

# Vendor-Assisted Validation and Deployment of a CDS Using the Life Cycle Approach

Image: Image 100

The complex processes involved in implementing a large multi-user computerized system pose a considerable challenge. Within a major CRO, serving many customers in a wide variety of both regulated and non-regulated industries, such a project can be an even more significant undertaking. This article describes the methods and procedures used in the successful implementation of a chromatography data system at Covance Laboratories.

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For more than ten years, Covance Laboratories Europe Harrogate (CLEH) used Thermo Electron's *Multichrom*, a legacy chromatography data system (CDS) based on the OpenVMS computing platform. This old technology, combined with the withdrawal of software support from Thermo and its increased use, made the system eligible for replacement. Validations of *Multichrom*, which were considered appropriate at the time, were now considered inadequate to meet the latest regulatory requirements and current internal standards — particularly those concerning compliance with US Food and Drug Administration (FDA) regulation 21 CFR Part 11 (electronic records and electronic signatures).

## User evaluations

During a period of several months, representatives from vendors demonstrated their CDS products, which Covance tested for a week to enable users to assess the systems in more detail. In evaluating which system would best meet user needs, the company's prime concerns were how the systems met the technical requirements of Part 11, and whether years of data could be migrated to the replacement CDS.

Following testing, Thermo's *Atlas* was selected, based not only on data migration and Part 11 requirements, but on its ability to integrate with the

existing infrastructure. This meant that there was minimum disruption to ongoing work and costs were minimized.

## Project planning and initiation

Four months were given to completely validate *Atlas*, whilst minimizing disruption to ongoing work. Because replacing a CDS in a multi-user laboratory is a major undertaking, implementation and validation require careful planning and project management. The project management team decided that assistance from Thermo would help complete the project within the time frame; ultimately Thermo assisted in project planning, training, and the installation and operational qualification (IQ/OQ) phases.

At the beginning of the project, members of the CLEH project team attended a validation workshop in which the vendor's regulatory affairs consultant presented the full requirements of computer system validation, providing CLEH with an overview of the steps required for an efficient and compliant validation. As a result, an implementation project quality plan (IPQP) was created, which documented the deliverables, project assumptions and dependencies, roles and responsibilities, and a detailed schedule.

Whereas an early decision was taken to use the validation expertise of the vendor, operating and

maintaining the validated system was the responsibility of CLEH. CLEH also needed to be capable of presenting and justifying the validation procedures to clients or regulatory authorities in the future.

Subsequently, CLEH conducted performance qualification (PQ) activities whilst the vendor focussed on IQ and OQ.

From the outset, the project was planned to meet aggressive deadlines and to deploy the new CDS with minimum disruption to current work by adopting a phased approach:

- Phase 1: to include IQ and OQ, validation of the major functionality and deployment of the software into the pharmaceutical analysis department.
- Phase 2: to validate any functionality not included from Phase 1 and deployment into the 5 additional departments on site.
- Phase 3: data migration from and formal retirement of the existing system to ensure continued readability of the electronic data.

### The project team

The project team comprised personnel from the information technology (IT) and quality assurance (QA) departments at CLEH, and laboratory system users. The Thermo members of the project team included a regulatory affairs consultant and a CDS validation specialist.

The vendor-provided automated IQ/OQ validation toolkit would be used, which could eliminate up to 15 weeks of manual labour. The Thermo project members generated (and later executed) the IQ/OQ plans and associated reports, which were reviewed by CLEH to ensure they met the requirements of internal policies and procedures for the validation of computerized systems.

The PQ execution was the responsibility of CLEH. As a result of a gap analysis, it was determined that CLEH would also write some additional tests to the OQ provided by the vendor. These were performed to verify that the CDS would meet its business requirements, including verification of the *Chromserver* (a network-based data acquisition device) capacity and recovery

**Table I** The key participants and responsibilities.

Personnel	Responsibility	Deliverables
Thermo Electron informatics services organization	<ul style="list-style-type: none"> <li>• Installation</li> <li>• IQ</li> <li>• OQ</li> <li>• Training</li> </ul>	<ul style="list-style-type: none"> <li>• IPQP</li> <li>• IQ</li> <li>• OQ</li> <li>• Training documentation and certificates</li> <li>• User manuals</li> <li>• Revalidation of Chromservers</li> </ul>
Information technology	<ul style="list-style-type: none"> <li>• Project co-ordination</li> <li>• Consultation</li> <li>• Production of validation documentation</li> </ul>	<ul style="list-style-type: none"> <li>• Project schedules</li> <li>• Validation plan</li> <li>• OQ plan</li> <li>• PQ plan</li> <li>• Summary report</li> <li>• SOPs for system maintenance</li> </ul>
Users	<ul style="list-style-type: none"> <li>• Acceptance testing</li> <li>• Instrument OQ</li> <li>• Test log execution</li> </ul>	<ul style="list-style-type: none"> <li>• URS</li> <li>• Additional OQ tests</li> <li>• Test logs</li> <li>• Release certificate</li> <li>• SOPs</li> </ul>
Quality assurance	<ul style="list-style-type: none"> <li>• Project review throughout the life cycle</li> <li>• Compliance consultation</li> </ul>	<ul style="list-style-type: none"> <li>• Audit reports</li> </ul>

function, and the CDS system capacity test. The vendor was also responsible for the physical implementation of the CDS.

All validation documentation was audited by the CLEH QA department. The review ensured compliance and consistency with company procedures and all documents were authorized in sequence before proceeding to the next stage of the project. Close co-ordination between the vendor and CLEH teams, and the careful delineation of responsibilities were crucial factors for the success of the project. The team responsibilities are summarized in Table I and Figure 1.

### Training

The joint project team placed great priority on a training programme that ensured users became competent in the use and management of the CDS. Training was scheduled and delivered for

- IT to administer the system
- members of the validation team to generate the required validation documentation
- laboratory users to execute the validation documentation

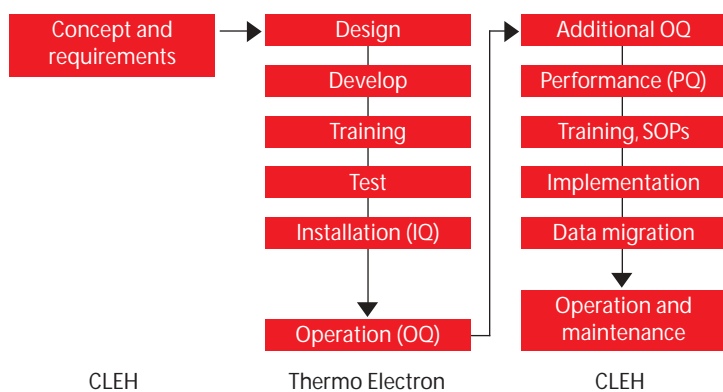
- 'super-users' to train all laboratory users prior to the CDS going live. Thermo facilitated the training for the five key CLEH members of the project team. These personnel were able to cascade the training to the super-users, who were then able to tailor training material specific to departmental needs.

### Phase 1 implementation

The decision to initially implement into the pharmaceutical analysis department was governed primarily by the availability of departmental resources. Validation documentation was produced for Phase 1 by Thermo (IQ/OQ) and CLEH (validation plan, additional OQ tests and PQ plan). The complete suite of documents comprised the following:

- implementation project quality plan (IPQP)
- user requirement specification (URS)
- validation plan
- installation qualification protocol
- OQ protocol
- IQ/OQ report
- PQ plan
- summary report
- release certificate.

Figure 1 Overview of Thermo Electron and CLEH responsibilities.



It was decided that a phased departmental approach required the preparation of a separate URS for each phase. The URS for Phase 1 was tailored for the major functionality of the system and to meet the requirements of the pharmaceutical analysis department. For Phases 2 and 3, the URS defined the requirements of the other departments, functions and requirements that were not included in Phase 1 and the requirements for data migration.

Each of the phases had separate PQ plans, test logs and summary reports. The PQ plans and associated test logs were prepared, developed and executed with the assistance of trained users. The tests performed for this phase of the validation comprised the following:

- security and access control
- data file integrity
- disaster recovery
- backup and restore
- archive and restore
- calibration — linear regression
- data reprocessing across the network
- audit trail
- export to Excel
- system suitability
- connection to LC instruments
- connection to capillary GC instruments
- connection to packed GC instruments
- connection to capillary electrophoresis instruments.

To complete the implementation of Atlas, the following supporting activities were completed:

- system user lists
- maintenance logs
- system history logs

- training for all users.
- The following standard operating procedures (SOPs) were prepared for Phase 1:
- installation of Atlas software
  - system user authorization and set-up
  - use of Atlas data collection system
  - security.

### Phases 2 and 3 implementation

Building on the successful approach of Phase 1, CLEH continued with Phase 2 of the project independent of the vendor. This phase was designed to complete the implementation into five remaining user departments on site that required the CDS. Functions from Phase 1 were postponed because of tight deadlines; they were excluded because they were not required by the pharmaceutical analysis department or were considered to be of low risk. The functionalities validated for this phase were

- data archive and restore
- weighted and unweighted regressions with internal and external standards
- export to Excel
- edit workbooks
- stop, start, suspend, abort workbooks
- instrument qualification
- operation of the pick-up node (automated back-up server).

Phase 3 of the project focussed on the migration of data and the retirement of the old system. This was also completed independently by CLEH. From the initiation of the replacement project, the ability to migrate data to the new CDS for

reviewing and processing was considered to be a fundamental requirement.

Historical data from the Multichrom system had been archived to two types of magnetic tape, and it was essential to show that this data could be successfully migrated into Atlas. A digital audio tape and a computer were used to copy and transfer the data. Following the validation of the data migration processes, the Multichrom was retired; this was documented in a summary report and a retirement outcome document.

### Summary

This article discusses the strategy involved in implementing a CDS into a large multi-user environment using the vendor to assist with the planning, validation and roll-out into the first major department. The project necessitated the implementation to be completed within aggressive timelines to minimize the disruption to the company's work flow and this was achieved by a three-phased life cycle approach. Careful planning and collaborative teamwork ensured that Phase 1 of the project was completed on time and the CDS was rolled-out into the pharmaceutical analysis department during a single weekend with no disruption to the work flow of the department.

Operation and maintenance were handed to CLEH 4 months after the project began, and the successful completion of Phase 1 with the assistance of the vendor ensured that CLEH could handle the subsequent phases unaided. The experiences of CLEH during this validation and implementation project illustrate the necessity of careful planning and the key role a vendor can play in achieving a successful outcome. ■

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Article Reprint Number: 0604