Webcast Q&A Responses – "Take Control of Your Laboratory Data"

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DEFINITION

QUESTION:

Is SDMS an Agilent trade-name, or a generic identifier, like "LIMS"?

ANSWER:

SDMS is a scientific and software industry acronym for "Scientific Data Management Software" or "Scientific Data Management Solution". The acronym refers to scientific document or scientific content management software systems.

Agilent OpenLAB ECM, a component of the Agilent OpenLAB software portfolio, is a SDMS solution. ECM stands for Enterprise Content Manager.

QUESTION:

Tell me about the **OpenLAB Enterprise Content Manager (ECM)**?

ANSWER:

OpenLAB ECM is Agilent's SDMS solution and is a cornerstone of the Agilent OpenLAB portfolio. By providing a secure central data repository and rich content services, this fully-integrated, single-vendor solution simplifies lab operation and helps you make more effective use of valuable scientific information resources. OpenLAB ECM manages all your raw data and human-readable documents—in any form, from any supplier.

- **Better Scientific Data Management.** Conquer your data mountain
- **Easily View & Share Data.** View data from many different sources. Readily share data with colleagues & co-workers
- **Simplify Data Searches.** Find all relevant data quickly and easily
- **Tap Your Company's Knowledge.** Feel confident, knowing that you have access to all the data generated in your lab or across your organization

QUESTION:

What makes OpenLAB ECM unique?

ANSWER:

There are four major areas that make the OpenLAB ECM solution unique:

(1) Managing Data

- OpenLAB ECM is a web-based electronic library that collects, organizes, indexes, stores, archives, and shares any electronic file – from analytical raw data and lab reports to compliance records, molecular drawings, Adobe Acrobat documents, Microsoft Office documents, web pages, pictures, video and audio.

(2) Searching for Data

- OpenLAB ECM allows you to easily search and review all of your data.
- OpenLAB ECM automatically extracts searchable metadata from files and provides powerful search capabilities.

(3) Sharing Data in your Lab

- Using filters, viewers and common data formats, OpenLAB ECM allows you to review and share your data

(4) Reporting

- OpenLAB ECM provides lab-wide, cross functional reporting through extensive tools, dashboards, and 3rd party interfaces

COMPATIBILITY

QUESTIONS:

Can OpenLAB ECM be implemented with:

- only Agilent chromatography instruments?
- Agilent Mass Spectroscopy instruments?
- a Varian Chromatography or Mass Spectroscopy instrument?
- a Thermo, or Waters or PerkinElmer instrument?
- instruments only; or can it be used with other equipment such as tensile testers, etc…?

What workstations can OpenLAB ECM be integrated with?

- any ChemStation system?
- an Agilent GC/MS or Varian system ?
- a Chromeleon or Empower system?
- a Thermo LC/MS system?
- Xcalibur software?

Does Agilent OpenLAB ECM communicate with JD Edwards software?

What is the compatibility of Lotus Notes to the OpenLAB ECM system?

ANSWER:

Agilent OpenLAB ECM offers extensive integration capabilities in the SDMS suite of products. OpenLAB ECM is compatible with external software at four possible levels of software integration:

1. Agilent OpenLAB ECM may be used to stored data created in any electronic file format created by any software package. A file stored in Agilent OpenLAB ECM may be re-opened or accessed using the file's native software. At this level, any electronic record can be stored in OpenLAB ECM.

2. When files are stored in Agilent OpenLAB ECM the files' content may be filtered to extract metadata which will be used for searches. Data filters for extracting metadata from stored files exist for many different file formats.

3. Viewers enable Agilent OpenLAB ECM users to view file content on client PCs without requiring the file's native software. File viewers are available for many Agilent, and non-Agilent chromatography and mass spectroscopy file formats.

4. Agilent OpenLAB ECM file management is fully integrated with Agilent Chemstation, Microsoft Word, Microsoft Excel, Microsoft Outlook, and Microsoft Windows Explorer. "File Save", "File Save As", and "File Open" functions within those programs may directly access Agilent OpenLAB ECM file storage via the integrated File Menu Bar. User login/logoff may also be accessed via the integrated File Menu Bar.

COMMUNICATION

QUESTIONS:

What type of interface is required to collect raw data from instruments?

How is manual test data handled, ie titrations, visual methods?

How are manually obtained data (ie. pH, conductivity) exported to the SDMS?

ANSWER:

OpenLAB ECM communicates with instrument PCs and client PCs via the intranet or internet. Electronic data files may be transferred to OpenLAB ECM from any source (i.e. instrument control PC, network drive) or retrieved from OpenLAB ECM to review on a client PC; provided the instrument control PC or client PC is accessible via the intranet or internet, and may be externally accessed (shared).

ADDING YOUR FILES TO AGILENT OPENLAB ECM

QUESTIONS:

Must the workstation be able to produce an Adobe pdf by itself, or are there other facilities to get the data into the ECM?

Is the data stored in its native format or is it converted to XML?

Who would convert documents to a pdf?

ANSWER:

SDMS systems differ with respect to how files or data are stored. Whereas some SDMS systems require all files be converted to .pdf format prior to storage; Agilent OpenLAB ECM stores electronic files in any format and does not require that files be converted to .pdf for storage. However, Agilent OpenLAB ECM does support storage of .pdf files. In addition to Adobe Acrobat, Adobe Acrobat .pdf format files may be created via "Print" functions of many software packages (i.e. Microsoft Office, etc.).

Files may be added to the Agilent OpenLAB ECM system using one of four methods:

1. Manual file upload
    - In a manual file upload, you use a familiar Windows®-like dialog box to select one or more files to upload. The file is stored in its original format.

2. Automatic file upload with a Scheduled Import Service (SIS) agent
    - The automatic file upload is a scheduled process that monitors computers, drives, or folders for files that meet user-defined upload criteria. The file may be stored in its original format, or, if the original format is a collection of files (and folders) the data file(s) and folder(s) may be compressed to retain the full package.

3. Automatic file upload through an integrated application
    - The automatic file upload is a scheduled process that monitors computers, drives, or folders for files that meet user-defined upload criteria. The file may be stored in its original format, or, if the original format is a collection of files (and folders) the data file(s) and folder(s) may be compressed to retain the full package.

4. Printing to an ECM print service
    - The ECM Print Services program is a print management system that can automatically upload files generated by third-party print drivers. The file is stored in Adobe Acrobat .pdf format.

Applications such as Agilent ChemStation, GCMS ChemStation, and Microsoft Office have an Agilent OpenLAB ECM integration option available that allows you to open, save, search, and retrieve files directly to and from the Agilent OpenLAB ECM system. Integration is through menu commands and toolbars that are added to the application's user interface. The file is stored in its original format, for easily opening them later, if needed.

QUESTION:

Is the system capable of test method validation data storage? Are there any templates to be created?

ANSWER:

SDMS systems, like OpenLAB ECM, can store ANY electronic data; be that test method validation or even bitmap files.

Extensive template tools that Agilent and 3rd party companies ship include:

- For Adobe-driven documents, Agilent provides a PDF Template editor
- For business process creation, Agilent packages and ships a Visio-based BPM Designer tool
- Across the entire Microsoft Office Suite; WORD, EXCEL, PowerPoint or PROJECT applications can be used as templates to design, build-out and store scientific data

VIEWING AND MANIPULATING YOUR FILES STORED ON AGILENT OPENLAB ECM

QUESTIONS:

Does ESC data review system allow the reviewer to see the extracted ion current profiles for GC/MS data?

PDFFor example, re-scale or overlay chromatograms at a later date? For example, to make a new or different report?

How is data reprocessed if it is saved as a PDF file? Is there a link to the native raw data format that then requires the native application?

If an error is found in the data-analysis, will the entire package need to be re-uploaded, or is the stored data editable?

So OpenLAB is a big database and cannot work with data?

ANSWER:

The power of a robust SDMS is that files can be stored in their original file format. In OpenLAB ECM files may be opened or manipulated on client PCs using the file's native software (i.e. ChemStation for ChemStation data files, MS Word for MS Word documents, etc.).

Files viewed via the file's native program may be accessed and manipulated to the full extent available within that native software package. In addition to using the native software, Agilent OpenLAB ECM users have the additional option to view files using Agilent OpenLAB ECM viewers. Viewers provide "view only" or "limited functional access" to users, allowing a lab to save money by not having to buy another license of a workstation application.

An extremely useful function that an SDMS solution provides is that when a file is viewed or accessed either with the native software or with an Agilent OpenLAB ECM viewer, the file is downloaded to the client PC. Then, if the file is revised; a new revised file is uploaded to Agilent OpenLAB ECM, keeping track of any changes to the file. In order to maintain revision control, files are "checked in/out" of the Agilent OpenLAB ECM system. Files may be checked in/out as either read only or with full read/write privileges.

QUESTION:

Does each user need a full copy of Adobe software?

ANSWER:

Files stored within Agilent OpenLAB ECM may be accessed with Adobe Acrobat Reader (available free from Adobe.com) for viewing purposes. A licensed copy of Adobe Acrobat Standard edition is ONLY required to create or modify .pdf files. Certain additional features within Agilent OpenLAB ECM require Adobe Acrobat Standard edition. These features include:

1. Scalable Vector Graphics Plug-in which allows users to copy a region or an entire page from a .pdf file and paste as Scalable Graphics or send a region or page directly to a MS Word document or MS Excel spreadsheet as Scalable Graphics.
2. Electronic Signature Plug-in for Acrobat which allows users to attach an electronic signature to a .pdf file.
3. Template Plug-in for Adobe Acrobat which allows users to define key fields and extract information for search purposes from .pdf files.
4. Adobe Acrobat Integration Services which installs an Adobe Acrobat plug-in allowing users to interact through the Acrobat application with .pdf files stored within Agilent OpenLAB ECM.

QUESTION:

Are the reports generated via Crystal Reports or is Crystal Reports needed at all?

ANSWER:

Reports are not generated via Crystal Reports; Crystal Reports software is not required. Additional Reporting software, such as Crystal Reports, is not required. A full reporting solution is provided by the OpenLAB ECM solution. Reporting package output, like Crystal Reports, can easily be stored; however.

EDITING AND/OR DELETING FILES & REVISION CONTROL

QUESTION:

How easy is it to "modify" or "correct" data that has been exported? And how do you document the approved change?

ANSWER:

SDMS systems provide very flexible and manageable file and revision control capabilities. Editing and/or delete permissions are defined and granted by the system administrator on the basis of users, groups, locations, and/or files. Permissions are fully customizable by the system administrator. A file may only be edited by a user to the extent allowed for that user, location, or file. File revision control is administered and assigned by the system administrator. File revision control and version recording may be implemented at the level desired by the system administrator. File edit/deletion is controlled and recorded via user name/password challenge. If the system administrator desires the user may be required to provide an explanation for any change and the explanation will be recorded along with the revision.

COMPLIANCE

QUESTIONS:

Is it cGMP allowable?

How do the FDA view the data storage system - does it require validation?

Is this software is compliance as per CFR 21 part 11?

ANSWER:

Agilent OpenLAB ECM contains all necessary features for a 21 CFR Part 11 content management solution. As installed the software is configured to be fully 21 CFR Part 11 complaint.ompliance configured. Agilent OpenLAB ECM users who do not require the full compliance features for a 21 CFR Part 11 environment may easily select (or deselect) any security feature.

Installed system validation is available from Agilent Technologies as an additional service.

OPENLAB ECM & LIMS

QUESTION:

What types of jobs that the LIMS can't do and need the ECM beside the storage? Thanks!

ANSWER:

OpenLAB ECM does a lot of raw data management that LIMS do not support. In most cases, the LIMS requires the final calculated values and is not equipped to store the original raw data. This can be a regulatory challenge and OpenLAB ECM is an effective tool to securely storing and managing raw data.

This centralized storage has additional benefits. OpenLAB ECM can extract selected data from incoming raw data files automatically from many different data systems, both Agilent systems and third party systems. OpenLAB ECM can serve as a single point of integration between multiple data systems with divergent formats and the LIMS at the same time as it is preserving the original raw data.

Finally, OpenLAB ECM can support raw data searches and reporting that would not be possible in the LIMS, simply because the LIMS does not extract ALL the available data from the raw data files, it only extracts the information necessary to the LIMS workflow.

QUESTION:

Why do you export to both LIMS and ECM?

ANSWER:

Dual export to LIMS and OpenLAB ECM is not necessary, but may be preferred based on the overall implementation. Because many LIMS systems are storing data from many different measurement devices, including directly interface devices such as balances, pH meters, and others, the preferred central integration point may not be OpenLAB ECM. However, the customer will likely still have a need to preserve and manage their raw data files from the more complex data systems.

In this scenario, they may export simplified generic results files (usually ASCII) from the various data systems and parse them into the LIMS in one step, while at the same time sending the complete raw data files to OpenLAB ECM to make sure they are preserved and secured appropriately.

QUESTION:

Can a LIMS like functionality be simulated with ECM?

ANSWER:

OpenLAB ECM is not designed to serve as a LIMS. Modern LIMS systems are highly complex and support detailed sample management, specification management, C of A generation, version control, auditing, training, in-process monitoring, etc. However, the workflows optimized for the LIMS typically rely on derived data, not raw data. Raw data storage is not a core competency for the LIMS, so OpenLAB ECM focuses on that.

QUESTION:

Isn't ECM a LIMS system? Why does he need 2 systems? What does one do that the other does not?

ANSWER:

A LIMS has a very complex workflow management capability, and includes detailed specification management capabilities. In most installations, one of the primary goals of a LIMS is to monitor and manage the comparison of results to target values or ranges. They also manage complex testing procedures with detailed decision trees, such as content uniformity and dissolution testing. Many contract labs will include invoicing capabilities within the LIMS. Specifications across multiple products, formulations, markets, grades are managed and compared. In process monitoring and workflows with conditional feedback loops are supported.

OpenLAB ECM is designed to focus on the data systems in the laboratory, while LIMS are designed to address a broader scope. The requirement to manage raw data files is not met by the LIMS, so OpenLAB ECM has been developed to meet that need, and provide additional benefit by allowing customers to extract desirable data from the raw data files and build advanced reports and workflows around the data therein.

AGILENT OPENLAB ECM IMPLEMENTATION

QUESTION:

How would you implement OpenLAB for a company with several sites scattered across the U.S.?

ANSWER:

SDMS systems, like Agilent OpenLAB ECM, ship with standard enterprise-level functionality, enabling multi-lab, site, and location deployments. This is accommodated from Log-in, through the database, and out through the deployment model that scales from small workgroup implementations in a single lab, out to multi-site Enterprise-level implementations.

QUESTION:

LIMS requires a lot of "tweaking" to get it usable. Does this program require just as significant changes to make it usable?

ANSWER:

Small implementations of an SDMS are quite simple to install, set up configure, and use. As a data storage configuration, the simplicity of the LCDF (Location, Cabinet, Drawer, Folder) is an extremely simple but powerful concept to understand and implement for a lab. Even within larger, enterprise implementations, although more complex to an IT group to roll-out, the same storage concept still applies.

QUESTION:

What if ECM crashes?

ANSWER:

SDMS systems, such as Agilent OpenLAB ECM, ship with standard enterprise-level functionality including redundancy and automated tools which accommodate periodic system crashes. Functionality such as scheduled, automatic file uploads provides a scheduled process that monitors computers, drives, or folders for files that meet user-defined upload criteria. Because these are scheduled and monitored, whenever a problem occurs logs are kept and uploads can be precisely seen where there was a problem, allowing a user or IT group to resume uploads/changes without disruption.

QUESTION:

I understand it will be very configuration dependent, but can you give me a round number for your budget for this installation?

ANSWER:

There are many different pricing, licensing and installation options for OpenLAB ECM and for our ChemStation offerings that accommodate the many different types of customer configuration needs including:

- Size and types of implementations
- Number of users accessing and using ECM
- Amount of data generated per user/workstation
- Number of instruments accessing ECM
- Number workstations accessing ECM
- Type of workstation accessing ECM
- Whether the installation is in a compliant environment

Agilent provides pricing configurations for small and medium laboratory needs with the OpenLAB ECM Workgroup and ChemStation offerings. These offerings accommodate as few as 1-2 workstations/users. The OpenLAB ECM offering could actually be configured to be on one server, called an All-in-One Server.

Further, for Fortune 500, enterprise-wide implementations of OpenLAB ECM; scaling to 1000's of users /ChemStation workstations are available.

Agilent can provide priced software and installation configurations that best meet your needs. The Agilent Life Sciences and Chemical Analysis sales team would be very happy to provide a quote to you for your specific needs.

QUESTION:

Sample receipt involves sample log-in and generation of testing requirement documentation. Does your data management system automate this process?

ANSWER:

A standalone SDMS system, like Agilent's OpenLAB ECM, can integrate sample log-in and the generation of testing documentation in a number of ways. First, by just enabling this to be stored into the SDMS repository in a standalone manner. Secondly, using a powerful workflow automation tool, like Agilent's OpenLAB BPM (Business Process Management), a lab's human and system workflows can be automated and work in a much more efficient and effective manner.

QUESTION:

Are newer generational chemists more adaptable to SDMS and new technologies vs. older generation chemists? It appears so in our organization.

ANSWER:

It is true that SDMS systems, like OpenLAB ECM, are new to the market over the last 10 years. Although existing workflows that have been used for decades might have to be changed, SDMS systems are meant to seamlessly work in the background of a chemists normal daily workstation use. This should allow any chemist, freshly coming out of school, to seasoned, experience veterans to easily adopt the use of this power tool.

ESC LAB SCIENCES

QUESTION:

How did ESC allow their clients to review the data directly? Did they have a dedicated line for their clients?

ANSWER:

The ESC website has a secure login into their LIMS database; where clients can access their project results directly, download their data, and build /review their reports.

QUESTION:

Does ESC use any other software different from ChemStations?

ANSWER:

ESC uses several systems such as Perkin Elmer WinLab, Dionex, Latchat, etc in their inorganics labs. In their organics lab, ESC exclusively uses Agilent ChemStations.

QUESTION:

What is ESC's current LIMS? How well is the LIMS integrated with the SDMS system?

ANSWER:

ESC designed and built their own custom LIMS. Because it is a custom solution, the integration with SDMS is an area that they would like to develop further.

Agilent has integration to packaged LIMS vendors, such as STARLIMS, LabVantage and Labtronics.

QUESTION:

How long did it take to turn the old data storage into the new one? Particularly, what did it take to get the paper versions into electronic format?

ANSWER:

The project took approximately three months to implement. It was mostly about the training and changing of ESC's work flow into printing pdf reports in place of hardcopies and storing them in the SDMS. The old warehouse data storage area was converted into productive laboratory space shortly thereafter.

QUESTION:

How much redundancy is built into the ESC system?

ANSWER:

On the backend of the system, ESC uses redundant two node active/passive failover clustered servers; both for the web server application and also one for the database server. The system is highly available and protected for hardware failure by redundant systems.

QUESTION:

For Tom, Were there e any difficulties fitting different test data into the four tiered system that ESC used?

ANSWER:

The four levels that the Agilent ECM system provided was completely sufficient for ESC's needs. Further, the upcoming version is allowing more levels to be defined.

QUESTION:

Does ESC also have a Document Management System?

ANSWER:

OpenLAB ECM is the document management system. It provides for long term retention based electronic document storage and handling.

QUESTION:

A question for Mr. White: How much time did you need to train people who had to use this system (analysts, supervisors, QA, etc.)?

ANSWER:

ESC held training sessions in small departmental groups and covered the basics within a one month period before going live. It was easily adopted and has a user friendly interface so retraining was minimal.