



## **LOW RISK APPROACH TO ACHIEVE PART 11 COMPLIANCE WITH SOLABS QM© AND MS SHAREPOINT©**

Implementation of MS SharePoint provides company-wide functionalities for general document management and workflow. The use of **SOLABS QM** provides GxP required functions for 21CFR Part 11 compliance made easy, e.g. e-signatures, audit trails, etc.

Official records produced in SOLABS QM are published in SharePoint to all users.

## E-SIGNATURE AND WORKFLOW IN GXP ENVIRONMENTS WITH MS SHAREPOINT

Microsoft SharePoint® is a powerful collaboration “platform” gaining more and more attention. Most likely it will reach your organization by one way or another in the near future – if it’s not already implemented. It is marketed by Microsoft as an “IT platform” which means that it is a generic technology that organizations can use to build or configure software services upon. For instance, it can be used as the underlying technology of an intranet. SharePoint also offers few off-the-shelf services such as document management.

The use of document management capabilities in SharePoint 2007 while achieving 21CFR Part 11 compliance provides a very interesting option for mid-size (tier-2) GxP-regulated environments looking to go paperless. SharePoint 2010 promises to be even more complete in terms of document management capabilities.

The present document presents the SOLABS QM / SharePoint solution. It explains how you can benefit from MS SharePoint and how SOLABS QM helps you overcome its limitations when trying to achieve 21CFR Part 11 compliance, such as e-signature, complex workflows and audit trail.

## ASSUMPTIONS AND LIMITATIONS

You want to use document libraries in SharePoint 2007 and make sure that you can use these libraries to store and publish controlled documents (i.e. demonstrate that document libraries provide a validated environment). The principal limitations of MS SharePoint when dealing with GxP sensitive documents are:

- SharePoint does not address 21CFR Part 11 out of the box;
- Maintaining a compliant audit trail can become a challenge (documents can be deleted, versioning can be set differently on a per document library level, etc.);
- SharePoint provides mostly document-centric workflow capabilities, thus managing forms involved in complex workflows (e.g. Change Control) can pose a real challenge;
- The validation of SharePoint as per GAMP guidelines is possible but labor-intensive;
- E-Routing of documents to correctly map GxP business processes poses another challenge.

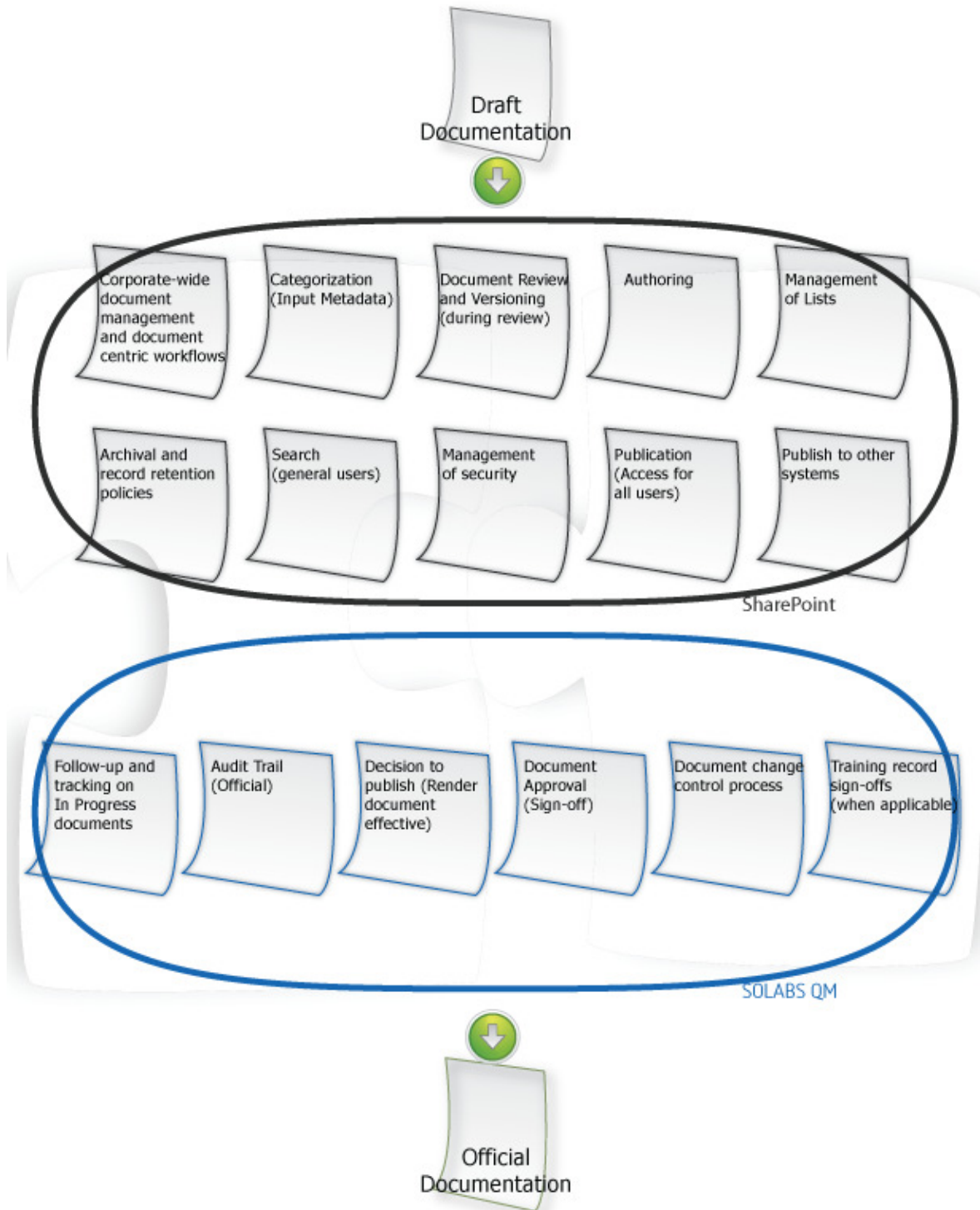
**SOLUTION**

The current document provides a low risk strategy to achieve 21CFR Part 11 compliance by considering SOLABS QM as a layer sitting on MS SharePoint. Refer to “Appendix A: SOLABS QM / SharePoint 2007” for more information on the technical infrastructure discussed herein.

**SEGREGATION OF FUNCTIONS**

The following table provides a summary of the main functions involved in the management of controlled documents in GxP environments, and describes how SOLABS QM and SharePoint can share responsibilities.

FUNCTION / CAPABILITY	RESPONSIBILITY	DETAILS
Document change control process	SOLABS QM	The control of documents initially starts with a request in SOLABS QM (see “Document Change Control Process” section on page 7).
Categorization (Input Metadata)	SharePoint and SOLABS QM	SOLABS QM replicates metadata typed in SharePoint (or typed in MS Office directly).
Authoring	SharePoint	SharePoint capabilities for authoring and review, especially when using MS office 2007 are exceptional and should be used as much as possible.
Document Review and Versioning (during review)	SharePoint	See line above.
Document Approval (Sign-off)	SOLABS QM	Documents automatically converted in PDF format with table of signature. This provides better control, easier publication and ensures documents cannot be modified.
Training record sign-offs (when applicable)	SOLABS QM	SOLABS QM can be used to confirm training records with SOPs for instance (optional).
Follow-up and tracking on <i>In Progress</i> documents	SOLABS QM	See “Document Change Control Process” section on page 7.
Decision to publish (Render document effective)	SOLABS QM	See “Document Change Control Process” section on page 7. SOLABS QM tracks document status.
Publication (Access for all users)	SharePoint	Use document libraries to publish approved and effective documents to all users.
Archival and record retention policies	SharePoint	Use <i>Record Center</i> capabilities in SharePoint.
Publish to other systems	SharePoint	Use “Send to” function in SharePoint or <i>SPS</i> service from SOLABS QM.
Restrictions on Access to Contents (Security)	ADSI/SharePoint	Privileges in SharePoint can be based on <i>ADSI</i> groups. SOLABS QM can use the same groups.
Management of Lists	SharePoint	Metadata tags, etc. can be centralized in SharePoint.
Audit Trail (Official)	SOLABS QM	Audit Trail functions in SOLABS QM are <u>always</u> enabled. It is designed to meet Part 11 specs.
Search (general users)	SharePoint	Available to all users
Corporate-wide document management and document centric workflows	SharePoint	You can use SharePoint document management capabilities (Content Types, Libraries, Workflows, etc.) throughout the enterprise.



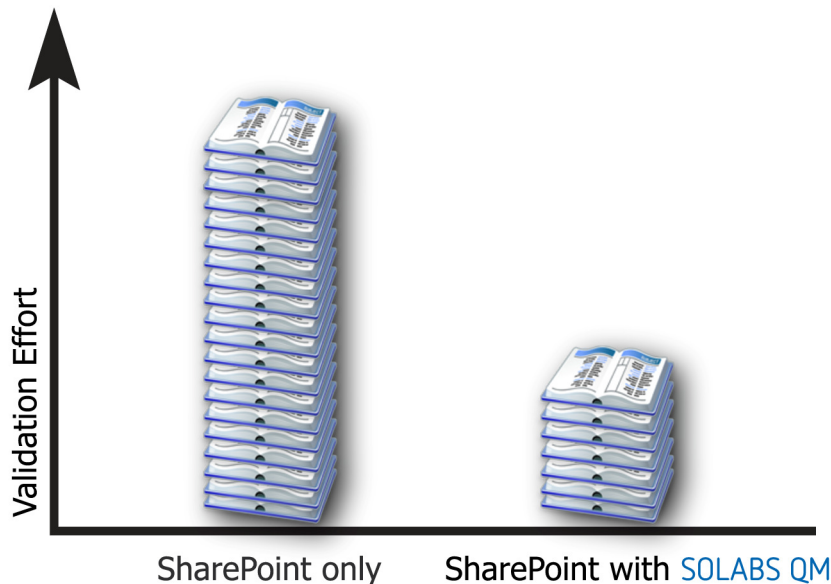
**SOLABS QM and SharePoint shared responsibilities on controlled documents.**

## VALIDATION APPROACH

By segregating typical document management functions between SOLABS QM and SharePoint, you can limit validation efforts, i.e. the scope of the validation effort applying to SharePoint can be reduced to:

- Verification of appropriate system installation and configuration (IQ);
- Setup and monitoring of backup and recovery procedures (SOPs);
- Test scripts (OQ/PQ) challenging the security model and functions used for the publication and archiving of GxP records;
- The monitoring and control of access to document libraries (SOPs);
- Appropriate system configuration management in accordance with current Change Control practices.

Then you isolate most of the 21CFR Part 11 requirements in SOLABS QM and still benefit from all the capabilities of SharePoint. SOLABS QM comes with a validation package (based on GAMP5) which reduces significantly the validation efforts for clients.



**SOLABS QM reduces validation efforts for GxP compliance**

## COMPLEX WORKFLOWS (NON DOCUMENT-CENTRIC WORKFLOW)

Here we refer to complex workflows or business processes such as CAPA, Equipment Change Control, Document Change Control, OOS (Lab. investigations), Non-Conformances, Deviations, IT System Access and Change Management, etc. Simply put it's a way to circulate e-forms.

The business process functions in SOLABS QM are based on a standard Business Process Engine (BPM engine). This allows clients far more flexibility than standard document-centric workflow engines like the one provided off-the-shelf with SharePoint.

Processes in SOLABS QM can be configured to match your SOPs or business processes allowing you to truly **enforce compliance**. Electronic forms build themselves as people fill information in processes (process task forms). The main benefits of such an approach are:

1. Important reduction in cycle times;
2. 100% visibility throughout your processes (where are we at and with whom?);
3. Ability to quickly identify patterns leading to recurrent & “non-desired” events;
4. Ability to easily track indicators such as the *Cost of Poor Quality*.

The following table provides the main capabilities of SOLABS QM’s **Process** module.

COMPLEX WORKFLOW FUNCTIONS (NON-EXHAUSTIVE LISTS)	DETAILS (WORKFLOWS BASED ON SOPs)
<b>What you see is what you need (WYSIWYN)</b>	You only see what you need to fill out in forms.
<b>“Return to initiator” made easy</b>	One-click “Return to Initiator” option for changes to forms instead of having to do it yourself.
<b>Attach external documents and secondary tasks to processes</b>	Related documents and secondary tasks are all linked together.
<b>Delegation and Re-routing</b>	Delegation of tasks when someone leaves (vacation, business trip, etc.).Or simply re-routing a task to someone in better position to execute.
<b>Notifications</b>	Notifications available on various steps of the processes (e.g. Supervisor Approval).
<b>Processes match your SOPs</b>	Assign tasks to individuals or groups of your choice for each process. Processes (e.g. CAPA) are NOT pre-configured.
<b>Reporting</b>	Reporting in SOLABS QM is based on SQL Server 2005 capabilities. Excel files can be made available in SharePoint report libraries for access by all users.
<b>SharePoint interface</b>	At the end of a process, a Summary Report (completed form) is available. This report can be transferred in a SharePoint documents library.

## DOCUMENT CHANGE CONTROL PROCESS

All organizations we have been dealing with over the last few years have one point in common: they have people in charge of controlled documents and it is our strong belief this should be your practice. We have found that somehow, organizations believe that this document control responsibility can be spread out to all authors in their company once they move to an electronic system. We do not believe this is the way to go! Document change requests should be centralized.

We also believe that controlling documents demands more than a review and approval workflow. E-Signature (possible simply using e-token technologies) does not provide visibility and reduction in cycle times. The real benefit of going electronic is the possibility to manage the life-cycle of a document and his status.

SOLABS QM document change control process centralizes change requests and brings visibility on current and future workload brought in by the management of controlled documents.

## CONCLUSION

If SharePoint is your platform of choice and you need to implement Part 11 compliant e-signatures and document workflow capabilities, SOLABS QM (layered on top of SharePoint) might be your best option.

SOLABS QM also allows your organization to handle complex workflows (business processes) that are not document-centric.

## ABOUT SOLABS

For the past 10 years, SOLABS has been helping companies around the world optimize quality processes with the ***Easiest QMS Software to Operate***. SOLABS is the leader in Canada for QMS software sold to GxP environments. SOLABS offers personalized implementation and support services in the US with partner QPharma and in Canada with partner RxGlobal.

For more information, please visit our website at [www.solabs.com](http://www.solabs.com) or contact us at [info@solabs.com](mailto:info@solabs.com).

**APPENDIX A: SOLABS QM / SHAREPOINT 2007**

**Figure 1: System Architecture for the SOLABS QM & SharePoint 2007 Architecture**

