

Is It Time to Replace Your Chromatography Data System?

Chromatography Data Systems (CDS) are an integral component of any analytical laboratory. Yet over time, a CDS may no longer address a laboratory's scientific application/regulatory needs; may not be compatible with current informatics technology such as PC operating system; and may no longer be supported by the vendor resulting in limited access to software updates. Furthermore, ongoing consolidation across a variety of science-driven industries resulting from mergers, acquisitions, and restructuring has left many organizations with several brands of CDS and a sizable inventory of disparate instruments and systems that should be addressed by a decision in favor of a new CDS. But how do you take all of these factors into account when replacing your existing CDS(s)? This white paper outlines the three main drivers for considering a new CDS and how your lab can benefit. It offers guidance in making the decision to replace an existing CDS and provides practical "factors to consider" that address common concerns.

KEY DRIVERS FOR REPLACING A CDS

1. No Upgrades, Inadequate Support

What You Have to Lose. Your existing CDS may have given you many years of quality performance that you could count on, but like any technology, it has become outdated (and even obsolete). It may lack capabilities, speed, and other desirable features compared to newer, more technologically advanced products.

When a CDS is no longer on the market or is being phased out, vendor support may dwindle or be inadequate to meet your needs. The vendor may not maintain a sufficient cadre of technicians trained to service and support the CDS, having shifted the focus of its resources and energies to newer systems. Additionally, regular software updates and opportunities to upgrade the system may be lacking. The vendor might even have ceased operations or merged with (or been acquired by) another company.

What You Have to Gain. Replacing a CDS offers the opportunity not only to equip your laboratory with a technologically advanced chromatography control and data management system, but also to establish a new business relationship and interactive partnership with a vendor that has knowledge of market trends, application needs, and regulatory changes, and that can support your lab by providing consultation, education, products, training, and services.

By selecting a high quality, state-of-the-art system from an industry-leading vendor with a global footprint and sound reputation, numerous science-driven organizations across a variety of markets have enhanced their laboratory operations. The result has been an overall improvement in productivity in individual workflows such as method development, method validation, data review, and sign-off, etc. In addition to more efficient laboratory processes, selecting an industry leading CDS also represents a proactive step toward preventing another unsupported CDS in the future, and you will have reduced the risk of finding your lab left with no or inadequate vendor support for critical lab systems. Introducing a new CDS with appropriate training for lab personnel will also help ensure that it is being utilized properly and to its maximum potential, taking advantage of its full range of capabilities. By leveraging the vendor to assist in the installation and configuration of the new CDS, you can be certain to start off on the right foot, minimize laboratory downtime, and integrate and tailor the system to meet the specific needs and workflows of your organization.

Lab staff will be eager to learn the new CDS and master its functions as it represents a new challenge and an opportunity for growth and career development (especially if it is the market leading solution), and the potential to enhance and simplify their work experience. Furthermore, future employees may be more likely to have experience with the new market leading CDS than with an older, outdated platform. Vendor offerings that combine training and support help ensure that analysts are all using the CDS in a similar way and are maximizing its potential. Once the relationship between vendor and user has been established, it is important to have confidence in the vendor's ability to provide ongoing support, including routine visits.

2. Does Not Meet Our Needs

What You Have to Lose. The CDS now in your lab may be operating as originally designed, but if it is no longer able to meet your needs and not equipped to adapt to your future growth, then you should consider replacing it. Ask yourself these questions:

- Can your CDS manage all current applications? How about likely future applications?
- Can it communicate and share information with other systems and technologies as needed? Is it scalable (single workstation to multi-site enterprise)?
- Is it adaptable for use with a new or existing laboratory information management system (LIMS) or electronic laboratory notebook (ELN)?
- Can it access and mine legacy data (via data import and conversion), and integrate and extract value from new and older data stores?

If your current CDS lacks any of these capabilities, you may not be maximizing the output that can be obtained from your chromatography equipment and benefiting from the wealth of information in your data stores. If your existing CDS lacks data management, it may be more challenging to comply with regulatory requirements.

What You Have to Gain. The activities and applications in analytical labs are continually expanding, changing, and increasing in scope and complexity. New CDS options are available that can fill the gaps unmet by your current system and perform additional functions. A new CDS will offer improved data management capabilities, including enhanced data viewing, processing, storage, retrieval, reporting, and sharing. Newer CDS

options will also support new techniques, instrument platforms and software architectures. Acquisition of a new CDS also provides an opportunity to reassess the current needs of the lab and to predict and plan for near-term expansion and change to accommodate new activities and applications.

3. No CDS Standardization, No Unified Platform

What You Have to Lose. The purchase of new instruments and devices and the acquisition of new CDS solutions over time or as the result of corporate mergers, site closures, or restructuring and redistribution of assets can create an inventory of disparate systems. This may present several challenges at the level of the individual lab and may complicate operations, oversight, administrative functions, and data-sharing within and with external partners across a global organization. It may also make it more difficult to work collaboratively.

When CDS solutions are not standardized on a uniform platform, the ability to consolidate, compare, and present analytical data from different experiments, laboratories, and corporate sites may be compromised. IT and Quality groups may not be able to track data efficiently within the organization. Managing historical data and maintaining audit trails and reports for each instrument and system as required for regulatory compliance will also be more difficult.

Additionally, a disparate collection of systems can be a cause of suboptimal asset utilization, as it will be far more difficult to track instrument usage, output, and downtime when that information is not available on one centralized system. With multiple systems in use, team members will likely have variable experience levels on different systems. Not all lab staff may have received adequate training on all of the systems in use, so some may be used regularly while others sit idle.

What You Have to Gain. The benefits of consolidating many different types of CDS into one unified system derive mainly from reduced complexity. This affects all aspects of the lab and organization, from administration to analytical operations, data management and IT activities, staff training, regulatory compliance, asset utilization and maintenance. The enhanced ability to share data both internally and with external partners and collaborators will translate into increased efficiency and productivity. By reducing complexity and streamlining operations, skilled scientific and IT staff can focus more of their valuable time and attention on performing their duties and developing new applications, and less time dealing with incompatibility issues and other system-related problems.

Consolidating the CDS and updating to newer technology facilitates standardization, which offers many advantages for organizations large or small:

- Leverage existing instruments in which you have already invested.
- Consolidate control of third party systems.
- Streamline integration with laboratory (ELN) and business applications (LIMS).
- Coordinate efficient training of laboratory personnel.
- Centralize vendor support – consolidate installation, maintenance, services, and consultation; leverage expertise and experience of a reliable and reputable industry partner.
- Improve regulatory compliance and reduce risk.
- Acquire advanced administrative capabilities including mobile access/control, system monitoring data backup and system security safeguards, and disaster recovery.
- Future proof your operation with the ability to accommodate and integrate with emerging advances in separation and detection systems, instrument control software, and information technology solutions.
- Demonstrate a return on investment by relying on evidence-based analyses to guide decision-making and realizing gains in efficiency and productivity.

FACTORS TO CONSIDER WHEN SELECTING A NEW CDS

When selecting a new CDS, it is important to consider not only the qualities, features, and capabilities of the products on the market, but also their history of reliability, longevity, ease of maintenance, repairs, and servicing, and long-term value. What factors should you consider so you do not find yourself in a similar future - with an outdated CDS that some analysts may not be using properly and for which there is inadequate support and service options:

- The vendor's regional and global footprint--are they well-represented and well-respected in the market space worldwide?

- Will future laboratory staff have experience with the CDS, products and platforms of the vendor?, *i.e.*, is the vendor a leading brand?
- Is this a popular, broadly used system that analysts will want to master for the purpose of career development?
- How able is the vendor to support my lab, from installation and training to implementation, routine visits, maintenance, and repairs?
- Is the vendor well-positioned in the market space and prepared to provide updates as applications and regulations evolve?

How can you best leverage the expertise of an experienced vendor?

- Engage the vendor for a broader scope of other needs – such as hardware, consumables, education, or consultation.
- Envision the scope and dynamics of an expanded business relationship with a CDS vendor and anticipate how your organization could benefit from such a partnership?
- For designing and customizing a CDS to suit your needs – e.g., hardware requirements, integrate with complementary enterprise solutions, validation services, built-in redundancy, and maximizing efficiency.
- For implementing risk-based life cycle software validation.
- Define a model in which the vendor would work with the IT group on initial installation and in an ongoing advisory role, assisting for example in performing ongoing instrument validation and in maintaining GxP compliance of computerized systems according to GAMP[®] 5 industry guidance. The vendor can provide records of tests already performed on qualified systems.
- Collaborate with the vendor to streamline the process of standardizing your laboratory on a unified CDS system. The vendor can help anticipate and avoid potential missteps, coordinate with other equipment and service providers as needed, ensure a complete and well-documented audit trail for the harmonization process and establish a centralized data management system.
- Recognize the wealth of knowledge and experience that the vendor can bring to the research, development, ongoing support and updating of the CDS.

Several characteristics of the CDS and what the vendor can bring to the table are important to consider:

- How scalable is the CDS?
- How different is a networked version compared to the stand-alone version – for example, of Waters' Enterprise software CDS?
- Will you need specialized IT staff to assist in its administration?
- How can you best leverage Enterprise technology, including CITRIX[®], VMware[®], and Oracle[®] High-Availability options?
- Is the CDS adaptable for use with advanced and emerging technologies such as mass spectrometry, capillary electrophoresis, supercritical fluid chromatography, gel permeation chromatography/size exclusion chromatography, and dissolution analyses? Can it perform the required data collection, calculations, interpretation, and reporting?
- Will you want to add or expand the use of LIMS or ELN, and what are the ramifications of doing so when introducing a new CDS – how complicated will the interface be and how can the CDS vendor and your IT group work together to facilitate this process?
- How can a new CDS such as Waters' Empower[®] 3 Chromatography Software allow you to streamline workflows and harmonize analytical lab systems?
- What are the benefits of the CDS for System Administrators? For example, Empower 3 provides the following capabilities:
 - Multi-vendor instrument control.
 - Reduces the cost of ownership.
 - Rapid deployment -- remote push installation, virtualization, integration of older hardware/software platforms, rapid validation test development and execution.
 - Security and flexibility – redundancy (cluster environment serving same database); high level of fault tolerance in case of server failure; load balancing (distribution of workload among nodes to optimize performance); automatic capacity adjustment dependent on business/laboratory needs; infrastructure sharing between multiple databases in a single cluster.
 - Scalability – non-disruptive adaptability to growth from single workstation to large enterprise.
 - Disaster recovery – site mirroring (remote, synchronized standby database) protects against hardware failure without the need for idle redundancy.

- Interoperability with external software in a WAN environment – application programming interface (API); improves performance and usability.
- How can the CDS improve operational efficiency?
For example, Empower 3 provides:
 - Automated calculations – peak area and quantitative determinations are performed within the system rather than exporting the data for analysis; if more efficient, reduces chances for errors, and offers advantages for regulatory compliance; logic functions alert user to a failure (if data are out of specification).
 - Mobile control – gives IT control (especially if not on site) more timely access to key control functions, such as unlocking a system, resetting a password, or accessing information.
 - Asset utilization and risk analysis – at-a-glance dashboard feature can help drive evidence-based decisions. Predesigned dashboard selections include: system summary (error, warning, and informational messages triggered by an application, a user, or the system); system usage (number of injections and sample sets analyzed by system and by time period); project usage analysis (allows you to compare resource usage); methods analysis (risk-based compliance tool); user analysis (optional tool to identify training needs or aid in decisions on distribution of workload).

A laboratory can realize tremendous value by selecting a CDS most appropriate for its needs. Improved workflows, increased operational efficiency, and enhanced asset utilization are clear examples. As new products and applications emerge, planning for the future needs of your laboratory means making sure it has the technology in place to manage increasingly complex analytical tools, techniques, and computational methods.

CONCLUSION

One way to boost the productivity of a laboratory is to simplify operations. Centralizing and harmonizing control and data management functions on a single CDS platform will eliminate the need to manage, service, and train personnel on multiple systems. Ideally, consolidation of all separations equipment onto one new centrally managed CDS would enable data collection from existing hardware as well as access to legacy data and reports (via data import and conversion). The ability to unify and standardize laboratory operations and make full use of current and historical data will increase the return on investment of implementing a new CDS and provide business benefits such as:

- Enhanced efficiency.
- More accurate results and better collaboration.
- Ease of maintenance and servicing.
- The ability to rely on a trusted vendor's knowledge and support.
- Improving CDS related data collection, mining, and reporting, administrative operations, and regulatory compliance.
- Developing and releasing product faster.

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