

OpenLAB Enterprise Content Manager An Overview

Specifications

The Enterprise Content Explosion

A recent study conducted by the School of Information Management at the University of California at Berkeley indicates the growth of data produced each year by organizations on a worldwide basis is on a near vertical growth trajectory (figure 1). This enterprise content explosion is generating 83 TB/year in electronic information that is stored on optical devices such as CDs and DVDs; 240 TB/year in paper, 427 PB/year on film, and an overwhelming 1,693 PB/year on magnetic media such as hard drives, servers, NT file shares and archival devices.

Over 75% of this information is "unstructured"; that is, it doesn't fit neatly into the rows and columns of a relational database where it can be cleanly organized and easily found. This unstructured information is in the form of documents, spreadsheets, forms, images, audio and video files. As such, a better way of structuring it is needed for organization, security, intelligence, and indexing to make this information easily searchable and re-usable for the knowledge workers in your organization.





Over 1,693 PB of information is being created per year on magnetic media, and 75 % of this information is "unstructured".



The Unfortunate Truth

Throughout the typical organization, there are many silos of this unstructured information, including financial data, customer information, standard operating procedures, corrective actions reports, project plans, product information, tax files, employee data, marketing collateral and even corporate emails (figure 2). What each of these content silos or applications has in common is that they all have some sort of repository associated with them (e.g. file system, PC hard drive, database, etc.) and each of these repositories is often deployed as a point solution to solve a specific business problem. What is needed is a centralized repository that can help organize this unstructured information, while ensuring that it is trusted, secure, and maintained with high integrity. This centralized repository needs to be globally accessible 24 x 7 x 365 through the Web, and scalable to meet the growing enterprise needs for availability and responsiveness.

ECM Connects the Disconnected Enterprise

OpenLAB Enterprise Content Manager (ECM) is a software platform that provides a secure, central repository and rich content services to create, capture, manage, archive, and re-use business-critical information scattered across the enterprise. These records can include any type of electronic record - images, documents, presentations, and spreadsheets, or scientific information, such as raw data, SOP's and reports (figure 3). Electronic records uploaded into the OpenLAB ECM repository are automatically indexed, allowing for searching



Figure 2

Disconnected sites of data in today's organizations.



Figure 3

OpenLAB ECM is an enterprise content management software platform that provides a secure, central repository and rich content services to create, capture, manage, archive, and re-use business critical information scattered across the enterprise.

and rapid retrieval of needed information. OpenLAB ECM ensures the integrity of your electronic content and provides a complete feature set for the entire lifecycle of your electronic content – from creation through destruction. Storing, organizing and protecting your company's critical electronic records are only part of the responsibility of a content management system. Making information accessible when, where and how you need it is what makes OpenLAB ECM a powerful tool for increasing your knowledge base. OpenLAB ECM was built from the ground up using industry standard technology. No major software applications are required on local computers. With just Microsoft's Internet Explorer, your employees can add, share or collaborate on anything instantaneously – from presentations and spreadsheets, raw data to reports – anytime, from anywhere in the world (figure 4).

OpenLAB ECM effortlessly fits into your existing network environment. With your choice of either Oracle or SQL Server databases, OpenLAB ECM can be scaled from a two-user system to enterprisewide, global implementation. The data you need is readily available with search tools ranging from a Web-style text entry search to a complex query generator, which allows you to build, save and edit increasingly complex queries.

As your electronic content ages and the need for immediate access diminishes, OpenLAB ECM can automatically migrate your electronic content from an on-line storage device to a secondary online, near-line, or off-line device. **OpenLAB ECM can support multi**ple storage devices on a wide variety of media - from secure network drives, Storage Area Network (SAN), Network Attached Storage (NAS), EMC's Centera device or any of the devices supported by Tivoli Storage Manager (including CD-ROM, DVD and magnetic tape). The modular nature of OpenLAB ECM allows a global implementation to have a central database with central storage, a central database with local storage, or local database with local storage -



OpenLAB ECM incorporates a browser-based Web client that allows customers, partners and employees to securely access corporate records on a global basis and 24 x 7 x 365.

with the ability to search all local data with a single query from any location. OpenLAB ECM record retention features provide the final stage in electronic content management; destruction based on corporate and regulatory regulations. File expiration policies are event-driven with configurable retention periods.

OpenLAB ECM Architecture

The modern, N-tier architecture of OpenLAB ECM offers users a variety of options for implementation. This modularity provides the flexibility to configure a system that best suits the way your company intends to use the system and the freedom to make adjustments to that configuration at any time as your company grows and needs change.

The entire system can be installed on single server, or modules such as the database, web server, application server, or file transfer server can be installed on separate machines. These functions – individually or together – can operate a single server, or be loadbalanced across a server farm.

Each OpenLAB ECM installation can be configured with multiple accounts. The accounts provide an administrator with an additional level at which both content and software functionality can be managed. All data, user management, file upload and archive schedules, storage devices and system services can be managed per account rather then across the entire installation. This separation provides the following benefits:

- A global implementation can share a central database, yet maintain file storage at various physical locations – all information is shared, yet WAN traffic is minimized.
- Separate installations can be maintained for complete separation of content management

needs. Users with appropriate privilege can search across all installations for data of interest.

- An implementation that makes OpenLAB ECM available to external customers – such as a core laboratory – can completely segregate data, creating a separate account for each customer, ensuring privacy.
- Different departments within a single organization may require dramatically different storage devices, archive schedules, user/group roles, and content access. Separate accounts and storage configuration allow specific configuration for each department's needs.

The Global Administration modules contain features and settings that apply to the entire OpenLAB ECM installation. The Account Administration modules contain features and settings that apply only to the current account. These administration functions, content, and metadata can be centralized or localized based on the specific needs of your organization.

Content Organizational Hierarchy

OpenLAB ECM's organizational hierarchy is immediately familiar to users. The Explorer style interface coupled with the concept of rooms or buildings (Locations) filled with file Cabinets that contain Drawers with Folders that contain files is easy to visualize in any work place. The Content node contains a list of all configured Locations that the user has permission to view. Each Location can contain an unlimited number of Cabinets, Cabinets contain Drawers and Drawers contain Folders. For each Folder, the files it contains are displayed. Although OpenLAB ECM Locations can reflect physical locations (figure 5), they can also represent a variety of other top levels of organization. For example:

- Data can be organized by Project (figure 6).
- Data can be organized by Department (figure 7).

OpenLAB ECM Locations, Cabinets, Drawers and Folders (LCDF) can represent any organi-

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Figure 5 LCDF example using Location.





Figure 6 Data organization by Project.

Figure 7 Data organization by Department.

zation hierarchy that suits a company's data storage needs.

Importing Content into OpenLAB ECM

Electronic records can be transferred into OpenLAB ECM from PC, Unix or Macintosh-based systems in one of the following ways:

- Uploaded with no user interaction with OpenLAB ECM Scheduled Import Services (SIS)
- Uploaded directly from a variety of common desktop applications (including Microsoft Office and Adobe Acrobat) with OpenLAB ECM Desktop
- Electronic files generated by a print operation can be transferred by the OpenLAB ECM Print Services
- Uploaded directly through integration with 3rd party programs
- Uploaded manually by the user through the OpenLAB ECM Web Client interface, and
- As part of an automated business process controlled by OpenLAB ECM Business Process Manager (BPM)

Before any file is transferred into the OpenLAB ECM repository, an MD5 hash checksum is calculated on the file in its source location. The checksum calculated for the file while in its source location is saved as part of the file's metadata. Anytime the file is accessed or moved, the file's integrity is checked against this value. When a file is uploaded to OpenLAB ECM, user defined keys are assigned and file information and metadata are extracted and stored in the database while the electronic file is transferred to a secure storage location. The file can be stored in several ways:

- A protected hard drive location
- A file server
- A SAN or NAS device
- Archived and kept on-line
- Archived and stored off-line

Regardless of the storage location, a user with appropriate privilege can view, retrieve, search, sign, and version-control any file. Even when archived and stored off-line, the file, they displayed in its OpenLAB ECM folder and is found in an appropriate search. If the user tries to view or retrieve an off-line archived file, they are asked if they'd like to send an email to the administrator requesting the off-line volume be re-mounted.

Disaster Preparedness

An advantage over archival storage devices such as EMC Clariion, NetApp NearStore, EMC Centera, and IBM Tivoli Storage Manager is that backup copies of the OpenLAB ECM repository can easily be created by snapshots, and disaster recovery copies can be created by asynchronous/asynchronous mirroring within a cluster, or replication to a remote site. These backup and recovery copies can be created for the OpenLAB ECM database and files to protect against disasters (e.g. fire, flood, earthquake, etc.) that can cause the loss of hardware and facilities.

Automated File Uploads

File transfer into OpenLAB ECM can be automated with the OpenLAB ECM Scheduled Import Services. Users can define a scheduled file upload task for any computer, drive, or folder location on the network. The criteria for file transfer can be based on the file name or extension, the file's source location, or the age of the file. When a scheduled file upload task is executed only new or altered files are uploaded.

OpenLAB ECM Scheduled Import Services are executed by two components; the Scheduled task within the Scheduler node of OpenLAB ECM and the Scheduler Agent, a service run on either a server or client machines with network access to the data to be transferred. The Scheduled task is used to set the criteria for file transfer. The Scheduler Agent monitors computers, drives, or folders for files that meet these criteria. One Scheduler Agent can push data from many computers, or an agent can be run on each client.

A specialized user interface has been developed for analytical applications such as OpenLAB ECM Scheduled Import Configuration Services for Bruker WinNMR, Agilent Cerity CDS and Agilent ChemStation Plus CDS that produce a directory structure or a series of files, which as a set make up the smallest functional unit of information for that application. This specialized user interface provides the upload options necessary for the data generated by those applications.

For standard file upload, users may specify a wide variety of upload criteria and options for all data types:

- The user may specify a file type to transfer based on file extension (*.doc) or a prefix in the file name, or *.* for all files.
- The user may specify a file type to transfer based on the name of the network folder in which it is stored.
- Files can be transferred from a single network folder, a series of folders, or series of folders and all subfolders.

- Files can optionally be associated to one another, for example all files contained within the same network folder, or files with similar names.
- Files can optionally be packaged together into a single functional unit, while each individual file remains functional within the unit.
- Files can be uploaded based on their age – immediately after file creation or after some user specified time period.
- Files can optionally be deleted from the client computer after they are successfully transferred to OpenLAB ECM. Users have the option to delete files from the source location immediately after transfer into OpenLAB ECM or after a user defined period of time has passed. The times for delayed deletion can be individually configured for each scheduled task.

The OpenLAB ECM Scheduled Import Services can transfer files based on a variety of time schedules incuding:

- on time only,
- on system startup,
- when the system is idle,
- immediately upon release from the native program,
- files older than a user specified time period,
- every day at a user specified time, or on
- selected days of the week at a user-specified time.

Integration with Desktop Applications

The successful implementation of a corporate-wide content management solution is dependant upon the end users utilizing the system. Providing users with an interface that is integrated with the desktop products they use on a daily basis



Figure 8 OpenLAB ECM desktop integration with MS Excel.

removes some of the intimidation and training issues. With menu items and tool bar buttons that are based on standard Windows functions, users can open and save files directly to OpenLAB ECM without having to learn another application.

Microsoft Office Applications

OpenLAB ECM Desktop adds a small tool bar and menu item to Microsoft Office Word, Excel and PowerPoint applications (figure 8). These tools allow users to search for, open and save files directly from the secure OpenLAB ECM repository. User's can compare two Word documents, or Excel spreadsheets to one another, whether different versions of the same file, or two different files. With these familiar tools, users can interact with OpenLAB ECM without leaving the familiar Microsoft Office applications.

Adobe Acrobat

OpenLAB ECM Desktop adds a small tool bar and menu to Adobe Acrobat products. These tools allow users to search for, open and save files directly from the secure OpenLAB ECM repository. User's can compare two PDF files to one another, whether different versions of the same file, or two different files. Users can send information from a PDF file, directly to an Microsoft Office application for the development of a compound document. This copied information can include a hyperlink back to the source data stored within OpenLAB ECM. When graphics are copied, they are copied as scalable vector graphics, preserving the resolution of graphics and text, as they are resized to fit any space. With these tools, users can interact with **OpenLAB ECM without leaving** the familiar Adobe application.

Windows Explorer

In the Send To function of Windows Explorer, the OpenLAB ECM Desktop adds OpenLAB ECM as a menu item. Users can select one or many files or folders, and send the files to the secure OpenLAB ECM repository. With this tool users can upload individual files, associate files together, package the files into a single containing unit, while maintaining the ability to search for and reuse the individual files. With this tool, users can interact with OpenLAB ECM directly from the Windows operating system.

OpenLAB ECM Print Services

The OpenLAB ECM Print Services are a print management system that manage the transfer of human- readable electronic documents to the OpenLAB ECM. An integral part of the OpenLAB ECM product, the OpenLAB ECM Print Services work with 3rd party print drivers from any operating system – Windows, Unix, Macintosh - and allow users to upload electronic records generated during a print operation from any application. The OpenLAB ECM Print Services can manage files generated by one or many printers, providing the user with a full suite of printing and file upload options (figure 9).

There are many commerciallyavailable programs for generating industry-standard Portable Document Format (PDF) or other file formats (such as TIF, JPG, BMP, PCL, and more) during a print operation. Additionally, most hardcopy print drivers have the option to generate an



Figure 9 OpenLAB ECM Print Services.

electronic file rather than a paper printout. The OpenLAB ECM Print Services can work with any print driver that generates any file type during a print operation from any application in Microsoft Windows, Mac or Unix operating systems.

Print drivers such as Adobe's Distiller have numerous options for generating electronic files such as, font embedding, color management, print quality and much more. With the OpenLAB ECM Print Services, the user has full access to all of the print options/ preferences available, regardless of the generating application.

To aid in compliance with federal regulations, the OpenLAB ECM Print Services can require the user to login prior to printing and confirmation of file transfer options. Options for transferring the file include:

- renaming the file,
- adding user definition metadata to the file,
- optionally printing to a hardcopy printer, and
- email notification to another user.

When printing a series of documents, such as reports from a sequence of analytical runs from a chromatography data system, the printer can be set to run in an unattended mode. This enables the OpenLAB ECM Print Services to print from a single printer with pre-set printing/uploading options with no additional user interaction. When a print job fails due to network failure, or inappropriate user privilege the data is not lost. The job is saved and the options can be reconfigured for successful transfer to OpenLAB ECM.

Manual File Upload

To manually upload a file into OpenLAB ECM, users simply select the Add File menu item from any file list view to open the File Selection dialog.

Figure 10 shows the standard Windows Select File dialog, allowing users to browse any computer, drive, folder where they have access and select one or many files for upload. The user is prompted to enter any user defined metadata to be associated with the file, to enter a reason for the addition of the file(s), and may optionally delete the files from their source location after successful file upload has been confirmed. The user defined metadata values and the "Reason for Upload" entry appears in the File Properties tab and in the audit trail and is searchable through OpenLAB ECM 's searching functions.

Upload by Business Process Manager (BPM)

Files can be imported into the **OpenLAB ECM repository as part** of an automated business process that is controlled by OpenLAB ECM Business Process Manager. For example, an automated process could query an external database and return a new record, which is imported in the OpenLAB ECM repository, indexed and linked to the appropriate business process. Alternatively, a business process task could ask a user to add a file from their desktop, and provide them with an appropriate dialog box for this. **Electronic Records in**



Figure 10 Manual file upload into OpenLAB ECM.

OpenLAB ECM

Files are stored and protected within OpenLAB ECM 's Location, Cabinet, Drawer, Folder hierarchy. When a Folder is selected, the files it contains are displayed in the Folder Contents list. The file list can be viewed in a number of ways; as small icons, large icons, a list, or with details. When details are selected, the user may define the metadata to be displayed in the sortable details columns.

The right mouse click with a drop down menu containing functions that a user can select for one or more files; check-in/check-out, electronically sign, view revision history, view file properties, move, retrieve or delete files or to associate files together.

Collaborating on Electronic Content

As a Web-based application, and with its various content management features, OpenLAB ECM is the perfect environment for users to collaborate on the development, review, approval, and publication of electronic content.

Check-In/Check-Out

When multiple users are involved in the development or review of content, the potential for lost input occurs. To prevent users from inadvertently overwriting each other's work, the check-in/ check-out feature can be used. When a user checks out a file, that file cannot be edited or signed by any other user. Once the check-out user completes their additions or revisions to the file's content, it can be checked back into the system. Once checked in, the file can be edited or signed by other users.

Copy with Traceability

When developing reports or presentations from content contained in a variety of documents, the Copy with Traceability feature can be used to provide a link back to the original source data. This can be a hyperlink, or text based link. This can be a tremendous benefit to reviewers or auditors.

OpenLAB ECM Scalable Vector Graphics (SVG) Plug-in for Adobe Acrobat

The Portable Document Format (PDF) is an industry-standard electronic file format. The availability of readers at no cost has made it the format of choice for publishing documents from hundreds of sources. The PDF file format contains a significant amount of information. It is NOT a screen capture or bitmap of a file print operation. PDF is an open file format that preserves the font. images, graphics and layout from any source document. When a PDF file is generated from a source application that includes scalable graphics, those graphics are preserved in the PDF file. When these images are copied from PDF files with the standard copy/paste tools the crispness of the lines and the integrity of the text are lost. The OpenLAB ECM Scalable Vector Graphics Plug-in for Adobe Acrobat allows users to copy images from PDF files as scalable vector graphics, preserving the sharp lines, and text. Reports generators can size and position the graphics as desired without losing content or resolution (figure 11).



Figure 11

The OpenLAB ECM SVG plug-in keeps graphics resizable.

Remediation Services for Microsoft Excel (RSME)

OpenLAB ECM can help users manage Microsoft Excel spreadsheets in a secure environment while allowing controlled access to users for periodic updates. Spreadsheets, like all electronic files stored in OpenLAB ECM, enjoy standard

features like complete version control, electronic signature, and automated metadata extraction – including the entire document content – for searching/reporting.

In addition to these standard software features, OpenLAB RSME provides a cell-by-cell audit trail that tracks the entire history of all worksheets within a spreadsheet. The OpenLAB RSME tools also provide a mechanism for users to protect worksheets, and unlock cell ranges for editing. When these activities are performed through the Excel application, a password is required. If that password is lost or forgotten, the file is useless. When protected through the OpenLAB RSME protection mechanism, the ability to protect and unprotect worksheets is controlled by user permissions – no passwords to remember – ensuring that the spreadsheet remains useful through its lifecycle.

OpenLAB RSME program limits a user's interaction with the spreadsheet's functionality and contents. The menus, tool bars, and hot keys present in the standard Excel application are removed, allowing user only the ability to edit unlocked cells within the sheet. This application allows user to open and save spreadsheets only to the secure OpenLAB ECM repository – no interaction with files stored locally is allowed.

Metadata Extraction

As files are uploaded into OpenLAB ECM, information about the file is stored in the database for searching. All files have metadata information stored, such as Creation Date, Modified Date, Upload User, etc. When something is known about the file type, a OpenLAB ECM Filter Pack can be written to peek inside the file and extract additional information.

On the General tab of the Folder properties is a list box with the available Filter Packs used to extract key pieces of information from stored files. A list of available keys for the key category selected and the current keys are shown. Figure 12 shows the configuration of the Filter Pack.

Re-Keying Files and Folders

OpenLAB ECM uses Filter Packs to extract key pieces of information from files for searching with either of the search tools. If, at some time after the Location, Cabinet, Drawer or Folder creation or any number of files have been added, a different set of key values becomes important, or if new or revised Filter Packs become available the key values can be reset and one or all of the stored files can be re-keyed.

Extracting Text from Documents

When PDF or Microsoft Office files are uploaded to OpenLAB ECM, the complete text content that those documents contain can be extracted and stored for searching or reporting.

OpenLAB ECM PDF Template Plug-in for Adobe Acrobat

Users also have the option to search a document for information of interest and save that information

Folder Properties х General Notification Access Archive Record Retention BPM Created by: ECM Administrator (BUILT-IN\admin) Where: \Manufacturing\plant 1\Laboratory 45_1-17 Name: chromatographic results Filters & keys Filters: ChemStore -User defined key defaults.. Keys: Selected keys: Compound ChemStation - Header - Method File ٠ ChemStation - Header - Operator Name ChemStation - Header - Sample Name ChemStation - Header - Start Run Time/Date i ⊞- Header ChemStation - Report - Acquisition Instrumer Instrument ChemStation - Report - Injection Number i≟-Method ChemStation - Report - Injection Volume i≟- Project ChemStation - Report - Sequence Line ≜-Result ChemStore - Compound - Amount i Bample ChemStore - Compound - Area ChemStore - Compound - Height i≜-Sequence ChemStore - Compound - RF ≜-User 4

Figure 12 OpenLAB ECM Attribute Extraction Services allow users to define the amount and type of metadata to associate with each file within the repository.

as a key-value pair for the file. When the full text is extracted from the document, a search for "A. O'Reilly" would find any file that contained the text "A. O'Reilly" anywhere within the document. With the PDF template plug-in option, the user search for the text "A. O'Reilly" becomes more focused and efficient. The PDF template plug-in searches within a specific region, on a certain page, or anywhere on the document. It can also find the text of interest based on its relative position to identifying text; for example, in a file contained the following:

Author Name: A. O'Reilly

The template can search a region, page or the entire document for the text "Author Name", and extract the text to the right as the key-value. In this way, when searching for a file the specific key-value pair can be searched:

Find all files where Author Name = A. O'Reilly returning a more focused result set. The key values extracted can be defined as date/time, number, alphanumeric, or graphic so that appropriate search operators can be used, like before or after for a date, "greater than" or "less than" for a number, or "contains" or "begins with" for alphanumeric.

User Defined Metadata

In addition to the key values that can be extracted from a file. users can define additional keys that can be associated with files. The keys might be a project name or number, a product code, or any other identifying piece of information that is important, but perhaps not contained within the file itself, so cannot be extracted. Users can specify the key as having a value that is alphanumeric, a number, or a date/time, and can specify an expected format. Data entry for these fields is either manual during data uplaod or automated from another file.

Email Notification

OpenLAB ECM can send email notification to specified users when specific file-related actions happen within the system. For example, a user can elect to receive an email whenever a file is added to folder A, whenever a file is signed in folder B, and whenever a file is deleted from folder C. The email contains a description of the activity and a link to the file of interest, so the user need only click to review (figure 13).

The OpenLAB ECM server supports SMTP and can send email notification as long as there is Internet access available. No specific email software is required on the Web server or the client.

User Access to Files

Access to the files stored within OpenLAB ECM is controlled through roles. Roles are userdefined groups of privileges that allow and prevent user access to files and software functionality. In the Access Properties tab users are assigned roles that allow them access to the Location, Cabinet, Drawer, Folder, Files and all of their associated functionality.

The Users/Groups list box contains the names of the users and groups assigned access to the folder and its files (figure 14). If a user is assigned roles both individually and through a group, the privileges allowed are the sum of those the roles contain. Users can also be assigned roles at the system level. When assigned a role in this manner, the user has the contained permissions throughout the entire Location, Cabinet, Drawer, Folder structure.



Figure 13 OpenLAB ECM can notify users by email of additions, deletions, or changes to content.



Figure 14



Viewing Files

From any of the file lists within OpenLAB ECM, if a user double clicks on a file, or selects Open from the file's right mouse-button click menu, the file is opened. If the program associated with the file extension can be opened within a browser window, it is opened. If it cannot be opened or has been specifically configured not to, OpenLAB ECM passes the file to that application. Any changes made to the file while opened in the native application are saved back to OpenLAB ECM as a revision of the original file.

OpenLAB ECM includes a viewer for chromatography data files collected with Agilent ChemStation, EZChrom Elite, Shimadzu Class VP, Beckman Coulter 32 Karat, and other systems (figure 15). This viewer allows users to manipulate the file display axis, graph colors, and annotations without having the entire application installed.

OpenLAB ECM also includes a viewer for mass spectroscopy data files collected with Agilent ChemStation, Thermo XCalibur, Waters MassLynx, Varian Star and other systems. This viewer allows users to manipulate the file display axis, graph colors, and annotations without having the entire application installed.

In addition to the viewers OpenLAB ECM contains, any browser-based file viewer can be installed (many are available on the Internet free of charge). In this way users can review a variety of file types without needing to manage and learn a variety of software applications. Many companies such as MDL, ACD, and Galactic



Figure 15

OpenLAB ECM Chromatography Viewer allows users to view a variety of data types without the generating software applications installed on their machines.

have file viewers posted on their websites that are distributed free of charge.

File Properties

The File Properties menu item opens a tabbed window that contains all of the information OpenLAB ECM is storing about the file. The Properties tab contains the following information:

- Name
- Version
- Size
- Creation Date
- Modified Date
- Upload Date
- Upload User
- Electronic Signature (number of signatures attached)
- Source Computer
- OS Owner
- Logged in User
- Source Computer Directory
- Checksum
- Reason User

(entered reason for upload) This information is stored for every file uploaded to OpenLAB ECM and is searchable through the OpenLAB ECM searching mechanisms. The other information contained on the File Properties tabs includes:

- **Description:** This tab contains a text entry field where users can enter comments about the file. The text entered in this field can be searched with any of the OpenLAB ECM search functions.
- Full Text Index: When a PDF or Microsoft Office file is uploaded into a OpenLAB ECM Folder, the user has the option to store the entire text of the document as a searchable key.
- eSig: This tab contains the electronic signature history for the file. These entries are searchable with any of the OpenLAB ECM search functions.
- Filter Keys: This tab displays the file's current extracted information keys. Each extracted key is displayed with its value. The Rekey button allows users with appropriate privilege to apply the current key selection to the file. Keys can be added or removed

from Files or Folders whenever the information needs change.

- User Defined Keys: This tab contains all of the user-defined keys assigned to the file. An unlimited number of user-defined keys can be assigned to a file. A single user-defined key can have none, one, or many values assigned to it.
- Audit Trail: This tab displays every entry in the audit trail that relates to this file.
- **Status:** This tab displays the current state of the file.
- Export Metadata: This button generates an XML file that contains all of the OpenLAB ECM generated metadata. This metadata includes the information on all of the File Properties tabs. This metadata file is archived along with the file.

Revision History

OpenLAB ECM keeps a complete revision history of each file stored. When Revision History is selected from the File menu in any file list each of the version of the file added to OpenLAB ECM is displayed (figure 16). Any version of the file can be opened, reviewed, and compared to any other version of the file.

File Associations

OpenLAB ECM can link files together in groups through file associations. Files can be associated with one another manually or through automated file uploads. When Show File Associations is selected from the file's right mouse-button menu, all of the file's association groups and files are displayed (figure 17). When a file with associations is retrieved, the user is alerted to the fact that there are other files that may be of interest.



Figure 16

The OpenLAB ECM Web client revision history file list.



Figure 17

OpenLAB ECM can link files either manually or automatically through uploads.

Retrieving Files

Users can retrieve copies of files stored inside OpenLAB ECM to their local computer. When retrieving files, the user has the option to recreate the file's original directory structure or retrieve all files to a specified location. When the selected file has files associated with it, the user has the option to retrieve just the selected file, or the selected file plus all associated files (figure 18)

Electronically Signing Files

OpenLAB ECM contains electronic signature tools that can attach a signature to any electronic file type. Files in the PDF file format are signed with a OpenLAB ECM e-Signature Plug-in for Adobe Acrobat. These signature tools were designed to help companies comply with the federal regulations governing electronic signatures (21 CFR Part 11). An example for OpenLAB ECM e-Signature is shown in figure 19.

Cerity e-Signature Plug-in for Adobe Acrobat

A user who is authorized to sign a document can select the Electronic Signature item in the file's right mouse-button menu. The user can review the file content and sign the document by selecting the Electronic Signature Tool in Adobe Acrobat.

The user is prompted with a dialog box to enter their User Name and Password, Location of the signing, and select a Reason for signing. The User Name and Password are compared to the OpenLAB ECM user list and privileges and, if the signature is accepted, a signature field is added to the document.



Figure 18

Retrieving files to a local machine through the OpenLAB ECM Web client is an easy, point-andclick operation.



Figure 19 OpenLAB ECM e-Signature Plug-in for Adobe Acrobat.

The signature is encrypted in the document to prevent attempts at falsification. The signature appears on all forms of the document – when viewed electronically or printed and includes the User's full name, the date and time of the signature with a Greenwich Mean Time offset, the user's job title, the Location where the signing took place, and the reason for signing the document.

Applying Electronic Signatures to Other File Formats

File formats other than PDF can also be signed within OpenLAB ECM. A user who is authorized to sign a document can select the Electronic Signature item in the file's right mouse-button menu when one or any files are selected. The user is prompted with a dialog box to enter their User Name and Password, Location of the signing, and selects a Reason for signing from the drop down list, or types in a reason (when that feature is enabled through Administration).

The User Name and Password are compared to the OpenLAB ECM User list and privileges and, if the signature is accepted, a signature field is added to the file's signature history tab. When a file is signed as part of a group rather than individually, it is reflected in the description of the signature in the audit trail.

The signature information on the signature history tab of the File Properties page includes the User's full name, the date and time of the signature, the user's job title, the location of the signing, and the reason for signing the document.

OpenLAB ECM Administration

OpenLAB ECM administration is accomplished through the combination of global settings and account-specific settings.

The settings that apply to the entire installation are included in the Global Administration node. The following software modules are included in the Account Administration node:

- **Email Configuration:** The mail server, authentication information, and system address are specified here.
- Account Creation: Within any OpenLAB ECM installation, one or many accounts may be created. All user management, file storage, archive options are specific to an account.
- License Manager: The management of available device and user licenses is shared throughout the installation.
- **System Errors:** Service errors can be monitored and cleared.
- Service Status: The activities of all services supporting the account can be managed here.

The settings specific to the account are contained in the Account Administration. The following software modules are included in the Account Administration node:

- Account Configuration Settings: Such as rules for user inactivity management, administrator email addresses, and search query time-outs.
- Adding and Managing Users: Such as define user information, change password, set rules for password entries, disable/enable users, and choosing groups to which each user belongs.

- Creating and Managing Groups: Such as define groups to which users can belong and adding users to groups.
- Adding and Managing Roles: Define role names, configure privilege sets for roles, and assigning users and groups roles at the system level.
- Adding and Disabling OpenLAB ECM Storage Locations:

Specify where OpenLAB ECM stores files that are added to the system.

- Setting Electronic Signature Options and Reasons: Enter user-defined reasons for performing electronic signatures and other options for electronic signatures.
- Managing Storage Locations: Monitor configured archive devices and mount archive media.
- **Keys**: Select Filter Packs to be applied to the account, define user defined keys and administer PDF
- templates.
- **Creating Synonyms:** Similar keys from Filter Packs, templates, general file information and user defined keys can be mapped to a single term to facilitate searching across file types.
- **Record Retention:** Document classes can be defined with retention policies, reviewer groups and disposition decisions for the various file types stored within the system.

Account Configuration Settings

The Configuration module in the Account Administration node contains options for a variety of OpenLAB ECM functions (figure 20).

These options include the following:

- User accounts for OpenLAB ECM managed users can be disabled after a user-defined number of bad login attempts.
- Users can be automatically logged out of OpenLAB ECM after some period of inactivity.
- A minimum password length can be set for OpenLAB ECM managed users.
- Email addresses can be entered on this page for the system and archive administrators. When an account is locked out due to too many failed login attempts, OpenLAB ECM sends an email notification to the system administrator. When a OpenLAB ECM user requests access to archived data that has been removed from the archive device an email request to re-mount the media is sent to the archive administrator.
- The services that are used to support this account for file transfer and file filtering can be configured here.
- Users can be required to enter a reason whenever requested for any activity throughout the account.

Adding and Managing Users and Groups

OpenLAB ECM can be accessed via a system managed user account or users can be validated against their domain login information. When using domain user validation, all user management is performed within the operating

Account Administration Configuration Security Network logon This user is responsible for obtaining the User and Group Lists from the domains. Lockout users after: unsuccessful login attempts Inactivity timeout: minutes Username: ssilengprocess Minimum password length: 0 Example: domain\username System email addresses Password: ****** System administrator email: paul.han@scisw.com Cluster configuration Archive administrator email: paul.han@scisw.com Application Service ... File upload options File Transfer Server .. Require entry in Reason fields. Transfer protocol: HTTP ΟK Cancel

Figure 20 General account administration features of OpenLAB ECM.

count Admir Isers Groups	Roles		
		Username:	Groups Edit 🚯
Full name:	BPMUser	🕵 a	
Title:	BPM User	& alc	
		any user	
Username:	opmuser	S arthy	
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User must	change password at next login	🕵 dferrante	
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		1.65 19	

Figure 21



system. There are no additional user management tasks.

Figure 21 shows how OpenLAB ECM managed user accounts are managed with the Users Tab of the Users/Group/Roles module in Account Administration. User account information includes the user's full name, job title, user name (login name), email address, password and description. The password is always displayed as asterisks and is stored encrypted in the database. Administrators can assign users temporary passwords when the account is initially established or in the event of a forgotten password, and require that the user change their password on their next login. Users can also be prevented from changing passwords, and their accounts can be disabled.

OpenLAB ECM access privileges can be assigned to individual users or groups of users. Roles can be assigned to OpenLAB ECM managed groups or a domain configured group (figure 22). When using domain group validation all group management is performed within the domain.

To display the group's membership, highlight the group name. When a user is added to a group they receive all of the roles and privileges of that group. When a user is a member of more than one group they receive the sum of all of the group's privileges.

Access with Domain Users

OpenLAB ECM access privileges can be assigned to individual users or groups of users through their domain accounts. When domain users and groups are used for OpenLAB ECM access, all management is done through the domain. Configuration options such as minimum password length and password expiration do not apply to domain users.

Creating Roles

Roles are groups of access privileges that may be assigned to users and/or groups. Users and

sers Groups Roles			
Roles:		Users Edi	
Approver XCell Administrator Archive Administrator Archive Agent Contributor Folder Administrator Retention Manager Scheduler Administrator Scheduler Administrator System Administrator System Administrator Saeed - SupObj Reader Saeed - SupObj Reader	n		
Description: Ability to electronically sign files for approval.			
		Res	et Roles
			1

Roles administration with OpenLAB ECM

groups who are assigned a role have all the privileges that are assigned to the role.

OpenLAB ECM is shipped with pre-configured roles that cover all user activities. These roles may be edited, deleted, used as is, or custom roles can be created. To create roles within OpenLAB ECM simply specify a role name, and select the privileges that the role includes.

Assigning Users Roles

Users can be assigned roles at either the folder or the system level. In general, when a role is assigned at the folder level, the user is granted the privileges that that role contains in that folder only, and when a role is assigned at the system level the user is granted the privileges that that role contains at the system level.

OpenLAB ECM Administrator Role

There is one permanent, non-editable role – OpenLAB ECM Adminis-trator. This role contains all privileges and access to all folders. When a new account is created, the initial user is given this role. The role OpenLAB ECM Administrator cannot be deleted and there must always be at least one user assigned to that role.

Content Storage

When files are uploaded into OpenLAB ECM, the file itself is not stored within the database. Instead, the file is stored in a secure storage location. There can be an unlimited number of storage locations of various types – SAN, NAS, EMC's Centera, any device supported by IBM's Tivoli Storage Manager. These locations are configured and managed within the Storage module in the Account Administration node. Figure 23 gives an example of possible content storage locations.

Electronic Signature

The electronic signature tab contains all of the options available for configuring electronic signature settings. Users can configure a list of reasons that are available for selection when electronically signing a document. Users can also be allowed to type in their own reason for signing if appropriate for your companies SOPs.

Electronic signature timers can be set for inactivity time-out of the signature dialog itself, and for continuous signatures. If the signature dialog is opened twice within the continuous signature time, the dialog opens with the last entries for User Name, Domain, Location, and reason for signature. The user is required to enter only their password.

Archive Storage Locations

OpenLAB ECM supports a wide variety of archive storage locations/de-vices including SAN and NAS devices, EMC Centera and any device supported by Tivoli Storage Manager including CD and DVD jukeboxes, tape, and magneto optical. Multiple devices are supported within a single account, in fact every OpenLAB ECM folder can be archived to a different device if desired.

When a file is archived in OpenLAB ECM, whether maintained on-line, near-line, or off-line that file can still be made available to users. When a user requests access to an off-line file the media containing that file can be mounted in any network location. Once mounted, users have full access to



Storage location features of OpenLAB ECM

vailabl	e filter packs		User defined keys				
		Edit	🔲 Show active keys o	nly		Edit	\times
Active	Name	A	Name	Туре	Format	Required	Actir 🔺
Yes	ACCESSCHROM		AlphaNum	Alphanumeric		No	Yes
Yes	ACD_HPLC		Author's favorite color	Alphanumeric		No	Yes
Yes	ACD_MassSpec		Branch	Alphanumeric		No	No
Yes	ACD_NMR		Branch Name	Alphanumeric		No	No
Yes	ACD_UVIR		Customer	Alphanumeric		No	No
No	Bitmap		Data Type	Alphanumeric		No	Yes 🚽
Yes	Bruker						
Yes	ChemStation						Ľ.
Yes	ChemStore		- Key templates				
Yes	EZChrom Elite						
Yes	Galaxie		Name		Туре	Active	\mathbf{X}
Yes	General		Peptide Report		PDF Templates	Yes	
Yes	Gif Files		Calibration Report		PDF Templates	Yes	
No	HTML		Purchase Order		PDF Templates	Yes	
Yes	JCAMP-DX IR		Loan Application		PDF Templates	Yes	
Yes	JCAMP-DX MS						
Yes	JCAMP-DX NMR	-					
4							

Figure 24

Metadata extraction options with OpenLAB ECM.

the data without a lengthy restore procedure.

Keys

This tab contains all of the

configuration settings for keys, both extractable, user-defined and template keys that are available throughout the OpenLAB ECM account (figure 24).

Metadata Extraction Modules

When the OpenLAB ECM system contains a Fileter Pack for a particular device type, the user can elect to programmatically extract a variety of metadata information directly from the file. Filter Packs can be added to the server at any time. New modules are continually being developed for OpenLAB ECM.

User Defined Metadata

When it is important to associate additional information with a file, and that information is not available to part of the metadata extracted by the Filter Packs, the user can define custom key-value pairs (figure 25).

The user-defined key feature also allows advanced definition of keys. Users can be presented with a custom user interface that presents users with pick lists of values based on their user ID or other file metadata, or guides them through a key-value selection process in which each choice affects the next key-value pair. External databases can be consulted for key value choices or value validation using advanced key definitions.

Templates

Templates are used to extract text from PDF files in specific key-value pairs for more focused searching and reporting. Text, graphics and tables of information can be extracted and stored with the file (figure 26).

The key values can be located within a user-specified region on the file, a particular page, or anywhere within the document. The values may also be found based on their relative position to search

User Defined Keys

Figure 25 User-defined metadata association.



Figure 26



text; for example, the value for a key named creator could be to the right of text reading "User Name:"

Synonyms

Different file types sometimes use different terms to identify the same information

For example; the Microsoft Office Filter Pack extracts a key called Author; the ChemStation Filter Pack extracts a key called Operator Name; the EZChrom Elite Filter Pack extracts a key called Analyst. Each of these keys extracts a very similar value from the file. To simplify writing queries across file types and across similar key values, these keys can be mapped to a single searchable term categorized as Synonyms in **OpenLAB ECM. Figure 27 shows** some synonym examples. Aliases can also be made for the synonym terms, allowing searches to be created in local languages.

User Preferences

In the User Preferences module users can change their password and define the metadata that is displayed in the details columns of the file lists.

Searching for Data

OpenLAB ECM has a Web-style key word search function and advanced query generator. These tools search through the file information stored within the database.

Quick Search

The Quick Search shown in figure 28, located in the OpenLAB ECM banner and on the front tab of the Search user interface, is a familiar Web-style search. Every file stored in OpenLAB ECM has metadata information stored in the database for searching.



Figure 27 Meta data mapping with synonyms in OpenLAB ECM.

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E Analytical results		104 10 59 51.pdf	\Phamacokinetic\Analytical results\HPLC\r	1	2/11/2005 5:18:37 AM	66
B-10 HPLC		104 10 59 54.pdf	\Phamacokinetic\Analytical results\HPLC\r	1	2/11/2005 5:18:37 AM	. 59
in results		104 10 59 57.pdf	\Phamacokinetic\Analytical results\HPLC\r	1	2/11/2005 5:18:37 AM	. 58
E IS MS		104 10 59 59 pdf	VPhamacokinetic\Analytical results\HPLC\r	1	2/11/2005 5:18:37 AM	. 59
Aglent 1100		104 11 00 01 pdf	\Phamacokinetic\Analytical results\HPLC\r	1	2/11/2005 5:18:37 AM	59
- D SU studies		104 11 00 04 pdf	\Phamacokinetic\Analytical results\HPLC\r	1	2/11/2005 5:18:37 AM	58
metabolite data		104 11 00 06 pdf	\Phamacokinetic\Analytical results\HPLC\r	1	2/11/2005 5:18:37 AM	59
Tip I in the second sec		104 11 00 09 pdf	\Phamacokinetic\Analytical results\HPLC\r	1	2/11/2005 5-18-38 AM	59
Calculations		04 11 00 12 off	\Phamacokinetic\Analutical results\HPLC\r	1	2/11/2005 5:18:38 AM	59
E Caculations		104 11 00 14 off	\Phamacokinetic\Analutical results\HPLC\r	1	2/11/2005 5:18:38 AM	50
D summary report-199711	108-	04 11 00 17 off	\Phamacokinetic\Analytical results\HPLC\r	1	2/11/2005 5:18:38 AM	59
Th summary report-199711	09-	04 11 00 19 odf	Phamacokinetic/Analytical results/HPLC/r	1	2/11/2005 5:18:38 AM	59
Ch summary report-19971	108-	04 11 00 21.edf	VPhamacokinetic/Analytical results/HPLC/r	1	2/11/2005 5:18:39 AM	59
- C presentation		0411 00 24 of	\Phamacokinetic\Analytical results\HPLC\r	1	2/11/2005 5 18 39 AM	- 55
training material		104 11 00 27 of	\Phamacokinetic\Analytical results\HPLC\r	1	2/11/2005 5:18:36 AM	- 50
laboratory 45_2-20		104 11 00 30 cell	VPharmanokinatio\Analytical results/SEPLC's	1	2/11/2005 5-19-29 AM	
E-G quality		104 11 00 32 eff	Pharmacokinatic\Analytical results\HPI C's	1	2/11/2005 5-19-29 AM	50
master SOPs		104 11 00 35 edt	Pharmacokinatic\Analytical results\HPLC's	1	2/11/2005 5-19-29 AM	50
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- 🥘 validation		04 11 00 39 est	Phamacelinatic Unablination and WIPI Ph	1	2/11/2005 5:10:40 AM	
📩 Inbox		04 11_00_33.pd	 Pharmaeekinetic Analytical resolution Cu 	1	2/11/2005 5:10:40 AM	
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- S Dearch 4 Hesuits (Complete)		CCM 3 Cyberninter XP Tran	whanuraciumg/plant 1% aboratory 45_1-17%.		2/11/2005 5:47:52 AM	. 53
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Figure 28

Search results page of a quick search.

When users have entered in their search parameters they click on Search, and a list of matching files is displayed. Users can perform Boolean searches with "AND" and "OR" operators, and use parentheses and quotation marks.

Smart Search

With the Smart Search (figure 30), users can write more focused queries using any general file metadata keys or synonyms. Search statements are created with drop down list boxes, guiding users through the query generation process. Query statements are joined together with AND and OR operators.

Advanced Search

The Advanced Search tool of OpenLAB ECM is a query builder. Complex queries can be created, saved, and edited (figure 30). The advanced query searches through all file information and extracted keys based on attributes and their values.

Statements are joined with AND and OR operators and can be grouped with parenthesis to enforce precedence. The Advanced Search also allows users to search for key sets within a single file. For example; a file may have two signatures applied; User A signed on Jan 1, and User B signed on Feb 1. A query like that below:

File information.Signature Information.Signing User = User A

AND

File information.Signature Information.Signing User = Feb 1

would find the above file. The SET statement in Advanced Search allows the user to search within the specific key set:

SET (File information.Signature Information.Signing User = User A

AND

File information.Signature Information.Signing User = Feb 1)

This query would not find the file above because the signature applied by User A is part of the key set that include a signature date of Jan 1. A second key set,

Key	Operator	Value	Condition
Sample ID	contains	"CytoC"	AND
Data Type	=	"HPLC"	OR
Data Type	=	"Supporting Documentation"	
			Clear

Smart Search guided query generator.



Figure 30

Advanced Search query generator.

within the same file includes the signature by user B on Feb 1.

As the user builds a query, instructions are developed though the fields listed above. These are added to the query display. To run the query, click the Submit button.

Searching Multiple Accounts and/or Databases

The Options tab of the OpenLAB ECM search tool allows users to specify other accounts, even accounts on other web servers to be searched with a single query.

Activity Log

All activities that occur within OpenLAB ECM are recorded in an Activity Log. This computer-generated, time-stamped log is divided into two modules: The Audit Trail, which records all file related and system security related entries and the System Log, which contains entries related to system maintenance.

Each entry in the Activity Log contains the date and time that the activity took place, the full name and user name of the user who performed the activity, a description, and a user-entered or systemgenerated reason for the activity, as shown in figure 31.

The date/time entries are stored in GMT and displayed to the user converted to their local time-zone settings to ensure an absolute time line.

These logs can be searched, printed and exported.

Archiving Data

Files stored within OpenLAB ECM can be archived to removable media or to permanent storage media to free space on the OpenLAB ECM storage locations and/or to store the data in a more protected location. Archive configuration is displayed in figure 32. When a file is archived it is still available to the user and can be found with the various OpenLAB ECM searching mechanisms.

OpenLAB ECM supports a wide variety of archive storage locations/devices including SAN and NAS devices, EMC Centera and any device supported by Tivoli Storage Manager including CD and



Figure 31



eneral Notification	on Access Archive Record Retention	
🕤 On demand	0 Months 0 Days 1 Hours	Archive Now
C Immediate	Start time: 2:00:00 AM 🔹	
C Daily	🗆 Sun 🔽 Mon 🥅 Tue 🔽 Wed	
Weekly	🗖 Thu 🔽 🖬 🗖 Sat	
Archive device		
EMC Centera	•	
Device: EMC C Computer:	Centera	



Folder archive configuration.

DVD jukeboxes, tape, and magneto optical. Multiple devices are supported within a single account, in fact every OpenLAB ECM folder can archive to a different device if desired.

Archive Schedule

Files stored within OpenLAB ECM are archived based on settings made at the folder level. Each folder can be archived based on a different schedule and to a different storage location.

Users can archive a folder's contents by clicking the "Archive Now" button or configure the folder to archive its files automatically with an archive schedule. A scheduled archive can be based on four different timed settings: Immediate (immediately upon transfer into OpenLAB ECM), Daily (each day at the time specified), Weekly (selected days of the week at the time specified), Files Older Than (files last modified prior to the specified number of days and hours).

Accessing an Archived File

Users access an archived file, just as they access any file stored within OpenLAB ECM, by selecting the file link. The file of interest can be opened and viewed. If the user tries to access an archived file which is located on a disk/ CD/DVD/tape that has been removed, there are two possible scenarios:

• If no email address is entered for the archive administrator a message that reads, "The storage location for the file you are trying to access has been removed. Please place Volume <<volume name of the media on which the file was archived>> into Archive Device <<device name>>." is displayed.

Record Retention Configuration	×
Retention Schedule Reviewer Groups Review	Arbitration
Classes S Classes	Description: This retention policy should be applied to any personnel related data
	Expiration Expire on: 10/12/2004 Expire: 15 Years 0 Months 0 Days After: File archived date Event description:
Available for assignment 🔲 Account default	Event Occurred
Audit Trail Purge audit trail with files Add audit trail for purge One entry for entire purge One entry per file	Disposition Purge Reassign class: New class: Vew class: Vew class: Vew class: Vew class: Vew class: Ve
	Apply Close

Figure 33

Records retention configuration features of OpenLAB ECM.

 If there is an email address then a message that reads. "The storage volume for the file you are trying to access has been removed. Would you like to send an email request to the archive administrator to replace this volume?" is displayed. The choices are Yes, No and Cancel. On Yes, an email notification is sent to the email address entered for the Archive Administrator. Once mounted, the User making the request can be notified through email that the requested media has been mounted.

Records Retention

The final step in a file's life cycle is destruction based on record retention policies defined by both regulatory requirements and corporate policies. The OpenLAB ECM record retention module

allows users to define document classes. Each class has a retention period that is either date or event driven, as shown in figure 33. On expiration, the files are routed through a review process and a disposition decision is made. When the disposition decision is purge, the files and all of their metadata are permanently removed from the system. The rentention configuration allows to decide how to proceed with the audit-trail of purged files. By default the audittrail is kept in the system, but optionally the audit-trail can also be purged.

In addition, users can decide to generate audit-trail entries for the purge process to the system, either one entry for the entire purge or one entry for each file. These entries are system-generated.

Summary and Benefits

OpenLAB ECM was designed to help organizations across a number of industries improve regulatory compliance, reduce operational costs, boost productivity levels, and increase customer satisfaction. The system's ability to capture, manage, collaborate, archive and re-use any type of electronic records provides a trusted repository of corporate knowledge assets. By creating a central repository that is available through the web 24 x 7 x 365, critical business decisions can be made faster by streamlining access to information. Instant access to critical knowledge assets also means these decisions are made more accurately.

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