



GxP Document Management for Life Sciences

BUYER'S GUIDE

Table of Contents

1	Introduction	3
2	Success Criteria	
	Ease of Administration	4
	Supports Regulated and Unregulated Data	5
	Holistic Compliance Posture	6
	Built-In Security	7
	Robust Governance	8
	Works the Way End Users Work	9
3	Summary	10



Introduction

As life sciences companies look to implement digital solutions for managing documents, including those auditable by regulatory authorities, seemingly endless potential solutions emerge. Choosing the right platform comes with daunting responsibility: compliance, usability, and adoption to name a few.

We created this Buyer's Guide to provide you with a tangible framework to evaluate varied solutions and, ultimately, identify one or more that meet your specific use case.

The guide is segmented into success criteria that are relevant to life sciences companies, like yours.

Easy Administration

Moving to the cloud can reduce administrative overhead.

No one ever intentionally tries to increase administrative complexity. Unfortunately though, poor choices often do just that.

Here's what to look for in a cloud solution:

☐ Integrations with Active Directory and SSO providers

If you are using now, or are considering using, Active Directory or an SSO provider, make sure the solution you choose includes it natively.

☐ Cloud-First Architecture

The cloud has proven to be secure and reliable while delivering faster time to value and less administration, so make sure your solution uses a cloud repository as the source of truth.

☐ Management of Mobile Devices

It's not uncommon for mobile devices to be lost or stolen, so make sure your solution can deploy and managed an end-user mobile application for document access.

☐ Integrated Redundancy

Businesses are no longer strictly 8 to 5, so make sure you look for a solution that employs 100 percent real-time redundancy to maximum up time.



Segregation of Regulated and Unregulated Data

A cloud solution will simplify operations

Having separate repositories for regulated and unregulated data is essential in keeping maintaining a validated environment.

Here's what to look for in a cloud solution:

☐ Independent Repository for Regulated Data

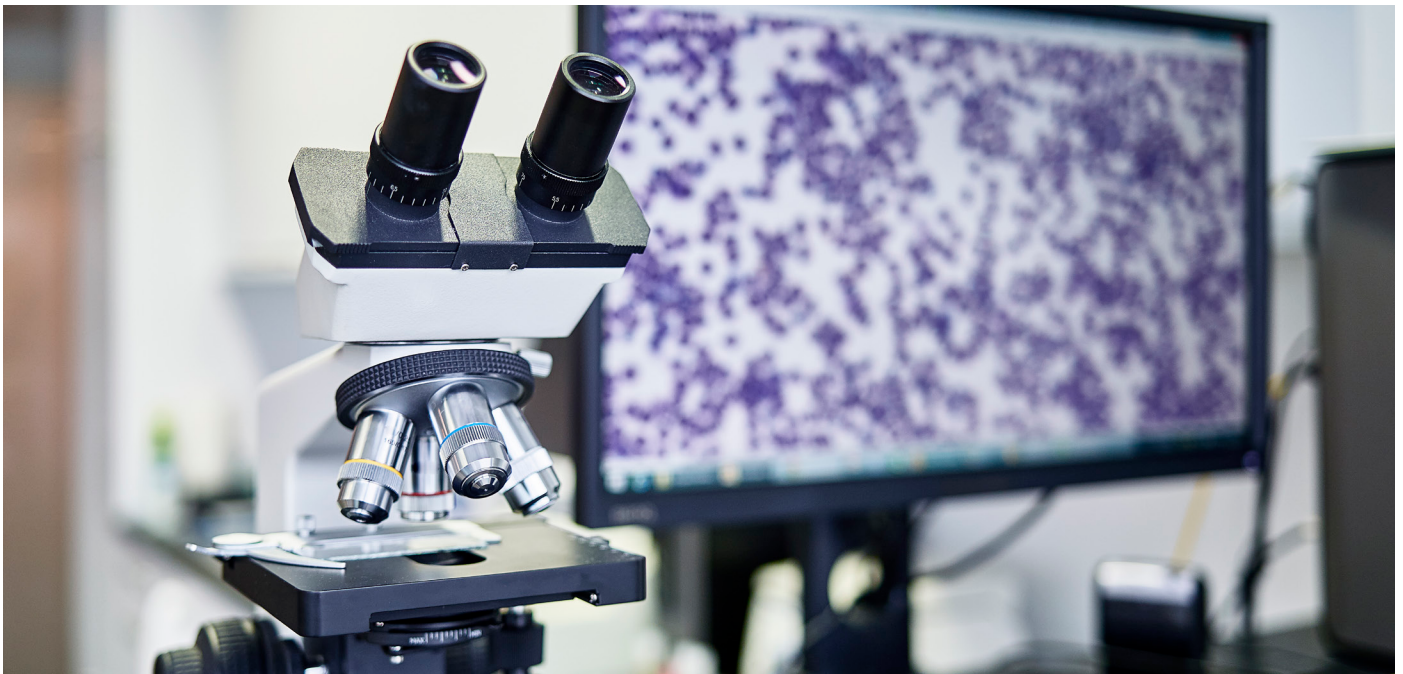
Regulated data has such unique repository requirements versus unregulated datasets. It requires separate access control, user audience, and structure, so make sure you choose a solution that supports this.

☐ Seamless Access Across Repositories

Make sure users who have the requisite access to both regulated and unregulated data are able to see both and that they have a consistent user experience.

☐ Holistic IT Administration

In order to optimize IT resources, look for a solution that has unified administration across both the regulated and unregulated repositories.



Holistic Compliance Posture

A cloud platform can provide better compliance

An effective compliance posture requires an end-to-end approach, and only looking at point solutions creates extra complexity and increases costs

Here's what to look for in a cloud solution:

☐ **GxP Validation Package**

In order to minimize time spent ensuring validation, look for a solution that includes documentation to support validation and customer implementation such as qualifications (IQ/OQ), requirements (FRS), and trace matrix.

☐ **Native FDA 21 CFR Part 11 Compliance**

21 CFR Part 11 and/or Annex 11 compliance is required for any solution that stores regulated data.

☐ **Integrated Regulatory Compliance**

Regulatory compliance is continuing to expand, and your solution should have out-of-the-box compliance with regulations like CCPA, GDPR, and Sarbanes-Oxley. It should also be able to support new and changing regulations.

☐ **Easily Created Custom Classification Policies**

Not every compliance requirement is regulatory. You need a solution that can adhere to contractual compliance needs too.

☐ **Integrated Remediation for Subject Access Requests**

There are specific timelines for responding to subject access requests and your system shouldn't be the bottleneck for compliance.

☐ **Support for Review and Approval of Standard Operating Procedures**

Workflows that support the creation and approval of a predefined set of Standard Operating Procedures that complies with industry best practices is an integral part of compliance.

☐ **Detailed Audit Trails**

Proving compliance requires detailed logging and reporting of all end user or administrative activities.

☐ **Data Integrity**

Having access to real-time data integrity verification of all documents via on-demand reporting makes proving data integrity fast and easy.

Built-In Security

A cloud-based solution can provide better security

Security goes beyond firewalls and virus protection and is where a cloud provider can rise above the rest if it provides these elements:

Here's what to look for in a cloud solution:

☐ Protection from Ransomware

Ransomware attacks can have devastating consequences to a company so make sure you go with a solution that includes native ransomware protection.

☐ Detection of Unusual User Behavior

Internal threats are just as real as external threats but are often harder to detect. Look for a solution that analyzes user behavior to identify possible internal risks.

☐ Compromised Account Identification and Disabling

The faster a compromised account is disabled, the faster the threat can be contained. Make sure your solution includes protection from compromised accounts.

☐ Continuous Security Monitoring

Threats can happen at any time, so you need a solution that will continuously scan all of your unstructured datasets and provide alerts for unusual user behavior, compromised accounts and ransomware.



Robust Governance

A cloud solution should provide cross-repository governance

Although essential, folder permissions are not the only element of governance. The broader the set of governance capabilities, the more control, and ultimately the more secure your data will be.

Here's what to look for in a cloud solution:

☐ **Retention Policies**

Retention policies vary by project and content so look for a solution that has an integrated policy-based retention, deletion, and archival of documents based on document contents and storage location.

☐ **Content Safeguards**

Sensitive data can easily reside in many locations, whether intentionally or accidentally. Address this with a solution that searches sensitive files in all repositories to ensure they are properly controlled.

☐ **Auto Retention**

If you have content that needs to adhere to specific retention requirements, then make sure your system prevents users from removing/deleting it for the specified period.

☐ **Lifecycle Management**

Keeping a repository clear of unused or outdated data increases performance and security. Consider a solution with integrated controls to automatically delete or archive this type of data.

☐ **Workflow Management**

Part 11-compliant workflows streamline and automate the review and approval process, removing bottlenecks for your regulated business processes.

☐ **Legal Hold**

Nobody expects to be involved in a lawsuit, but having a solution that can allow you to easily preserve all potentially relevant information will make your life much easier if it happens.

☐ **User-Access Control**

One of the easiest ways to ensure proper governance is by using granular folder access permissions. The traditional "waterfall" method can lead to permission model that doesn't align with actual need.

Works the Way End Users Work

A cloud-based solution doesn't have to be disruptive to users

It's important to maintain the user experience and functionality because it minimizes disruptions for your users. In addition, you want them to embrace new workflows in order to increase their productivity

Here's what to look for in a cloud solution:

☐ **Secure Collaboration With Anyone**

Collaborating on content is no longer exclusively between employees. Your solution should also facilitate external collaboration without impacting ease of use or security

☐ **Access Files from Anywhere**

Working outside of the office is continuing to gain popularity, so make sure your solution supports remote work without requiring a VPN

☐ **Desktop and Mobile Access**

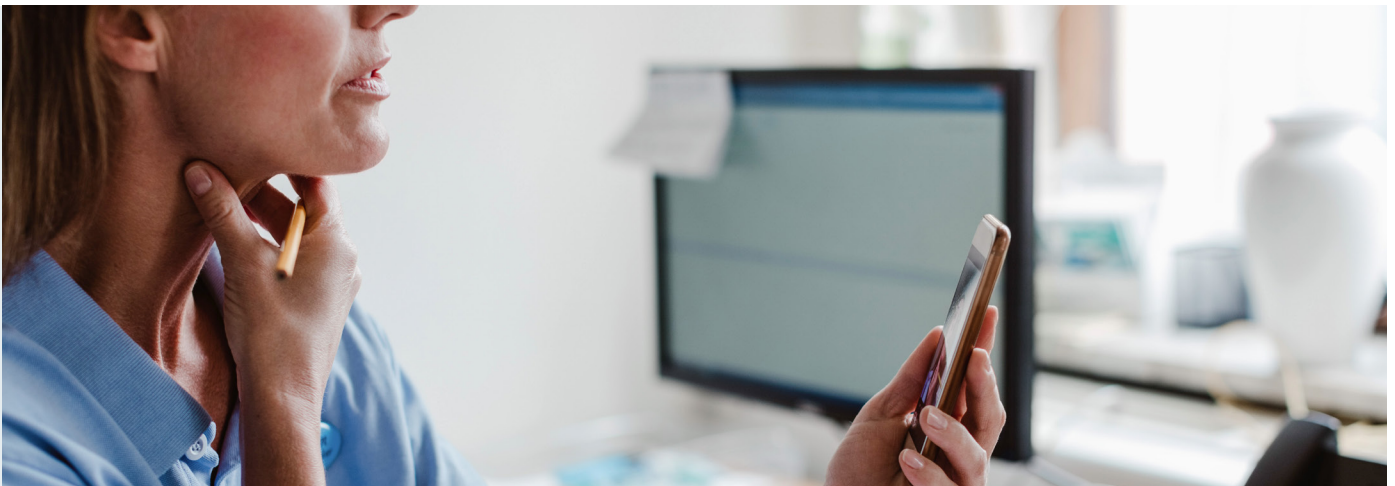
Deliver a consistent user experience by providing access to content from anywhere from desktop or mobile devices. It should also include collaboration and search capabilities, and offline access.

☐ **Integrations with Popular Productivity Apps Like Microsoft 365 and G Suite**

Nearly every company uses Microsoft 365, G Suite, or both, so make sure you can integrate directly with them for easier collaboration and governance

☐ **Integrations with Life Science Applications**

Having direct integrations with industry-specific applications can streamline user workflows, eliminate data silos, and increase security.





Summary

Don't worry though, we've helped over 400 life science companies manage compliance, collaboration, and control over their digital files. Our platform, which integrates with the tools you use most, streamlines your workflow and protects your data.

biotechne

SYGNATURE
DISCOVERY

veeva

TRAVERE
THERAPEUTICS

Reach out to us at :

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