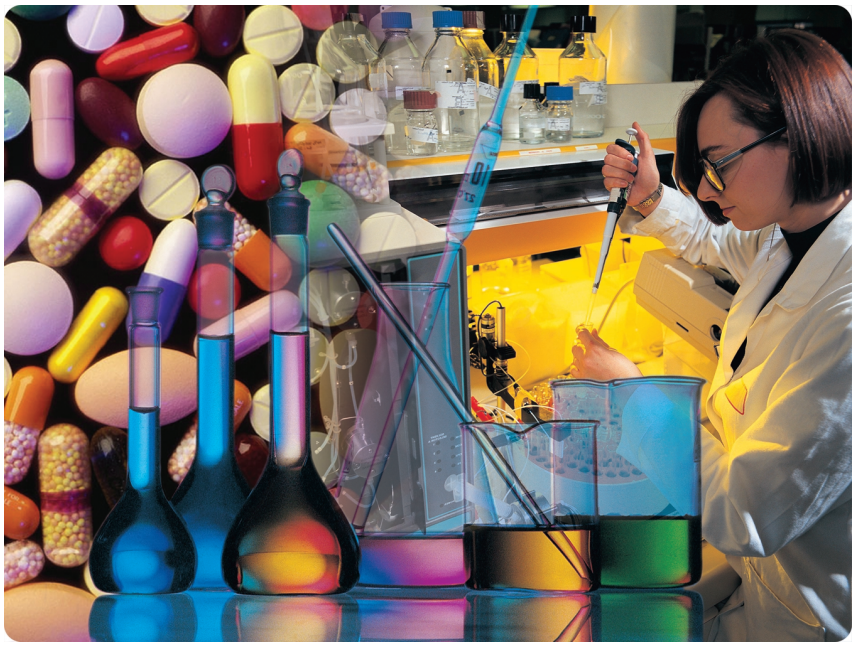
EZChrom *Elite*™ CDS Features for the Pharmaceutical and GLP/GMP Laboratory



Key Benefits

- Fully address 21 CFR Part 11 and GLP/GMP issues to facilitate compliance.
- Be efficient with a single cost effective solution with control of over 300 analytical instrument modules from 26 different manufacturers or analog acquisition from any source.
- Protect your investment with a scalable solution, from workstation to enterprise client/server deployments.
- Enhance productivity and tailor a solution with RapidControl™ and EZChrom *Elite* Automation ToolBox™ technologies.
- Respond automatically and intelligently to real world conditions with SmartSequence™ technology.

The EZChrom *Elite* Chromatography Data System is in widespread use in a number of chemical analysis laboratories throughout the world. It has been used in many different laboratory markets including pharmaceutical, environmental and the petrochemical/chemical market. A number of built-in software capabilities position EZChrom *Elite* ideally for the Pharmaceutical and GLP/GMP industry.

Scalable CDS Operation

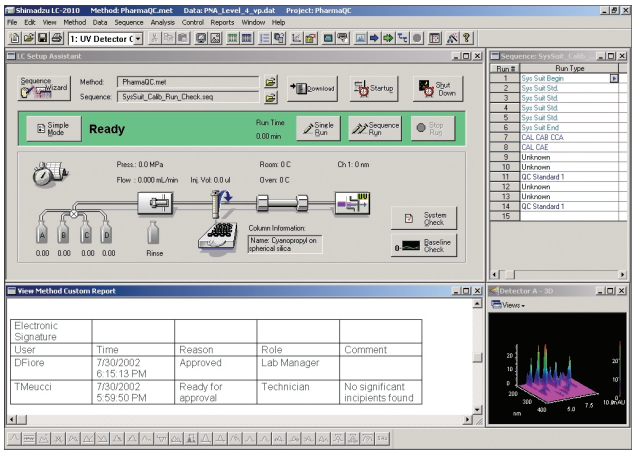
EZChrom *Elite* is designed as a scalable CDS software application, that can be readily deployed as a single user/single instrument system to a multi-user/multi instrument client/server application. In this way, EZChrom *Elite* is particularly well suited for the pharmaceutical and GLP/GMP industry as it can be flexibly deployed for a particular laboratory operation and then easily scale as the laboratory environment grows and changes.

Agilent Technologies

Regardless of whether EZChrom *Elite* is used for a single user or multi-user environment, the same core software is used to ensure a uniform software interface for all environments.

Multi-Vendor Instrument Control for HPLC and GC

Designed to provide integrated instrument control with CDS data handling capabilities, EZChrom *Elite* can offer instrument control for more than 300 different GC and HPLC instrumentation. Moreover, as part of Agilent Technologies' "open" system approach, the instrument control capabilities in EZChrom extend to leading instrument vendors such as Agilent, Shimadzu, Thermo Electron, Varian, PerkinElmer, Waters and others. Laboratories in the pharmaceutical and GLP/GMP industry are often populated with a number of manufacturer's equipment, many of differing generations, will appreciate the ability of EZChrom to effectively control and process data from these multi-vendor environments. End users can work with one single software platform to make software operation easier and more efficient in support of this wide variety of different instrumentation.



For example, EZChrom *Elite* today offers instrument control capabilities for virtually all of the world's leading commercial HPLCs including the Agilent 1100 HPLC, Waters Alliance HPLC, Shimadzu LC 14, 17, 20A, and 2010 HPLC, Hitachi La Chrom and La Chrom Elite HPLC, Jasco series 2000 and 1500 HPLC, Thermo Electron SpectraSYSTEM and PerkinElmer Series 200 HPLC. No other CDS package offers this broad range of integrated instrument control. Moreover, many of the world's leading instrument specialized devices such as high throughput precision autosamplers from CTC Analytics, or the charged aerosol detector from ESA can be readily added and controlled to EZChrom for a completely integrated solution.

EZChrom's integrated instrument control is extensive and deep, taking advantage of many of the specific features and capabilities in each HPLC or system. Many HPLC's equipped with PDA or Diode Array Detectors, for example, can be supported so that pharmaceutical laboratories interested in processing PDA data with their HPLC runs can take full advantage of this capability in EZChrom. Extended calculations for peak purity and component matching are available.

Software Features Specific for Pharmaceutical Needs

In addition to addressing data reduction commonly used by these operations, EZChrom provides some key features that are ideally suited for the pharmaceutical and GLP/GMP operation.

1. **Data File Integrity:** EZChrom *Elite* files are provided with standard features ensuring ensuring file integrity – "tampering" with files (access to files outside of the intended software application) is controlled through the use of embedded checksums to ensure file integrity at all times.

2. **Data File Protection:** EZChrom *Elite* will not allow a user to "overwrite" a file. Reprocessing files appends the new results to the end of the data file, preserving all previously accumulated information.

3. **Traceability and Recovery of Changes:** EZChrom *Elite*'s unique compound data file structure allows for total traceability of results. Each data file contains the raw data, acquisition parameters, instrument configuration and audit trail. Each time the file is analyzed, a copy of the analysis parameters and results are appended to the original file. Even though a data file may have undergone a series of re-analyses, it is always possible to recover the original (or any intermediate) analysis and instrument parameters and results, as well as the instrument parameters used to generate the original file.

4. **User Security Features:** EZChrom *Elite* has a built-in option to setup user accounts with control of access and operational privileges on an instrument by instrument or project by project basis. By controlling who has access to a particular instrument you can address concerns where you wish to restrict "unauthorized" operation of an instrument. By controlling who has access to a project, you can address concerns where you wish to restrict who can "see" certain data.

5. **Audit Trails, System Logs, and Instrument Logs:** EZChrom *Elite* provides features to track and record changes to files and to the system. Audit Trails are maintained for any changes to

methods, sequences and results. These audit trails record who made the change, what was changed, when the change was made, and why (the reason) for a change. System and Instrument logs provide a systematic unambiguous record on all changes to the system and activities on the instruments.

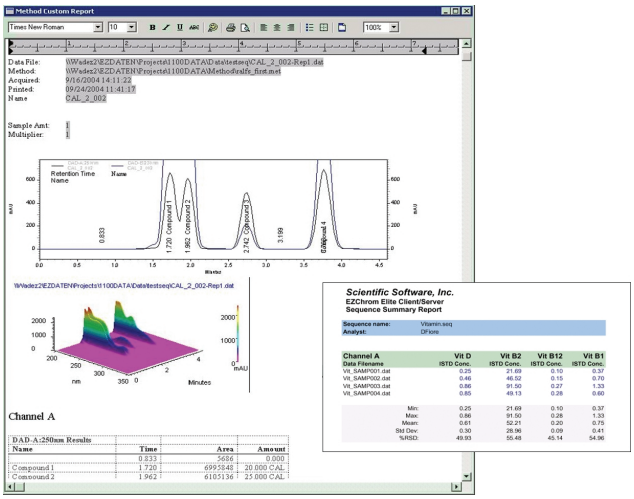
6. **Electronic Signatures and Signoff Capabilities for 21CFR Part 11:** If desired, you can use Electronic Signatures in EZChrom *Elite* in accordance with 21CFR Part 11 rules. Flexible signoff procedure to allow multiple levels of signature for submission, review, approval, etc. if desired. One to 5 levels can be used. Other GLP/GMP features including User Security (passwords, controlled access), Audit Trails, System and Instrument Logs, etc. address all 21CFR Part 11 issues.

7. **Agilent Instrument Controller Network Appliance for Networked Data Acquisition Addresses GLP/GMP Issues:** EZChrom's unique system architecture through the Agilent Instrument Controller allows networked access to all instruments and can be especially important to the pharmaceutical operation. It provides a "closed" system design to control unauthorized use and access. Its powerful data buffering capability maintains data acquisition even if network is inoperative.

8. **Controlling Changes to the System**: In a perfect world, users could setup their CDS and then simply run the samples, without ever needing to make changes once acquisition has begun. But in the "real world", this rarely happens. How well a system controls these changes is important to a GLP/GMP laboratory. Whenever data is analyzed (or re-analyzed) in EZChrom, the results are appended to the data file and are traceable. Original results or intermediate results can be recalled and viewed — they are never overwritten. User Security lets you control access to your methods and sequences. In this way, you can restrict who can work with your methods and sequences. You can permit other users to use your methods but not change them. Changing actively acquiring sequences: Once a sequence has been started, users with the proper authority can modify the method and the system will automatically ensure that the changed method is used for the next injection. If a run has already started you can shorten or EXTEND the run time. Depending on the hardware control, you might be able to change some conditions (change temp, flow rate via direct control toolbar). Any of those changes are put into the Audit Trail.

Wide Range of Flexible Reporting

EZChrom *Elite* puts ultimate report customization and automation for many pharmaceutical operations. In addition to a wide selection of ready-made, desktop publishing-quality report templates tailored to general methods, EZChrom *Elite* also allows custom-made reports to address specific needs. Reports can be appended with any data originating from EZChrom *Elit*e, including run, calibration, system suitability, and even summary reports. Custom parameters specific for the analysis can be easily added to reports for extended custom calculations.



Practical Automation Features

Using SmartSequence™ technology, EZChrom *Elite* enables intelligent analysis and decision-making by providing "go/no-go" acceptance of results. This powerful capability allows the pharmaceutical lab to setup truly automated system suitability testing. Conditional actions to re-calibrate, run shutdown methods, even issue automated e-mail alerts in case of deviation of expected results can be established for each HPLC EZChrom reports and data can be easily generated in appropriate format for third party applications such as Excel though built-in format options.

21 CFR Part 11 Compliance

EZChrom *Elite*'s security and compliance tools enable adherence to regulations such as the FDA's 21 CFR Part 11 for electronic records and signatures. Audit trails are comprehensive, recording every event starting from file creation. Once electronically signed, data files are tamperproof. All audit trails provide "who, what, when, and why" traceability and are CRC check-summed to prevent unwanted manipulation.

Providing Well Established Validated Solutions

EZChrom *Elite* and the worldwide network of Agilent Technologies service and support are available for any laboratory involved in validating the system. A wide range of built-in features, optional products and services are available to assist in the task of validating every EZChrom deployment. The unique ISO9001 and TickIT quality certifications in place for the Agilent development of

EZChrom mean that every system shipped is backed by a comprehensive quality management system based on well established standards of software development quality.

Simplifying Validation with Client/Server Architecture

EZChrom *Elite* fits nicely in the corporate network by adhering to Microsoft® and industry standards and minimizing network traffic. With user management administered through a company's current NT domain security, there is no need to manage multiple systems for usernames and passwords. In a client/server deployment with thin client configuration, acquired data is processed centrally. Data is maintained and buffered even in the event of a network failure. Using Citrix Metaframe XP, EZChrom *Elite* clients require only the installation of the Citrix ICA client application. No further validation of the client computers is required. Moreover the unique design of the Agilent Instrument Controller permits a "validate once – deploy many" approach which can save time for the pharmaceutical laboratory. Each Agilent Instrument Controller variant is identical so that laboratories do not need to validate and re-validate each Agilent Instrument Controller individually.

Agilent Technologies Compliance Services

Agilent's Compliance Portfolio can address all the qualification needs of your Agilent networked chromatographic systems including the LAN and WAN infrastructure itself. The **Software Edition** products provide efficient and accurate IQ and OQ for your EZChrom *Elite* chromatography data system (CDS). For the equipment connected to the CDS, Agilent's new **Enterprise Edition** is the perfect solution for vendor-independent hardware qualification of most LC's and GC's. In addition, the laboratory network infrastructure can be validated with our metrology-based qualification services called, **Network Edition.**

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