

# XYBION'S RESPONSE TO AUDIT DOCUMENTATION AND MANAGEMENT SOFTWARE SOLUTION RFI

## The Office of the Washington State Auditor

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### Washington, United States

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# 1. Corporate Overview

Xybion Corporation, an NMSDC Minority-owned Small Business Enterprise (MBE), is a leading software solution and consulting company, dedicated to helping corporations in regulated arena solve business problems and create new capabilities. Xybion headquartered in Princeton, NJ has been in operation for more than 40 years; supported more than 150 customers in 16 countries, and successfully implemented, supported and maintained software solutions at several large organizations including City of Boston, Maine Health, US Food & Drug Administration, US Army Medical Research Institute of Infectious Diseases, Bayer Crop Sciences, Pfizer and Novartis etc. Xybion offers global delivery of solutions through our on-shore, off-shore and near shore delivery centers and local footprint in key geographies with 185+ employees across locations. Our current data centers are in the US and Singapore and we are working on establishing new ones in Europe. Our implementation approach is based on configuring our COTS software modules to satisfy each customer's own requirements – **Your Process-Your Way**. Our solutions include:

**Xybion's Digital Acceleration Platform (XDP)**- a low-code, rapidly configurable cloud platform, that allows customers to configure the business process domain to suit its requirements, including the data stored, screen layouts, report layouts, customized documentation, filters and workload presentation.

**Enterprise Content Management ECM XD**- A single, secure cloud platform architected to integrate end-to-end enterprise processes and manages the entire digital ecosystem for the organization by allowing the capture of various types of structured and unstructured content, documents and images. ECM XD™ helps create a true Digital Workspace for all stakeholders to holistically manage the organization's internal and external digital information mesh to deliver fast ROI.

**Total Quality & Compliance Risk Management**- A total compliance end to end solution comprising descriptive, diagnostic, prescriptive and predictive risk and compliance solution including Quality Management, document/content management, credentialing and data integrity solutions.

**Workplace Health, Safety, Care, Case and Claims Management- Emidence™**: A unique, digital workplace on cloud and mobile platforms where all stakeholders, in Workplace Health, Safety, injury management, medical care and Return to Work processes, utilize security based permissions to seamlessly create, share and move core data on the injured persons and claims while complying with guidelines and regulations.

**Digital Lab Execution System- Labwise- XD** – A modular, integrated, and all-inclusive end-to-end BPM platform to support all workflows in the labs – Test Methods, LIMS, ELNs, QMS, ECN and Customer Portal. Xybion has been named as one of the top 10 Laboratory Information Management System (LIMS) Solution providers in 2019, by pharma Tech Outlook in their annual publication.

**Preclinical R&D Execution System Pristima XD** –Pristima XD is our gold standard solution for end to end pre-clinical research, SEND and submission. This unique solution delivers key features that effectively bridge the gap between the business, animal management and scientific aspects of research, absent in many of today's preclinical software solutions.

Xybion today is the result of a successful initial execution of a strategic vision of creating a global software driven solutions company with specialized software and services. Its core platform is architected to build multiple interconnected application from the same core database and sharing all data and information thereby assuring quality, compliance and data integrity.



## 2. Proposed Solution- ECM-XD

### Our Understanding

Xybion understands that The Office of the Washington State Auditor (SAO) is seeking a vendor to replace their existing audit documentation and management software solution. The proposed solution must securely support work processes and central data collection for multiple concurrent users. Xybion further understands that, the proposed solution must satisfy the following objectives:

- Should be expandable with little impact to the users.
- Fully compatible and integrated with MS Windows and all MS Office Products and should have the ability to achieve the following functions: Electronic Workpaper Management, User Authentication, Edit / Sign-off / Review tracking, Edit History, Data Collection / Analysis / Reporting
- Supports both online (connected) and offline (no internet) environments.

### Proposed Solution- ECM XD

Based on SAO requirements specified in the RFI, Xybion would like to propose its ECM-XD solution, built on Xybion's Digital Platform (XDP). Xybion's ECM-XD provides a single cloud platform architected to integrate end-to-end enterprise processes and content for highly regulated industries. In addition, the process rules, security, faceted search capability, powerful query builder and report capabilities allow data to be retrieved at the right time by the appropriate people, which can include partners, external service providers and other stakeholders via secured solution and mobile platforms.

Some key distinctive features include:

- A single document repository with unlimited digital storage capabilities.
- Allows creation, storage and retrieval of information in multiple formats. The document management system provides powerful versioning, rendering, approval, search and expiring capabilities.
- The system is **robust and flexible**, creating several business benefits, will evolve according to the change in process, **scalable to have more (internal and external) users**, ensuring compliance and capacity to **integrate with other systems** as identified by SAO.
- The system is compatible with MS Windows and all MS Office products.
- Allows annotation of documents which can then be save and shared with other users in a secured manner.
- Powerful, customized Dashboards: Purpose-built, configurable information views based on role, Task management, Recent Activities, Roll-up information, favorites, Each widget securable, Charts, graphs, trendlines, Drill-down diagrams, Location-based data,
- Templates and Forms: XDP's Document Management System (DMS) allows documents templates to be created and used as needed to be filed into a user-configurable hierarchical "folder" taxonomy. This taxonomy supports setting document permissions at a higher level if desired.
- Allows annotation of documents which can then be save and shared with other users in a secured manner.
- Check-in/check-out, versioning, rendering, approval, search and expiring document tracking capabilities with full text search and retrieval: Provides controlled, secure access and flexible revision capabilities. Workflow allows documents to be routed for review, approval and distribution. Ability to capture, record, edit, track and update classification and retention of information on all documents.
- Linking of workflows and documents: Documents and other workflows are organized by "Your Process-Your Way" – such as by departments, location, document type, claims number, job types,

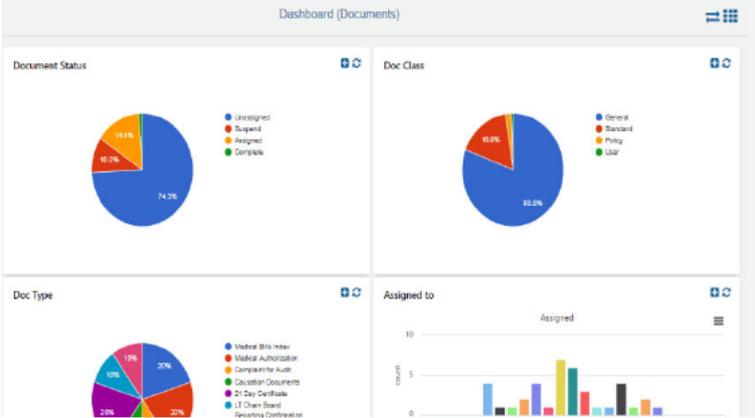
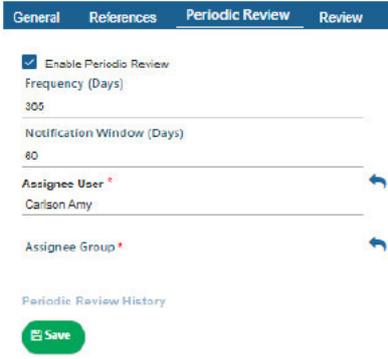
etc. Documents can be routed through all applicable reviewers and approved in a controlled manner.

- This system can receive documents in multiple formats – paper, e-fax, SFTP and e-mail attachments. The system can drop the documents into a Drive like Google Drive or Dropbox where these documents are digitized through an automated OCR process and transitioned to our document storage system. This process works for both small and high-volume digitization needs.
- Automated workflows ensure that documents are routed through all applicable reviewers and authorized in a controlled manner that complies with regulated document management requirements, including the collection of electronic signatures for specified workflow actions.
- It offers a sophisticated linking function which enables relationships to be created between all the objects as necessary.
- Supports automated versioning and obsoleting of documents when a new version becomes effective. Workflow allows documents to be routed for review, approval and distribution. Ability to capture, record, update, track, update classification and retention of information on all documents
- The user can easily see the records as well as the workflows and the status of individual tasks all on a searchable monitoring panel.
- The system allows users to attach the associated documents and record for the defined task fields and workflows.
- Records (Task and Workflows) can be assigned to a user or user group
- Audit Trail and visualizing status: Comprehensive audit trails support compliance. Visual status indicators alert users to the status of a document at a glance.

**Sample of functional capabilities available “Out-Of-The -Box”:**

<b>Dashboard</b>	<ul style="list-style-type: none"> <li>• Customized user view, configurable information views based on role, Task management, Roll-up information, Recent Activities</li> </ul>
<b>Document Upload and Indexing</b>	<ul style="list-style-type: none"> <li>• Contact, Organization, People, Vendor</li> <li>• Secure FTP based document upload</li> <li>• Document Indexing workflow</li> <li>• Document Annotation</li> <li>• Task based Workflow</li> </ul>
<b>Document Management</b>	<ul style="list-style-type: none"> <li>• Electronic Content Management for version control, security, centralized search and history</li> <li>• Multiple views (structures) of the files in the ECM structure. Metadata to tag and perform auto-filing.</li> </ul>
<b>Searches</b>	<ul style="list-style-type: none"> <li>• Query builder, Simple and Advanced Searches</li> </ul>
<b>Effortless-Integration-Framework</b>	<ul style="list-style-type: none"> <li>• Active Directory Integration, E-mail integration. Both push and pull allowed the targeted master system to retain control over its data</li> </ul>
<b>Audit Trail &amp; Administrative Controls</b>	<ul style="list-style-type: none"> <li>• Full audit trail with searches and field level tool-tip audit trails.</li> </ul>

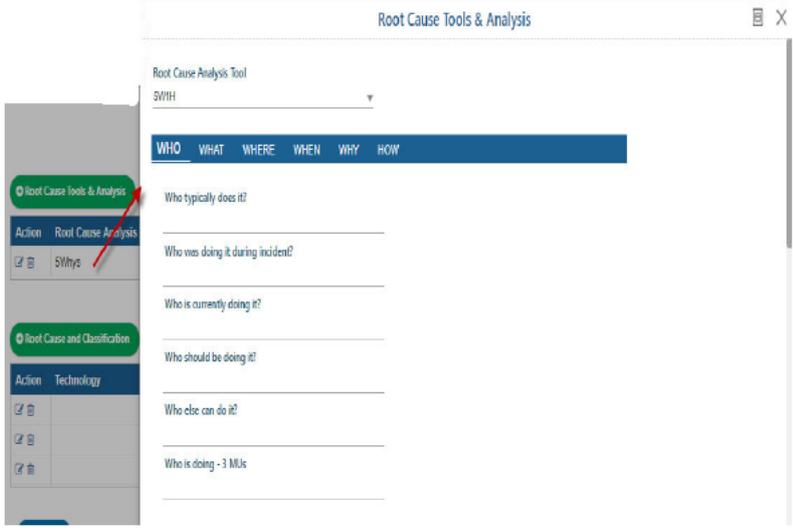
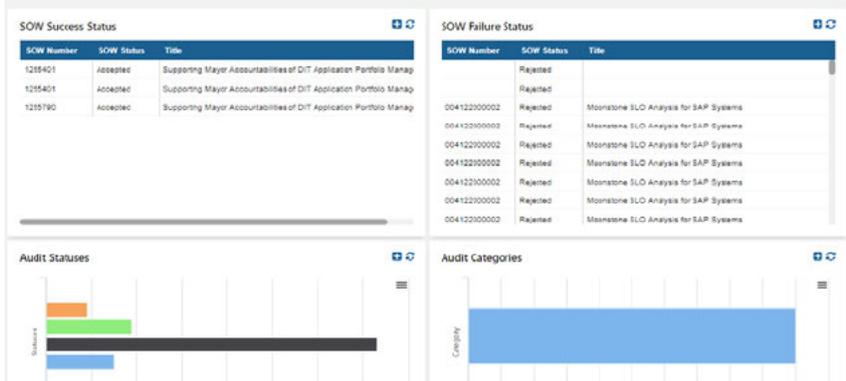
Xybion recommends implementing the following modules for SAO, based on the RFI requirements.

Module/Component	Description
 <b>Document Management System</b>	
<b>Document Management</b>  <b>General</b>	<p>The ECM-XD is a secure web-based system that offers out-of-the box compliance without customization. The ECM-XD provides full versioning, a flexible folder/file structure; workflow-based collaborative document review, approvals and distributions; full text searches and notifications. It allows drag and drop and with the integration with the workflow engine, the user can drop a file into a field on a workflow and it can be auto filed in the folder structure.</p> <ul style="list-style-type: none"> <li>• Electronic Content Management for version control, security, centralized search and history</li> <li>• Multiple views (structures) of the files in the ECM structure.</li> <li>• Document Types for classification of document metadata.</li> <li>• PDF rendering with stamping schema</li> <li>• Upload documents</li> <li>• Document training records</li> <li>• Powerful, securable dashboards with lists, charts and favorites</li> </ul>  <p>Workflows for the periodic review, review, approval, publishing and expiry of documents.</p> 



Module/Component	Description
	<div data-bbox="568 255 1307 875" style="border: 1px solid black; padding: 5px;"> <p>Control Type: Controlled   Status: Active</p> <p>Periodic Review</p> <p><input checked="" type="checkbox"/> Enable Periodic Review</p> <p>Frequency (Days): 1</p> <p>Notification Window (Days): 1</p> <p>Assignee User: kashf.dmsuser7</p> <p>Assignee Group:</p> <p>Automatic Numbering</p> <p><input checked="" type="checkbox"/> Enable Automatic Numbering</p> <p>Numbering Schema: XY   Prefix: XY   Counter: 5   Suffix: DN</p> <p>Increment: 2</p> <p>Padding: 5</p> </div>
<p><b>PDF Ingestion and Annotation Services Module</b></p>	<p>The annotation Module allows PDF documents to be scanned and annotated along with the collection of relevant metadata. These documents can be distributed in combination with e-mails.</p> <div data-bbox="568 1025 991 1579" style="border: 1px solid black; padding: 5px;"> </div>
<p><b>Document Metadata</b></p>	<p>The document properties include out of the box metadata that can be configured to provide additional customer specific fields. The documents can be linked to their relevant locations and other impacted documents.</p>

Module/Component	Description
	<p>System ID: 221</p> <p>File Name: High-Mini-Design-Documents.docx</p> <p>Name: DOC 1.0</p> <p>Reference Number:</p> <p>Owner: Seharaj (Des)/Premath</p> <p>Document Type:</p> <p>Sequence Launch:</p> <p>Control Type: <i>configurable metadata autopopulate based on document type</i></p> <p>Controlled:</p> <p>Author:</p> <p>Description:</p> <p>Information</p> <p>Status: Under Review</p> <p>Version: 1.0</p> <p>Effective Date:</p> <p>Expiry Date:</p> <p>Initially Uploaded By: Seharaj (Des)/Premath</p> <p>Creation Date: 2019-07-10</p> <p>Last Saved By: des_premath</p> <p>Download URL: <a href="https://172.16.4-010.ecm.com/secure/document/052502030194969120124">https://172.16.4-010.ecm.com/secure/document/052502030194969120124</a></p> <p>Categories: Document Category #1, Document Category #2</p> <p>Locations: MS Channel</p> <p>Standard Keywords: Document checked reference #1</p> <p>Keywords: Keyword #1, Keyword #2</p> <p>Other Documents: <a href="#">Link to impacted documents</a></p>
<p><b>Integration and Indexing with 3<sup>rd</sup> party sources</b></p>	<p>The indexing module allows the company to upload documents from external sources, index and process them in accordance with a set of rules and run them through a workflow process and pass data back to the third party source.</p> <p>Document Index ▾ Details ▾ Workflow</p> <p>Have you entered the required information into risk master?</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>Have you annotated the document with the adjuster you would like the Claims Technician to assign?</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>Who is the adjuster on this claim?</p> <p>Benji Frank ▾</p> <p>Have you assigned the adjuster and done any other required work in Riskmaster?</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p>Is this a lost time claim, have you completed the EDI, and have you attached the Lost Time Claim Checklist?</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p>Have you generated the letters for the claimant?</p> <p><input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p><a href="#">Advance</a> <a href="#">Suspend</a> <a href="#">History</a></p> <p>Date: 2019-07-25</p> <p>Suspended Reason: Medical Record Missing ▾</p>
<p><b>CAPA (Corrective Actions-Preventive Actions) and Audit Management</b></p>	
<p><b>Action Management</b></p>	<p>The ECM Action module delivers an integrated out-of-the-box workflow process that enable proactive management of Corrective Actions / Preventive Actions in a timely manner. Managers can create and store action plans in library for reuse saving valuable time in planning actions. Aging, overdue flags, color coded alerts and notifications/escalations, supervisor and manager monitoring information ensure that tasks do not slip through the cracks. With the already embedded integration to every module, it ensures the source of the actions are tracked and maintained with the CAPA. This module may be interesting if there are any document deviations within an organization.</p>

Module/Component	Description
	
<b>Audit Management</b>	<p>The ECM Audit module incorporates a robust feature set that empowers your team to plan, prepare, and execute quality audits and inspections and accomplish day-to-day operational tasks needed to proactively ensure continuing compliance with company, customer and regulatory mandates. Includes a role-based security model that provides easy access to all information relevant to each audit, while protecting sensitive data from unauthorized use. Questionnaires can be created within libraries and used to assess compliance. Findings (observations) can be logged and categorized so that the organization can monitor trends and the status of corrective actions. Auto audit report generation and an audit program conflict management capability provide managers mechanisms to easily identify and communicate issues throughout the process. This module allows organizations to audit quality, operational, EHS, financial and other elements of the organization, including audits of procedures and other documentation.</p> 
 <b>Platform</b>	
<b>XD-Core Platform</b>	<p>The XD Foundation incorporates the Administration Core (system options, security, user/group, audit trail), Support Core (other out of the box modules such as PEOPLE, ORGANIZATIONS, LOCATIONS, JOB ROLES, EQUIPMENT, CUSTOMERS, SUPPLIERS, PRODUCT &amp; SERVICES, SYSTEMS &amp; APPLICATIONS), the Task Management Core (workload, Dashboards, out-of-office, notifications,</p>

Module/Component	Description
	<p>calendar), the Search/Report Core (panels for advanced and quick searches, producing reports, and query builder) and Workflow Core.</p> <p>The various XD modules are built upon the Business Process Management capabilities to deliver automated workflow and task management, notifications and powerful searches and reports to users.</p> <p>The query builder is a powerful, configurable query engine that support cross workflow metadata searches, conditional filters and pick and choose which fields to include in the results. The security allows the query to be shared with the appropriate groups in the various dashboards and reuse at a field level to select values with precision.</p> <p>The Workflow Core allows the creation of new workflows with custom forms and fields to automate compliance and business processes. It also means that out-of-the-box modules can be easily “tweaked” for enterprise adoption. The Workflow Core provides capabilities to configure list data, create new fields, set traceability and e-signature rules. In addition, the user can set business rules and lifecycle states within the workflow and form designer and set the labels and granular security. The flexible layout options provide the navigational ease to ensure that the solution is suited for all types of users. With over 80 types of fields supported, including image map, tables, RTF and dictation types; the capability for field level permissions; and the ability for dynamic form adjustment, the workflows promote efficiency and accuracy. The core delivers task management, notifications and powerful searches and reports to users and provides the configuration capabilities to set global system settings.</p>
<b>External Systems Integration</b>	<p>The core platform comes with features that promote integration with external systems thereby leveraging the company’s IT investments. These powerful time-saving capabilities can be enabled with assistance from Xybion’s experienced professional services team. Active Directory Integration, E-mail integration, website integration, and external system and database integration. Both push and pull from the external sources have been done, on a synchronized scheduled and real-time. Integrations include:</p> <ul style="list-style-type: none"> <li>• HR systems</li> <li>• ERP systems</li> <li>• External fields – link to third party databases to pull information</li> <li>• System tasks – pull/push data from/to external databases.</li> <li>• API Launch – pull data from external database based on a trigger and start a process/filling the form.</li> <li>• Synchro – import data from external databases on a schedule.</li> </ul>
 <b>Tools &amp; Components</b>	
<b>PDF Converter</b>	<p>Add-on tool for rendering documents. Includes capabilities for watermarking, headers/footers, signature pages.</p>
<b>System Records</b>	<p>Report Mapping - XD supports the capability to drop in report templates in Word and excel with mapping to the fields in order to generate reports in other modules. In addition, the Interfaces capability allows the system to establish interfaces with other external systems for the push and pull of data.</p>
<b>Integration Framework</b>	<p>Active Directory Integration, E-mail integration, website integration. Both push and pull allowed the targeted master system to retain control over its data.</p>

## Xybion Response to RFI Requirements

The following table addresses the specific requirements raised in the RFI document:

Requirement	Response
<p>Allows for efficient documentation and review of audit work and recommendations in compliance with professional standards, accommodating a wide variety of external audit types and sizes</p>	<p>ECM-XD supports this requirement. ECM-XD provides an out-of-the-box, yet highly configurable solution to holistically manage all of your content, Documents, Images in a single digital environment.</p> <p>ECM-XD helps businesses simplify collaboration, create content, and transmit and assure compliance across all parts of the business processes. ECM XD's built-in regulatory controls enables holistic management of compliance. The proposed solution allows for efficient documentation and review of audit work and recommendations in compliance with professional standards. Workflows can be configured to allows documents to be routed for review, approval and distribution in a controlled manner.</p> <p>There is no restriction on file size. The system supports file types that include Word, PDF, Gif, Excel etc.</p>
<p>Customizable User Interface, perspectives (user views) and terminology that allow the workflow to be customized</p>	<p>ECM XD enhances business user productivity with intuitive interfaces for managing the lifecycle of content.</p> <p>Workflows can be customized to include specific terminologies. These workflows are built on the document workflow designer which these workflows to be modified to meet the customer needs, if necessary, with customer metadata, business rule routing, and specialized tasks.</p> <p>The system provides configurable dashboards that is role-based and provides important information relevant to that section/task. The proposed solution supports a powerful, customized Dashboards and Purpose-built, configurable information views based on role, Task management, Recent Activities, Roll-up information, favorites, Each widget securable, Charts, graphs, trendlines, Drill-down diagrams, Location-based data.</p>
<p>In addition to laptops and desktop computers, ability to use mobile devices and tablets for access</p>	<p>The proposed solution is a web-based interface and can be accessed via handheld devices such as tablets. The solution is compatible with all standard and major browsers.</p>
<p>All associated server environment data (operating system, data base brand and architecture, required framework and/or stack)</p>	<p>Xybion provides a flexible deployment options, for this engagement, we have included details on On-Premise installation as well as AWS hosted model. The hardware and software requirements and network architecture are provided in the later part of the document.</p>

Requirement	Response
Ability to operate on current MS Windows 10 OS and future patch releases and updates	ECM-XD supports this requirement out of the box. The system has the ability to operate on MS Windows 10 OS and future releases.
Compatible and fully integrated with latest versions of MS Office Products, including Office 365 (cloud and desktop clients) and Office 2016	ECM-XD supports this requirement out of the box. The system is compatible with latest versions of MS Office products including Office 365 and Office 2016.
Compatible with latest versions of common web browsers (Google Chrome and Microsoft Edge)	ECM -XD is compatible with latest versions of common web-browsers including Google Chrome and Microsoft Edge.
Compatible with common electronic document file types and associated 3rd party software, including but not limited to .PDF portable document files (Adobe and Nitro Pro), .JPEG and BMP digital images, .TXT text files, and .ZIP compressed data files	The proposed solution is compatible with the specified file formats.
Ability to attach external files (i.e. pdf, docx, xlsx, jpg, bmp, tif, etc.) to all work flow items	The system allows the user to attach external files to all workflow items.
Workflow tracking (edit history) including status designations (such as prepared and supervisor reviewed)	ECM XD supports this requirement out of the box.
Electronic workpaper management including version control and automated assignment of workpaper identification numbers (audit reference codes)	The system supports workflow-based assignments and version control. The system can be configured to include automated assignment of audit reference code. Specific requirements will be gathered during business discovery and the system will be configured accordingly.
Ability to restrict editing or changes to engagement projects or workpapers for retention purposes (i.e. finalization, freezing or archiving procedures)	ECM-XD supports this requirement out of the box. The appropriate user- role based access can be configured in the system to restrict editing or changes to engagement projects.
Ability to set engagements and workpapers as confidential (limited or restricted access)	ECM-XD supports this requirement through the role- based user access functionality. The data integrity is managed through detailed and comprehensive audit trail functionality available in the system. The solution has full audit-trails which track all activities with username, date and time stamps. Changes can be tracked down to field level. Only users with administration rights can access these audit logs.

Requirement	Response
Ability to search by keywords, attributes, and/or values	ECM-XD supports this requirement out of the box
Ability to meet compliance regimes that may include storage and transmission requirements for health records, payment card information, personally identifiable information, or other types of confidential information	Application supports Audit and permissions to handle confidential information
Exception and audit issue tracking for follow-up corrective action	CAPA module delivers an integrated out-of-the-box workflow process that enable proactive management of Corrective Actions / Preventive Actions in a timely manner. Managers can create and store action plans in library for reuse saving valuable time in planning actions. Aging, overdue flags, color coded alerts and notifications/escalations, supervisor and manager monitoring information ensure that tasks do not slip through the cracks. With the already embedded integration to every module, it ensures the source of the actions are tracked and maintained with the CAPA. This module may be interesting if there are any document deviations within an organization.
Ability to support real-time digital collaboration through dashboard reports and supervisor reviews (edit comments)	<p>The proposed solution provides Purpose-built, configurable information views based on role, Task management, Recent Activities, Roll-up information, favorites</p> <ul style="list-style-type: none"> <li>• Each widget securable</li> <li>• Charts, graphs, trendlines</li> <li>• Drill-down diagrams</li> <li>• Location-based data</li> </ul> <p>Auto generation of formatted reports with ingested system data that can be edited onscreen or sent to other formats such as Word or PDF for utilization. The system provides standard (out of box) and customizable reports and has the ability to create pre-defined reports.</p>
Provide real-time tracking of work flow and project status	ECM-XD supports this requirement out of the box. The system supports real time monitoring of KPIs including content, users, and workflows.
Ability to add hyperlinks and bookmarks for cross-referencing and efficient navigation	The system allows records and documents to be linked with other associated documents/reports/records. Documents, records, tasks and workflows can be associated and/or assigned to a user or user group. The status of individual tasks can be monitored on a searchable monitoring panel. The system also allows users to embed internal document hyperlinks to support key regulatory processes requiring internal document links.

Requirement	Response
Ability to create and maintain templates of our knowledge base which can be imported into the audit documentation software	Standard templates can be uploaded for reference as a document.
Administrative capabilities to establish and update user accounts, system polices, and workflow preferences	Security is controlled by login using LDAP-based authentication and system-based authentication. User and Security Profiles (roles) can be set up in the system. Permissions are very granular and can be set for both users and security profiles. User Management functionality will be made available for Admin roles.
Administrative rights to specify user access policies and permissions (controlled user access). User permission and access controlled by System Administrator	Admin roles can be defined in the system through the Admin module. The Admin role will have the privilege to add/remove users, assign user groups, modify access rights and define system time out settings. Other specific privileges can be configured as needed.
Open APIs or other means for integration with other software modules and applications, dashboards and reports	The ECM XD system has been built with interoperability as a part of the design. System exposes REST APIS which can be consumed by third party applications. This helps create records in the system and export data from the system to outside applications.
Ability to copy, duplicate, transfer, and generate printable reports for all work product within the software solution	ECM -XD can be customized to support this requirement. Specific requirements will be gathered during business discovery and the system will be configured accordingly.
Offline System Capable, without network connection to cloud or main server, while maintaining central database	The proposes solution is a web-based application and needs networking capabilities to access the functionalities.
Supports data backup and recovery. Prefer ability to recover individual audit files without having to roll back the entire database	System facilitates an automated daily incremental backups and weekly full backups. Individual audit files can be recovered without rollback.
Auto-Sync Capable with conflict identification and resolution features	The proposes solution is a web-based application and needs networking capabilities to access the functionalities. The system currently does not support offline workspace or auto-sync capabilities.
Ability to import and export (e.g. project rollover) information and work product within the software solution. Please specify acceptable data formats for import/export and inter-application analysis and reporting	System allows to import and export files within the solution. The data can also be imported/exported from external systems using REST APIs

Requirement	Response
Ability to customize configurations based on preferred workflow using specific fields and values such as: project names, client names, client types, engagement numbers, engagement types, reporting periods, and report issue dates	Workflows can be configured as needed.
Policy and Terminology Configuration Management: structured hierarchy; provides for configuration updates that associate all data with the assigned configuration item. All data auto-populates based on administrative configuration	Yes, the policies and terminologies can be configured as part of workflow configuration.
Online tutorial and offline manual and help functions	Xybion provides offline manuals such as Admin Guide and end user guide. Specific instructions help icon can be added for specific fields/functionality in the system.
System Training to cover administrative needs and availability during regular business hours to support product issues	Xybion provides Super User and end user training. Training approach has been detailed in the later part of the document.
Expandability and integration support for new technologies (i.e. follows software development best practices and has an active development plan / business plan that will ensure continued compatibility and integration with new technologies)	Yes, Application can be integrated with any system using REST APIs.
Vendor offers enterprise level product and/or service	Yes. Xybion offers enterprise level product and service.

## ECM-XD Functional Overview

ECM-XD, based on Xybion’s Digital Platform (XDP), provides a single cloud platform architected to integrate end-to-end enterprise processes and content. In addition, the process rules, security, faceted search capability, powerful query builder and report capabilities allow data to be retrieved at the right time by the appropriate people, which can include partners, external service providers and other stakeholders via secured solution and mobile platforms.

An embedded document management system drastically cuts time when managing vast amounts of documents and can be configured to prompt users to add the right type of documentation at the correct step. Even with file “heavy” processes, the intelligent tagging of content metadata to allow auto-filing in the content structure along with full text searches and smart views allows customers to find documents



rapidly. Xybion’s document management systems have been implemented for various clients in the last 20 years.

**Business Applications**

The ECM-XD provides full document control over different types of file formats, keeping a detailed history of all changes. ECM-XD provides full life cycle control over the creation, approval, modification and archival of documents. Automated workflows ensure that documents are routed through all applicable reviewers and authorized in a controlled manner that complies with all regulated document management requirements, including the collection of electronic signatures for specified workflow actions. Document tasks are sent to a centralized workload and notifications to the user’s e-mail facilitating the timely completion of critical document activities.

ECM-XD can increase return on investment, by providing a content management application that can be easily configured to business needs, which will enable organizations to quickly deploy and manage a wide variety of content, including but not limited to:

- SOP Management (policies and procedures)
- Document Management
- Document Change Control
- Policy Training
- Content Management
- Reference Library
- Videos, pictures and other media types

ECM-XD accelerates your compliance processes by empowering regulatory knowledge workers to configure your repository to meet the specific needs of your company without customization. ECM-XD supports regulatory business processes and includes built-in best practices for compliance with various regulations.

ECM-XD provides best practices through its numerous embedded capabilities and content management features such as:

**BUILT-IN DOCUMENT CONTROL BEST PRACTICES**

Feature	Description
Regulatory Compliance	Supports electronic signatures, records archival, and reporting.
Advanced Search and Retrieval Capability	Centralized search including full text search over document content.
Comprehensive Reporting	The goal of most business operations is the painless generation of detailed <i>reports</i> and holistic analytics over complex levels of metadata.  Auto generation of formatted reports with ingested system data that can be edited onscreen or sent to other formats such as Word or PDF for utilization.
Audit Trail & Administrative Controls	Includes searches and field level tool-tip audit trails.

Feature	Description
Comprehensive Library Services (Version Control)	<p>The standard check-in/check-out feature provides controlled secure access and flexible revision capabilities.</p> <p>Informative document history showing document revision history and document workflow information.</p>
Seamless Integration with Desktop Productivity Applications	<p>Configurable e-mail notifications and tasks to alert affected users of periodic reviews, document tasks, and changes in the document status.</p> <p>Notifications sent to MS Outlook or other MAPI compliant email system with links to open the critical task in the system.</p>
File Format Neutral	Constraints can be set to restrict upload of potentially harmful file types, but the system otherwise is file format neutral.
Configurable Document Folder Structure	System allows user created hierarchy of folders and an auto folder creation system.
Powerful, Integrated Document Workflow Capability	<p>Out of the box document workflows for periodic review, collaborative review, approval, publishing, training and expiry. These workflows are built on the document workflow designer which these workflows to be modified to meet the customer needs, if necessary, with customer metadata, business rule routing, and specialized tasks.</p> <p>Integration with other ECM-XD modules so that content from the repository can be included in other compliance processes such as audits, for example.</p>
Collaborative Document Lifecycle Process	Multiple reviewers can collaborate with comments and document markups.
Comprehensive Document Security	ECM-XD offers a robust, configurable security model that allows you to apply security profiles based on document life-cycle stages.
Document Import/Export	Import tools allow rapid upload of bulk documents.
Embedded PDF rendering and annotation capabilities	Users have the flexibility to specify automatic PDF conversion for documents within the repository. Additionally, users can import and annotate PDF documents.

Feature	Description
Predictive Compliance capabilities	Automated review and predictive compliance of submitted documents versus established company templates.
Document Taxonomy	Document Type specifications which allow users to specify rendering schemes, unique numbering and document roles for similar groups of documents.
Configurable Dashboards	Securable, configurable dashboards provide transparency and drill down capabilities to rapidly assess high priority areas and act on them.

### Ease of Use

ECM-XD enhances business user productivity with intuitive interfaces for managing the lifecycle of content. With ECM-XD, organizations can enable their business users to:

- Manage tasks with a unified roles-based management console that support the entire content lifecycle.
- Manage content as objects related to their specific compliance processes.
- Automate and control the content lifecycle with streamlined compliance process workflow to maximize efficiency and consistency.

### XD Platform- Key Features

Xybion Digital Acceleration Platform (XDP) is a purpose-built, web-based Business process management application designed to allow customers to configure the domain to suit their requirements, including the data stored, screen layouts, report layout, customized documentation etc. The platform incorporates adaptable BPM capabilities and out-of-the-box governance, complaints & incident mgmt., compliance, quality and risk features that allow organizations to manage various data collection, cases, issues, actions, follow-up, complaints, audits, checklists, events, ethics and compliance, and many other types of business activities. XDP allows customers to configure the business process domain to suit its requirements, including the data stored, screen layouts, report layouts, customized documentation, filters and workload presentation. The platform ensures process fidelity, data integrity, and chain of custody protection across your organization. This Unified Operational Ecosystem provides the functional breadth and depth companies need for highly regulated industries. By ensuring ingrained quality and embedded compliance, it greatly simplifies IT architectures and releases resources back to the business.

Feature	Description
Controlled Workload Management	The process rules, security, faceted search capability, powerful query builder and report capabilities allow data to be retrieved at the right time by the appropriate people, which can include partners, external service providers and other stakeholders via secured solution and mobile platforms.

Feature	Description
Dashboard	<p>Purpose-built, configurable information views based on role, Task management, Recent Activities, Roll-up information, favorites</p> <ul style="list-style-type: none"> <li>• Each widget securable</li> <li>• Charts, graphs, trendlines</li> <li>• Drill-down diagrams</li> <li>• Location-based data</li> </ul>
Rapid Input and Mobility	<ul style="list-style-type: none"> <li>• Multi-lingual capability</li> <li>• Bar code readers</li> <li>• Integrated touchless phone calls</li> <li>• Touch screen enabled system</li> <li>• Mobile enabled</li> <li>• Voice over command for data entry and sending texts</li> </ul>
Easy to Navigate Interface	<p>Configurational Options for Navigation and User Displays with the powerful options for workflow layout. This is critical as many end users often struggle with legacy system's confusing and "rabbit hole" navigation which leads to loss of productivity.</p>
Effortless-Integration-Framework	<p>Active Directory Integration, E-mail integration, API and Integration Framework for Connectors for Device/Instruments. Both push and pull allowed the targeted master system to retain control over its data</p>

**Additional Distinctive Features:**

The Foundation of the XDP Platform consists of several Cores: Code set Management, Task Management, Dynamic Workflow Management, Case Management, Search & Report, Integration framework & tools, Enterprise Content management and Administrative and Support.

Code Set Management	<p>The heart of our low-code platform is Code Set management. These code sets define thousands of small sets of functionalities which can be combined as needed to create large functionalities, workflows, forms etc. This creates infinite freedom for the users to have "Your process-Your way".</p>
Flexible Task Management & Triggering of Workflows, Tasks, Events and Changes	<p>Activities, tasks planning, and assignment can be done automatically based on business process template configuration or ad-hoc by users. XDP supports business rules, dynamically adjusting forms, and incorporation of root-cause analysis ensure that the right data is being collected at the right time.</p>
Dynamic Business Process and Workflow Designer	<p>The designer allows simple to complex business processes to be modeled including business rules, sub processes, easy form configuration, conditional routing and robust notifications and alerting.</p>

Form Builder	This module is used to manage forms. Forms can be created with multiple fields. These fields can be of simple types (e.g., textbox) or complex types (e.g., document viewer).
Rules Engine	The rules engine is used to configure rules in the system and is based on query management. A rule is created, and a query is associated with the rule. If the query returns data, the rule is triggered, and the action is taken in the workflow. XDP Platform Architecture.
Query Builder	The query builder is a powerful, configurable query engine that support cross workflow metadata searches, conditional filters and pick and choose which fields to include in the results.
Report Mapping and Report Creation	XD supports the capability to drop in report templates in Word and excel with mapping to the fields to generate reports in other modules. In addition, the Interfaces capability allows the system to establish interfaces with other external systems for the push and pull of data. This allows for complete digital process of creating the final report without needing any further manual workarounds.
Integration Framework and Tools	Active Directory Integration, E-mail integration, website integration. Both push and pull allowed the targeted master system to retain control over its data.
Export and Import functionality:	The system can export reference data, workflow data, forms and query results in csv/excel/plain text file format. The user interface allows users to select fields to export and to add conditions to filter the exported data.
Other Integrations	XDP integrates with Twilio, eFax etc., and can integrate with any system which provides integration API's. This makes integrations with other systems including ERP systems very easy.
XDP APIs:	XDP exposes APIs which can be used by external systems to connect with XDP.
Support Modules:	People, organizations, locations, customers, suppliers, job roles, products & services, etc. are set up initially to capture multi-site organizations structures, locations within a site down to a file cabinet where a document may be stored. Every person, partner organization, supplier and customer are working inside these sites are fully profiled with their job roles which defines their permissions and security levels.
Appointment Management:	This module provides the ability to schedule appointments and is directly linked with workflow data.
Audit Trails	Audit trails of any activity in XDP is available to authorized users. Everything in XDP is audit trailed and can be configured for eSignatures. Reports can be configured based on requirements.
Multilingual	Multiple languages support is inbuilt in the platform. Users set their default language in their user profile.
User Management, Roles and Security	Security is controlled by login using LDAP-based authentication and system-based authentication. Other means of authentication e.g. SAML, oAUTH are also supported. Roles and groups can be configured to allow users to access certain parts of the application (role-based access) down to a field level if required.

## Implementation Approach

### Xybion Response:

Xybion projects are initiated with project kick off and project planning which includes detailing the project plan based on SAO stakeholder availability. Based on the requirements specified in the RFI, Xybion estimates the below timeline for this engagement. This is subject to change post the RFP process and business discovery.

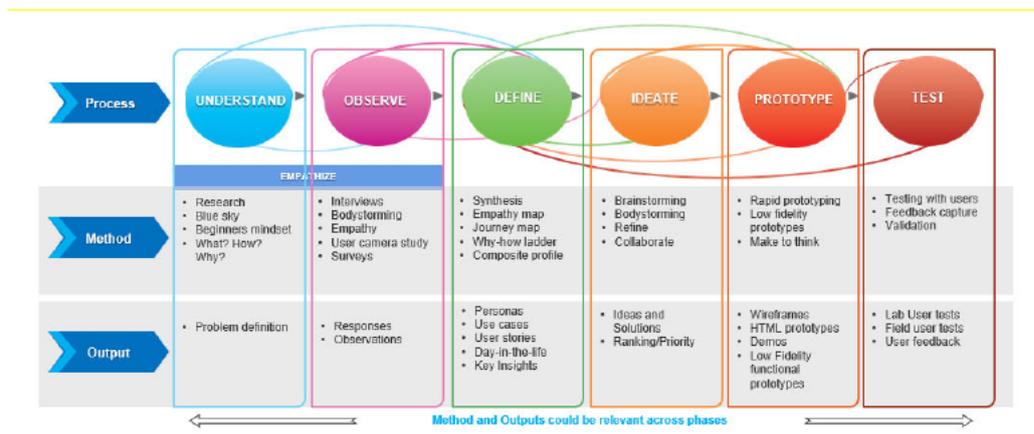
Xybion estimates a 4.5-month timeline for out of the box implementation.

Primary Focus	Work Stream	Month 1	Month 2	Month 3	Month 4	Month 5
Implementation	Project Management	Project Planning and Management				
	Business Discovery	Business Discovery Phase				
	Installation and Configuration	Installation and Configuration				
Testing	Testing			Testing		
Migration	Migration			Migration		
Training	Training				User Training	
Go-Live	Go Live & Support					Go-Live and Hypercare

Xybion subject matter experts and Solution Architect manage the Business Discovery and Requirements Gathering to understand the business, integration and migration requirements. Based on the configuration and business requirements, system configuration is completed, tested and integration and Migration is completed. Training, UAT support and Go-Live Support as part of the Implementation Approach are planned with SAO project team.

**Project Kick Off** - The project kick-off will be organized through joint working sessions with a common goal to establish and confirm key objectives, project methodology and socialize with key stakeholders across SAO. Xybion will also work with SAO to establish meeting schedule (interviews, workshops) during business discovery, with key stakeholders and draft a high-level project plan.

**Business Discovery using Design Thinking** - The Xybion team will work closely with SAO project team to detail out the specifications for each business requirement. Based on agreed requirements, a high-level solution design will be created. The basis for the analysis will be driven around current and future business need and requirements. An illustrative approach is outlined below:





Xybion would work with the SAO team to leverage ‘Design Thinking’ to come up with a long-term solution to support growth and innovation, current and future business needs and requirements, manage ecosystems and reduce TCO (total cost of ownership). We could leverage features from Design Thinking principles such as context analysis, problem finding and framing, ideation and solution generating, creative thinking, sketching and drawing, modelling and prototyping, testing and evaluating. Based on agreed requirements, a high-level solution design will be created.

This approach allows Xybion subject matter experts in the business discovery to confer with your experts in order to design the best implementation of the solution for SAO’s needs.

### **Installation, Configuration and Deployment**

Based on the requirements and high-level design, detailed functional requirements will be elaborated, and ECM XD solution will be installed and configured. SAO will be involved in solution walkthroughs to provide feedback during the implementation process. At the end of the configuration phase, the solution will be deployed to a testing environment.

### **Deployment Options**

As requested in the RFP, Xybion has presented both the On-Premise option as well as Xybion hosted model for SAO review:

#### **On-Premise Installation**

Xybion often works with our clients to enable them to host our applications. For this important effort **we recommend the SAO to procure the following hardware to host our application:**

Server	RAM	HDD	Software
2 Application Server (APP Server 1 and 2)	16 GB	80 GB	OS :- RHEL/Ubuntu/Linux/Windows JDK 8 Tomcat 8.x
2 API Server (API Server 1 and 2)	16 GB	80 GB	OS :- RHEL/Ubuntu/Linux/Windows Node
1 solr Server	16 GB	200 GB	OS :- RHEL/Ubuntu/Linux/Windows JDK 8 Solr
Database Server (1 Master + 2 slave - Optional )	32 GB	500 GB	OS :- RHEL/Ubuntu/Linux/Windows JDK 8 mongodb 4.0

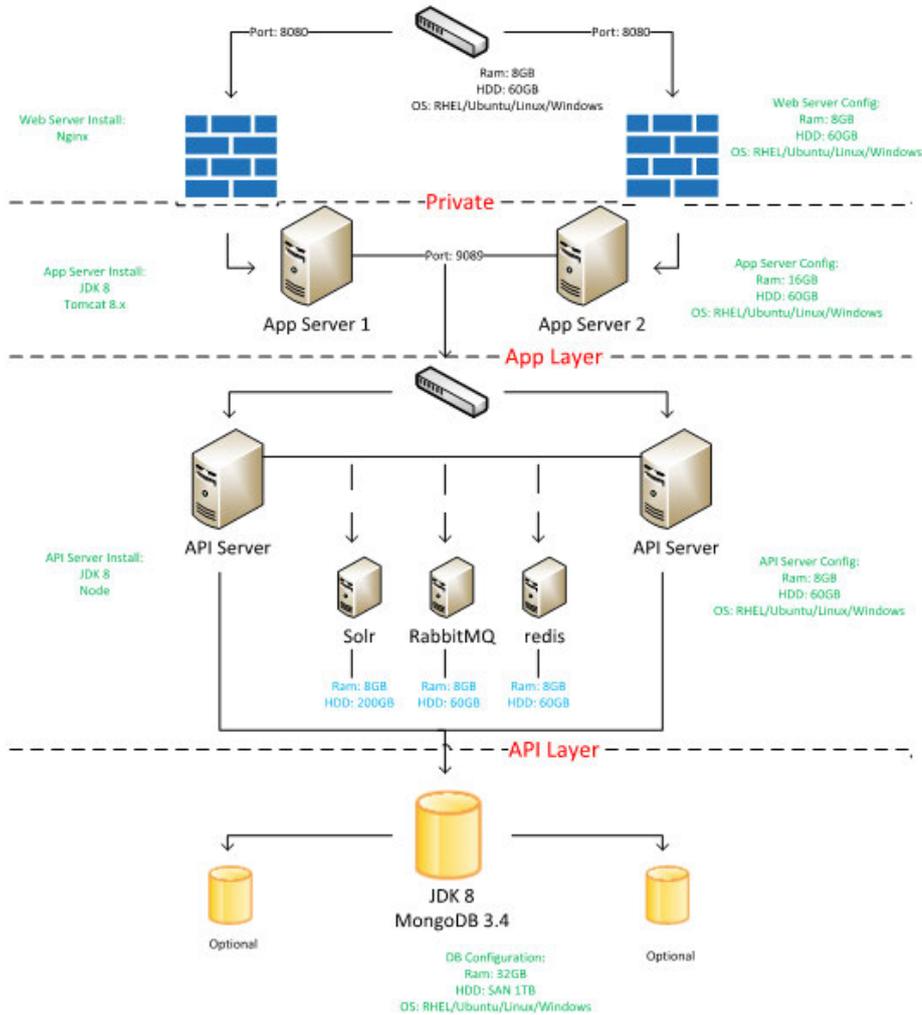
We will guide you to install each operating system and application to insure a solid and robust client hosted solution.

#### **Xybion Hosted Model**

Xybion has always had a customer centric flexible hosted model approach to our client’s needs. We also have seasoned experience hosting our client's platforms in AWS. Our DevOps teams utilizes the latest automation tools which facilitates enhanced flexibility to insure optimal End User experience at a minimized cost structure. This is accomplished by flexing needed AWS assets based on end user demands, or simply put we expand, and contract needed AWS assets based on the number of end users on SAO system. All of our AWS implementations are standardized facilitating efficient and effective customer support ensuring maximum uptime for SAO. Our goal is to relieve SAO from infrastructure administration enabling you to focus your efforts on your customers.

### Advantages

- Flexible scaling
- Best End User experience
- Utilizes latest security technologies and techniques
- Little to no IT involvement



**Testing-**The testing teams will operate independently of development teams to ensure highest quality output. The test planning activities will be initiated during the design & configuration process. The test team will work closely with the configuration and development team to support the iterative development process. This approach has proven to be optimal without compromising quality. The SIT Testing and UAT approach allows for testing standard functionality first then client-specific functionality secondly to cover the full spectrum of requirements. This approach assumes that the software is not a custom-written application and thus some degree of dependency on the vendor’s testing is assumed. Xybion will leverage the test scripts for pre-existing functionalities. Xybion will cover all the tests identified by SAO as part of the requirements.

### User Acceptance Testing (UAT)

Xybion team will work with the client to provide UAT Support and will create a UAT Testing Plan as specified in the RFP. Xybion will provide a working UAT application in a separate environment that would support all Production-sized system testing and regressing testing for migrations and upgrades and



establish a process to record all defects found during UAT. All defects will be tracked in the defect log and will be corrected, re-tested prior to Production Deployment.

**Migration-** Xybion analyses the structure of the data and extraction capabilities of the legacy systems, the volume of data to be transferred, and the differences between the legacy system's data model and our solution. We then produce a migration plan, specifics of the data migration mapping between the systems and then complete the data migration and in a validated and reproducible fashion. Detailed requirements will be gathered during the business discovery phase and a migration plan will be created to execute data migration from the legacy system. Migration will be carried out in the following phases: Analysis, Planning, Configuration, Small Data Migration, Data Migration and verification, Signoff and Clean up. Xybion will ensure that there is no impact on users during the migration phases. They can continue to work on the legacy system until the system is decommissioned.

### **Transition to Full Operations**

Xybion release and deployment team will plan all deployments across environments based on the project plan, work with client project and IT teams to ensure timely deployments. All deployments ensure follow of release process and documentation including release notes and Test documentation. Xybion's solution deployment is tightly integrated with automated testing and security checks to ensure elimination of defects and security vulnerabilities. Xybion performs penetration and vulnerability testing to ensure that there are no internal and external threat to the system. Xybion offers to provide 2 weeks of hyper care for this engagement.

### **Support**

Xybion provides world-class technical support for all our clients. Xybion will work with SAO to identify a SAO "Support Coordinator" to be the primary contact for Xybion. All correspondence from Xybion shall be made to the Support Coordinator(s).

Perceptive clients realize the value of Premium Support. This service provides a dedicated support person who has a detailed understanding of SAO applications, environment, and Xybion's solution. He/she can facilitate an effective and efficient response to any inquiries, training opportunities, product functionality and issues that may arise. Xybion offers Premium Support services at an additional cost. This dedicated support team can support the client with any specialized report requirements, etc.

We utilize the latest in modern support tools that enable our Support organization to see troubling trends and address these trends before they affect our production environments. Our applications and infrastructure have support "Bots" built within the applications and our infrastructure that communicate alerts to our Support team so they can be addressed before issues are experienced by our clients. Support is available by telephone, JIRA tickets or emails 24x5.

Xybion technical support personnel are available to answer questions regarding system operation, validation, the operating environment, and other issues related to the installation and use of ECM- XD. Xybion evaluates, classifies, and schedules the resolution of reported Issues to assure that all are resolved in as timely a manner as possible. Infrastructure Support is provided 24x7.

### **Incident Management & Resolution**

Xybion follows a well-defined Incident management process for issue resolution. Clients share details of an incident as a Software Performance report (SPR). SPRs are submitted and responded to

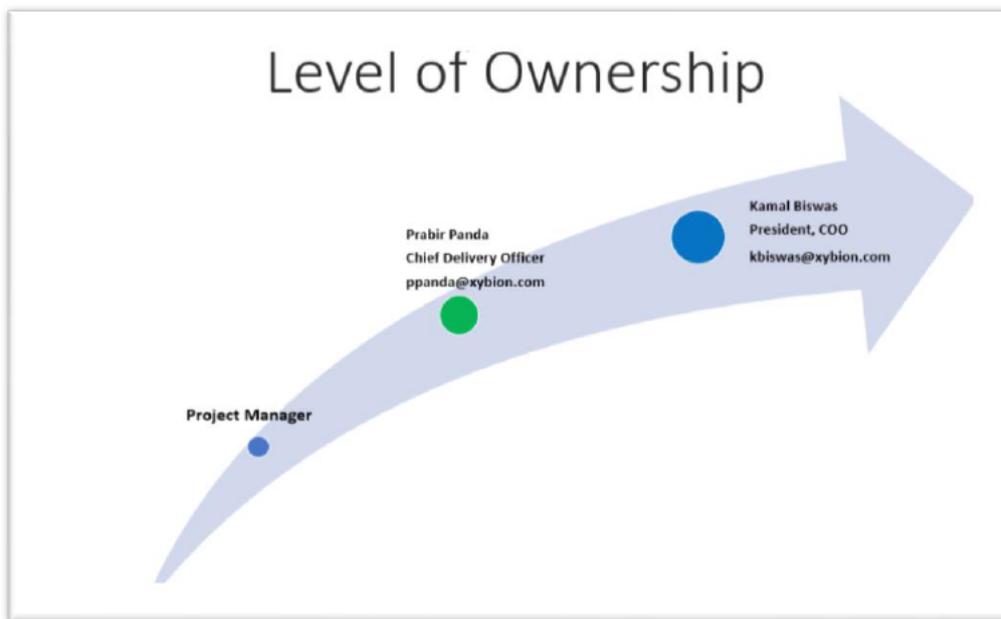
electronically, but a phone call between Xybion and the Support Coordinator may be required to obtain clarifying details. Incidents will be tracked and resolved based on the defined SLAs.

The following definitions shall be used in determining an Incident’s impact on client operations:

Impact	Definition
Severe	Substantially limits client’s ability to use the product as intended. This includes consistent unavailability of major functions, data corruption, or other extensive problems. Further, there is no workaround and the client cannot reasonably continue to work with the product.
Moderate	Seriously impacts client’s ability to use the product as intended. However, there is a workaround, or the client can continue a portion of its work with the product.
Minor	A loss or interruption of functionality that does not significantly impair client’s general use of the product. Important long-term productivity may be affected, but there is no immediate work stoppage.

### Service Escalation

Xybion will provide an escalation matrix to resolve any issues during the course of the project. For every engagement, Xybion maintains a three-tier structure and level of ownership to ensure smooth implementation of all projects.



For this engagement, the first level of ownership lies with the Project Manager who will be responsible for the day-to-day management of the project, identify issues and risks and recommends possible issue and risk mitigation strategies associated with the project.

The second level of ownership lies with the Chief Delivery Officer, who will be involved in all aspects of the project and continuously seek to understand and act upon SAO’s needs, concerns and priorities.

The third level of ownership lies with the Xybion Sponsor, who will assure that the Xybion Team is properly resourced and will work with the SAO’s Program leader to deliver the engagement outcome to the highest level of satisfaction for SAO. The ultimate responsibility of ensuring a successful implementation lies with Kamal Biswas, President and COO.

## Training

Xybion will provide training to key resources using the ‘Train the Trainer’ approach. Xybion has the capability of delivering both hands-on and remote training to the various types of users including all the user groups specified in the RFP. This project will include the following training:

Type	Description	Comments
Super User/ Admin Training	Provides overview of the system needed to perform User Acceptance testing in accordance with SAO policies and procedures.	Typically, the end user and super user training events are done prior to system go-live. The training is conducted on a training environment. The super user/end user hands-on training is conducted prior to go-live. The end user training typically uses train-the-trainer approach.
		Based on client requirements, Xybion can conduct multiple training sessions.
End User Training	Provides training on the transactional (day-to-day) usage of the configured system to ensure that users maximize their efficiency and competency of performing their associated compliance tasks within the system.	The training materials are structured using a building block approach of sessions by roles. The first sessions start with the most basic materials that everyone will need to have and ends with the highest-level types of activities.
	Training sessions will be defined and scheduled in conjunction with SAO core team and project schedule.	Typical sessions are classroom style and face to face with hands on training using the solution. Detailed user guides are created to help users navigate the solution functionalities

Xybion will involve all the required stakeholders in the training sessions and ensure complete knowledge transition as required. Prior to a training event, a training plan is developed which provides the training methodology, training and logistics requirements, agenda of training sessions, training participant recommendations, and training calendar of the sessions. The training plan will be created based on the project plan, SME availability, user roles etc. to ensure smooth coordination and execution of training. During the training sessions, the trainer provides use cases and examples of similar functionalities implemented for other clients.

The training is tailored to customer specific modules and functionality. Training sessions are typically recorded for customers to use as needed. Training sessions are conducted as instructor led, use interactive sessions. The goal is for users to work along with the training, so they get a good understanding of the system functionality. During the implementation phase there are typically two iterations of the training. The first round focuses on system functionality and the second round focuses



on customer specific utilization, as the system is highly configurable. Remote sessions are scheduled as needed throughout the implementation phase.

Training sessions are conducted as instructor led, use interactive sessions. The goal is for users to work along with the training, so they get a good understanding of the system functionality. During the implementation phase there are typically two iterations of the training. The first round focuses on system functionality and the second round focuses on customer specific utilization, as the system is highly configurable. Remote sessions are scheduled as needed throughout the implementation phase.

The training materials are not meant to reproduce the User Guide which is more topical in nature.

The training includes:

1. Conceptual presentation and usage of system features.
2. Demonstration & examples.
3. Training online with practical exercises.
4. Questions and Answers

## Security and Firewalls

Xybion prioritizes our approach to security. We utilize modern security tools and take a proactive purpose to facilitate the highest level of security. We utilize AWS Web Application Firewalls (WAF) with years of experience and many client implementations to foster first rate cyber security controls. We actively monitor our environments; Production, Test/validation, and Development via state-of-the-art security tools with a dashboard that gives Xybion full visibility of our global resources. In addition, our automated security platform isolates intrusions on a real time basis to reduce risk.

The solution has full audit-trails which track all activities with username, date and time stamps. Changes can be tracked down to field level. Only users with administration rights can access these audit logs.

All data in transit via the Internet is encrypted using Secure Socket Layer (SSL) encryption and digital certificates, providing isolation from other data traffic. The transmission of data is secured between the users and the data storage point (Database Servers).

## Backup and Disaster Recovery

In addition to a sound security framework we have a robust backup program that is designed to enable complete confidence with your clients recover quickly with very little data lost (RPO/RTO). This program varies with each client, but we have the capability to recover within 8 hours of a catastrophic event. In addition, we recommend nightly backup with the following cadence:

- Daily incremental backups for 8 days
- Weekly full backups for 5 weeks
- Monthly full backups for 13 months
- Yearly backups with a 7-year retention period

### 3. Proposed Fees

The proposed fees for this engagement are provided below based on a cloud hosted solution for a total of up to 50 users and ECM-XD's DMS & CAPA Modules.

Xybion will provide the use of ECM-XD via a Software as a Service subscription. In this model, an annual payment covers access to Xybion's help desk and customer support and system administration including upgrades. Cloud hosting costs are included in the annual subscription.

SAO does have the opportunity, to review the user distribution by function/module, to help better the total cost of ownership. The schedule and estimates will be re-evaluated after business discovery to ensure the implementation is right sized to your scope and objectives.

#### Tiered Pricing



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## Pricing Assumptions

- Xybion assumes that Client stakeholder availability on time to ensure smooth project delivery.
- The proposed pricing has been estimated for up to 50 users for AWS hosted solution. For additional users, AWS Hosting charges will be revisited.
- For On-Premise deployment the above-mentioned Hosting charges will not be applicable.
- Annual Subscription includes the product support. Any custom requirement or enhancements will be estimated separately and submitted for approval.
- The proposed pricing is exclusive of Integration and Migration effort.
- The proposed pricing is inclusive of taxes.
- Subscription is valid post deployment in training environment
- Travel expenses if any, will be billed at actuals