

beyontics

CIQ

Customised Instrument Qualification in Empower® and Chromeleon®

beyontics CIQ for Empower® and Chromeleon®

Customised Instrument Qualification in Your Own Data System

With beyontics CIQ the qualification for all chromatography instruments controlled by Empower or Chromeleon runs consistently and without further validation effort.

beyontics CIQ - Customised instrument qualification with full respect to regulatory demands.

Customised and harmonised.

In contrast with most instrument qualification software programs, beyontics CIQ takes into account the analytical work of your lab, providing harmonised test procedures, instead of following different specifications from various equipment manufacturers.

Full integration into your present CDS.

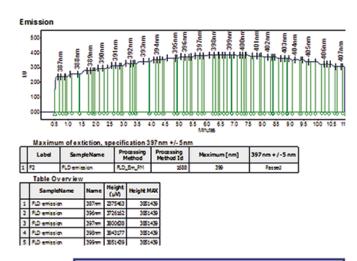
beyontics CIQ is implemented as an Empower project or Chromeleon eWorkflow and equipped with adaptable methods and customisable reports. All data and results are stored in your own CDS. By this, full access is given to all meta-data that was generated during qualification. Test outcome is assessed for each single test point and for the whole qualification providing a final PASS or FAIL statement.

Ready to use. No further validation effort.

As beyontics CIQ is provided as an Empower project or Chromeleon eWorkflow the product can simply be installed into your CDS using the existing procedures for importing projects or eWorkflows. The whole product is designed using the proprietary options of your CDS. The customisations are delivered in a validated state.

beyontics CIQ - 100% Compliance to your needs.

The complexity of the tests as well as the limits are defined according to your requirements: Only the relevant instrument modules are tested!



Wavelength Accuracy: Passed

Saving time and resources. Minimising downtime for your instruments.

Fully automated procedures.

beyontics CIQ for Empower and Chromeleon ist designed in a way that allows for a minimum of efforts for carrying out a qualification run. Templates are offered for all tests and because of that a qualification run just needs to be started and after completion is evaluated as a whole in the CDS and can be reported with the CDS's own tools. Assistance of external evaluation programs is not needed at all. Qualification runs of several instruments at the same time is thinkable.

Minimising training effort for service staff.

beyontics CIQ is designed in a way, that only a basic user knowledge of the applied CDS is needed due to the high automation of the product. In addition a user guide is provided giving a step by step guidance for the qualification procedure. Training or introduction is offered by beyontics.



beyontics CIQ from a regulatory point of view. Secure and traceable.

Avoiding redundancies.

Following aspects need to be respected when instrument qualification is carried out by an external service engineer with vendor specific software and hardware:

- » Is the software the engineer was using 21 CFR 11 compliant?
- » Is the computer hardware and software installation that were used during qualification qualified accordingly?
- » How can the electronic raw data be provided in a human readable form during an audit?

For this purpose a qualified installation of the software the service engineer was using would be needed. Do you want to purchase the software and keep a qualified installation in place merely for this purpose?

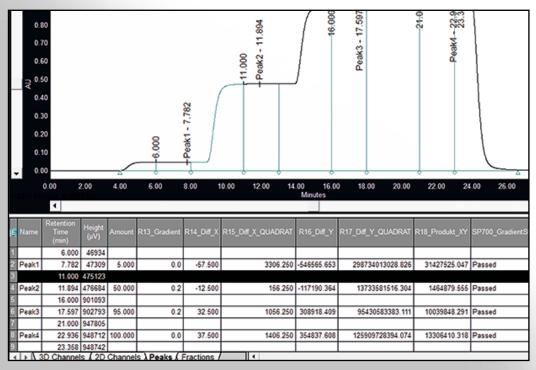
beyontics CIQ for Empower and Chromeleon is the simplest answer to your regulatory demands.

Many customers who need to pass an audit say, No.: They prefer their instrument qualification to be performed in their present CDS installation. Those customers would need to provide methods and validated reports and they

would also need trained service staff. All this is covered by beyontics CIQ.

beyontics CIQ at a glance.

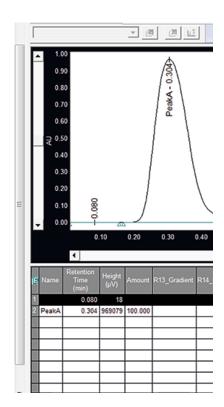
- » CIQ is an Empower Project/ Chromeleon eWorkflow for instrument qualification, adapted to your requirements
- » Can be used for GC and LC
- » Qualification is controlled by your CDS and is fully automated
- » Documentation of the whole qualification in Empower/Chromeleon
- » Manual entry of physical measurements (e.g. flow rate, temperature)
- » Evaluation of the qualification results through Empower/Chromeleon
- » Automated Report function
- » Possibility of paperless qualification with the Empower Sign-off//Chromeleon-Electronic-Report function
- » Avaliable for any CDS release state



Your benefits & chances.

- Harmonized qualification for all instruments controlled by Empower/Chromeleon
- Storage of raw data in Empower/Chromeleon
- Proof of raw data in Empower/Chromeleon >>
- Increasing the efficiency via automation of the qualification
- Less equipment downtime **>>**







Our services.

- Adapting the CIQ Project/eWorkflow to your specific requirements
- Coaching the project during the implementation; if needed in coordination with an executing service partner
- Preparing the validation documents according to customer requirements
- Ongoing support for the productive project

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