

Q-Pharma & SOLABS - Achieving Regulatory Compliance with SharePoint - Webinar Q&A - January 27, 2010

Note you can access documentation on the SOLABS QM / SharePoint approach to 21CFR Part 11 here:

<http://solabs.com/en/info-center/>

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| <p>1. I thought that validation of MS products was enormously costly because they don't provide their code on the enterprise level.</p> | <p>Generally for Microsoft products you (as the client) assume 100% responsibility in the validation of their product so in some ways it can be costly. It is not really an issue of the code availability though, as there is more focus in ensuring the software was built using a robust software development lifecycle. This is usually verified by performing a supplier audit of the vendor and a successful audit can help reduce the risk and your validation burden. Audits are rarely, if ever, done for MicroSoft, although the fact that they have a huge user base and the high availability of bug and support data mitigates some of the risk here. For the specific instance of SharePoint, assuming that you use it only as a compliant "repository", you can narrow the scope of the validation effort to the following elements/activities: I.Q, Backup, maintenance and security of SOPs, and functions used in the Publication and Archival of documents (e-records).</p> |
| <p>2. What kind of approach are you suggesting for an implementation from scratch?</p> | <p>First of all we believe that the establishment of a software platform should be considered as a project on its own. When selected as a corporate collaboration platform, SharePoint should be deployed without being tied right away with a project bringing direct end-users benefits such as "Becoming a Document Repository and Workflow platform for Compliant Information."
The complexity and design choices related to the deployment of SharePoint (IT components alone) justifies a project. Once this is done, user-specific requirements can start to be fulfilled e.g. E.C.M., Web Content, Extranet.</p> |
| <p>3. SharePoint Integration: Can SharePoint work with HP Chemstation software?</p> | <p>We believe that SharePoint will become a standard, and as it becomes standard, the question will become more: Can HP Chemstation software integrate with SharePoint? However note that SharePoint is fairly easy to integrate with out of the box.</p> |
| <p>4. What about SharePoint Integration with Documentum?</p> | <p>Among other things, SharePoint can be used as a Front-End to Documentum as back-end. In this scenario, Documentum will be used as a storage and archiving system and SharePoint as a Web interface for all users.</p> |
| <p>5. When printing a controlled document from SharePoint (like a spec sheet) can Share Point assign a unique, sequential number to the printed document?</p> | <p>Controlled printing is a typical QMS software function and available off-the-shelf in QMS software systems. SharePoint does not offer controlled printing functions "off-the-shelf".</p> |

6. Can you give some examples of QMS systems available?

First of all let's respond to the first question: What is a QMS? A QMS software allows you to do the following electronically:

1. Workflows/Forms management for: Change Control, Deviations, Non-Conformances, OOS, Investigations, CAPA, Audits and Complaints.
2. Controlled Documents management: Specs, SOPs, Methods, Protocols, etc.
3. Training Records management.

Examples of QMS software systems: SOLABS QM, Trackwise, Pilgrim.

7. How do I get corporate compliance and QA comfortable with SharePoint being a repository for compliance records?

By stating that you are using SharePoint as a compliant "repository", you can narrow the scope of your validation effort to the following elements/activities: I.Q, Backup, maintenance and security SOPs, and functions used in the Publication and Archival of documents (e-records). That would mean that for instance you would categorize and publish a scanned version of a change control form (officially signed-off on paper). Also, ensure that all of the applicable Part 11 requirements are reflected in the user requirements that you develop for your solution.

8. I'm looking to implement an e-change request system (validated) for application and Infrastructure changes in SharePoint.

An e-change request system will typically include these components: e-sign + workflows+ audit trail. We did not touch Forms and Infopath in the Jan-27 Webinar as it will be a topic for a future webinar. That being said, the main items to address from a regulatory perspective are: e-signature, audit trail, and validation. Here I would encourage you to consider the 3 options discussed in the webinar as e-Change Request processes are considered "off-the-shelf" in QMS software systems.

9. Does SP have e-publishing capability?

Yes it does offer some basic publishing capabilities e.g. you can have an "Approved document" (Not part 11 compliant off-the-shelf) automatically published to all users. Also there is a "Send To" function in SharePoint that can be used on a per document basis to address certain publishing requirements. SharePoint does not offer advanced publishing functions such as those rendered possible with e-CTD publishing suite.

10. Which SP version is current for QMS integration?

SharePoint 2007

11. Is it possible for you to demo or show us solabs integrated with sharepoint?

Yes: please email info@solabs.com.

12. In your opinion, what is the best e-signature add-in for SharePoint Services 3.0?

The SAFE-Biopharma Association might be a good source to obtain neutral information on this subject. We have not performed an evaluation of the e-signature add-ins for WSS 3.0.

13. When talking about "options 2 and 3," you need MOSS (versus WSS), right?

Option 2 will lead you towards MOSS where in option 3, as the QMS component is independent of SharePoint, you are free to choose the role of SharePoint when dealing with compliant information. For instance you might want to use WSS 3.0 on a corporate-wide basis and leave all "Compliant Actions" in the QMS software. The interface between the 2 systems could be limited to having the QMS Software send "Approved and Effective" documents in a SharePoint site for general access.

14. What does Solabs offers in term of services regarding sharepoint?

SOLABS and QPharma can help you enable SharePoint ECM functions in a compliant manner, covering everything from requirements gathering through to implementation and validation. (info@solabs.com)

15. What are the benefits of Office 2007 over 2003 in working with Sharepoint? Future upgrade plans/ benefits in 2010?

Defenitively Office 2007/2010 have important advantages in dealing with SharePoint 2007/2010 e.g. the possibility to compare versions in Word directly, the possibility to start Workflows, etc.
You can find more details in searching for "office 2007 sharepoint integration" in google.

16. Can we see what sharepoint actually looks like meaning the interface?

You can easily find comprehensive demos on office.Microsoft.com e.g.:
<http://office.microsoft.com/en-us/sharepointtechnology/HA102055631033.aspx>
Also the SharePoint 2010 (soon to be released) site is:
sharepoint2010.microsoft.com

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