis and visualization of data measured by TMI-Orion data loggers.

Qlever features:

- Define the validation and qualification parameters of your processes (load plan, normative values...)
- Generate, verify and approve industry specific reports.

Qlever software is easy to use, intuitive, and allows customization by the user.

Qlever software works in combination with specific application modules to answer the needs of pharmaceutical industry, laboratories, health facilities, equipment manufacturers, medical device manufacturers.

**Compliance with directives and norms:**

**- FDA 21 CFR Part 11**
**- EN 554**
**- ISO 17665**
**- EN 13060**
**- EN 285**
**- EN 868**
**- EN ISO 15883**
**- FD X15-140/IEC 60068.3.11**
**- JJF 11-01-2019**
**- YY/T 0649-2022**

# Qlever SOFTWARE MODULES - PHARMACEUTICAL INDUSTRY & MEDICAL SECTOR

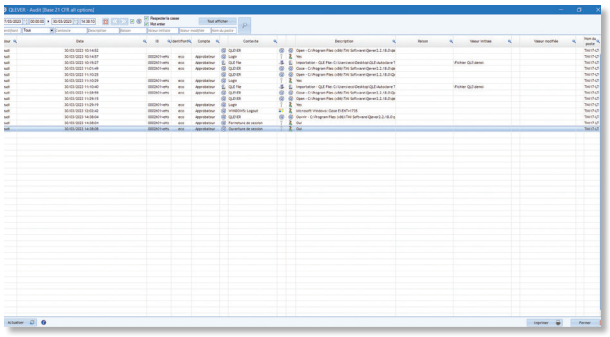
**TMI-Orion offers a number of software modules dedicated to various applications which can be combined to answer the needs of the pharmaceutical industry and medical sector.**

### • Authentication-tracking module – FDA 21 CFR Part 11 compliant :

- Secured management of user access, with creation of different accounts and access levels. (Administrator, approver, operator). Report verification and approval.

- Verbose audit trail with complete tracking of processes and data, including addition, deletion, modification operations.

The functions of this module are also included in the Pharma module.

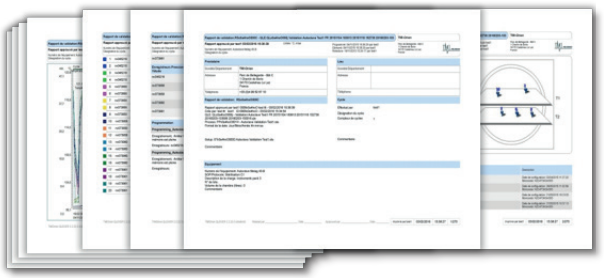


*Audit trail example*

### • LDAP module for user management

The Administrator may use the Microsoft Windows Active Directory LDAP to override Qlever user management. This optimizes consistency in user authorization management throughout the company information system.

This module requires the Authentication-tracking module or the Pharma module.



*Validation report example*

### • Pharma module – Integrates the Authentication-tracking module - Compliant with FDA 21 CFR Part 11

Dedicated to operational analysis and qualification of thermal cycles in chambers.

Extensive measurement report with detailed statistical calculations including up to 3 cycles and 3 stages per cycle.

### • Mapping module

Data treatment and presentation in an extensive report compliant with **FDX 15-140 / IEC 60068.3.11**,

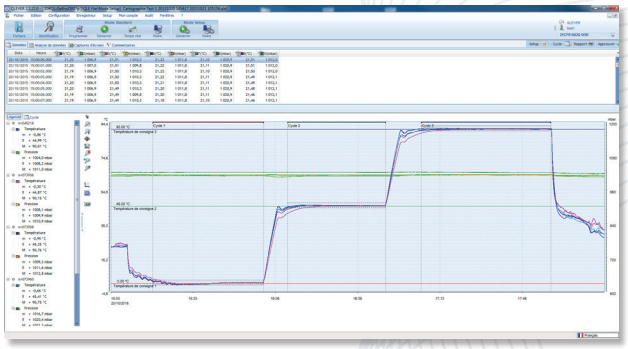
Intended for characterization and checking of temperature and humidity in climatic and thermostatic chambers or other kinds of thermal regulation devices such as rooms, ovens, autoclaves.

Door opening and power cut tests with recovery time calculation.

Creation of relative humidity calculated channels with:
- data loggers placed in the chamber
  + 1 temperature data logger and 1 humidity data logger,

OR

- data loggers placed in the chamber
  + 1 Optidew® hygrometer.



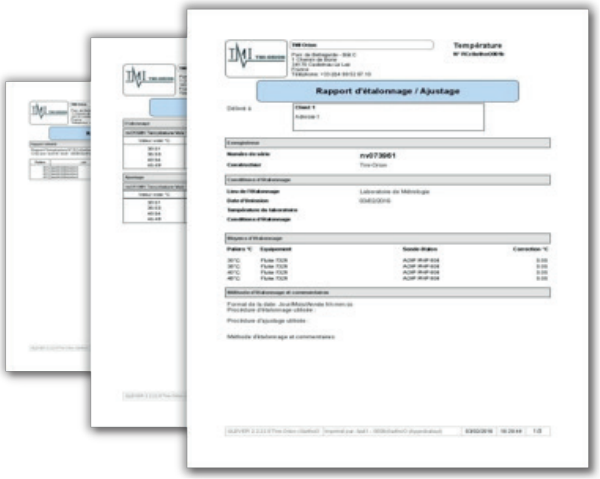
*Mapping module visualization example*

### • Calibration module

Dedicated to TMI-Orion temperature and humidity loggers calibration process: calibration, adjustment, checking and editing of a report.

Computerized management of calibration equipment including baths, ovens, and reference probes.

Delivers an adjustment and calibration report. Expert mode, Automatic mode and Manual mode available.




*Calibration report example*

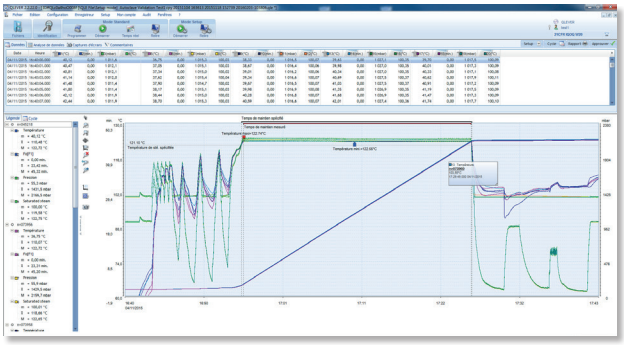
### • Autoclave validation module

Data treatment and presentation in an extensive validation report compliant with **ISO 17665 / EN 13060 / EN 554 / EN 285 / EN 868 / YY/T 0649-2022.**

Intended for autoclave qualification and sterilization cycles validation (Bowie & Dick, Prions, Helix).

Analysis of vacuum test, pre-treatment phases, plateau phases…

Calculation of saturated steam, calculation of F0 sterilization value, calculation of dynamic pressure, air evacuation calculations for heat penetration analysis in sterilization cycle pre-treatment (Bowie & Dick, Prions, Helix).



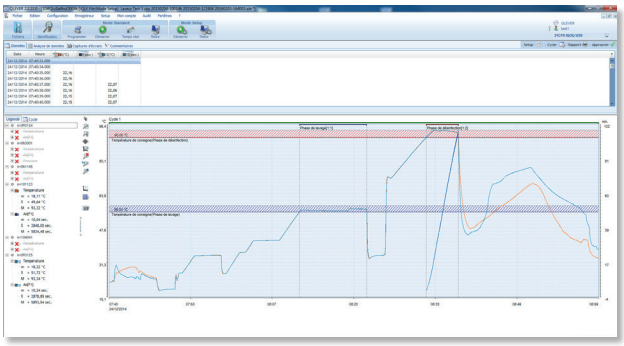
*Autoclave validation module visualization example*

### • Washing-disinfection module

Data treatment and presentation in an extensive validation report compliant with **ISO 15883**.

Intended for analysis of washing and disinfection cycles.

From 1 to 3 cycles and from 1 to 3 washing phases and 1 disinfection phase per cycle. A0 calculation.



*Washing-disinfection module visualization example*

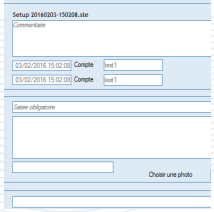
## SUPPORT

### IQ/OQ validation protocol

TMI-Orion offers an optional documentation support including the installation qualification protocol and the operational qualification protocol (IQ/OQ - Installation qualification and Operational Qualification) of each Qlever module. The validation protocols are usually integrated in the customer quality process. Optional IQ/OQ protocol validation support.

### Commissioning

Optional commissioning support for TMI-Orion system.



# Qlever SOFTWARE

## KEY POINTS

- Data treatment and presentation in an extensive validation and qualification report **compliant with applicable norms.**
- **Creation of setup library per application** describing the configuration, the setup of TMI-Orion datalogger and customer equipment, as well as calculations to apply on collected data.
- Data and access tracking, modifications follow-up, for compliance with **FDA 21CFR Part 11** directives.
- **Real time supervision of industrial processes,** with TMI-Orion FullRadio or radio data loggers placed inside the processes.

## FUNCTIONS

### Data collection and treatment

- Collection and logging of measured data,
- Up to 30 encrypted databases, locally or on the server,
- Collection and real time visualization of data with radio or FullRadio data loggers,
- Standard calculations: F0, A0, saturated steam, dew point, etc.,
- Creation of calculation libraries, automatic calculations upon reading data,
- Possibility of raw data export to a spreadsheet.

### Data analysis and viewing

- Compliant with FDA 21 CFR Part 11,
- Data and statistics analysis: minimum, maximum, average, maximum gap, gap type, time above, time under, ramp time, equilibration temperature, MKT, slope calculation, etc.,
- Validation and qualification report editing, verification and approval.

## TECHNICAL SPECIFICATIONS

- Multilingual environment.
- Data files in TMI-Orion proprietary format.
- The database is encrypted and cannot be modified.
- Database administration services (user account and access management, restore and save, reindex...).
- Single station or multiple stations database use (user data sharing)
- Keyword search engine.
- Secured data file import or export.
- Multiple station Qlever licence.
- Compliant with Windows® 7/8/10/11.
- Minimum requirement for software installation:

- RAM: 8 GB
- Disk space: 200 MB (Not including data measured by the loggers)

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