STRONG ELEMENTS IN FAVOR OF SOLABS QM©

THE GREEN MACHINE!

The Implementation of **SOLABS QM** provides a cost effective solution to go green.

Produce electronic official records in **SOLABS QM** as easily as when dealing with paper!

OUR HYPOTHESIS: CONCEPTION ABOUT PAPER IS WRONG

SOLABS QM has been developed on the hypothesis that we – IT engineers – often have a wrong conception about paper. When your job is to develop and deploy computerized systems replacing paper-based system, your conception about how people use paper is quite important. Design choices affecting how people interact with your system are highly correlated with what you are trying to replace – i.e. in SOLABS' case a paper-based QMS (quality management systems).

We have designed SOLABS QM with one important thing in mind – it has to replace a system that has been in place forever and has proven to be effective in addressing quality system regulations. Interesting challenge we found!

Over the years, we have seen many systems trying to *mimic* paper forms, assuming our clients or soon to become clients idolized the look and feel of paper. We believe this is a strong perception – but nowhere close to reality.

Our hypothesis is the following:

"What people like about paper is not the format by itself – it's the flexibility it brings!"

True, just imagine the limitless possibilities paper brings: easily find a paper form on your desk (it's definitively somewhere in the pile), easily send it back to a colleague with comments, write a few words and come back at a later stage to complete the form, etc.

This hypothesis has been driving the evolution of SOLABS QM.

PAPER VS SOLABS QM – THE GREEN MACHINE!

Today the vast majority of companies would go electronic and stop wasting paper if they had an equivalent option. With SOLABS QM, we did our best to offer a smooth transition from a paper-based system to a computer-based environment.

The following table provides a summary of the main SOLABS QM capabilities involved in the management of controlled documentation, and describes how SOLABS QM can help you move to a **greener** environment, easily!

Note: This table refers extensively to "Processes". An introduction to SOLABS QM processes is provided in the following section. If you are not familiar with automated business processes, you might want to consider reading this introduction now, and then come back to the following table.

SOLABS QM - CAPABILITIES	HOW CAN THIS BE DONE WITH PAPER?	HOW CAN THIS BE DONE WITH SOLABS QM?
1. Return forms to initiator for changes instead of having to do it yourself. (JBPM- real business process engine)	Cumbersome: Requires logistic management	**Easy** : one click (*Return to Initiator* option)
2. You only see what you need to fill out in forms.	Challenge: People usually do not cut forms in many pieces...	**Easy:** WYSIWYN You are presented only the fields you need to fill-out in forms.
3. The electronic forms are built in PDF as you fill in the data, in sync with the progress of quality processes.	Cumbersome: After making a few changes on a paper form, you may require an expert in cryptography to read the form...	**Easy:** A "Summary Report" is generated in PDF containing only official data confirmed (the audit trail is displayed independently).
4. Processes are graphically represented in a flowchart with real time indication of **the progress of the process.**	Not available	**Easy:** System users appreciate to view where they are at in a Change Control process for instance. However, the real underlying advantage of our processes is how they help you enforce compliance.
5. Attach external documents to processes (e.g. Change Control evidences)	Challenge: You can easily attach documents. The problem is to keep those organized…	**Easy:** Each process in SOLABS QM is created with the possibility to add external documents to it.
6. Assign secondary tasks (not planed at first) e.g. tasks required in a Change Control implementation phase.	Challenge: You can easily get lost in following up with secondary tasks.	**Easy:** Each process in SOLABS QM is created with the possibility to assign secondary tasks to anyone, and to track those until completion.
7. From the moment a process is created, it is indexed – searchable	Not available	**Easy:** Type a product name, a batch number, an instrument number, etc. – if it's been entered, you'll find it.
8. Access to processes is linked to privileges.	Challenge: As long as your binders are well organized and safely stored.	**Easy:** If you have nothing to do with CAPAs, you won't see any of them.
9. Processes have a life; they are opened or closed (visibility)	Challenge (Status logs need to be maintained manually)	**Easy** (real-time visibility)
10. Reporting is easy, reports are clear	Easy *(but* often after the fact)	**Easy** (real-time visibility)
11. Notification on particular events to individuals that are not involved in the process	Challenge (Manual via coordinators)	**Easy** (Automated via email)

SOLABS QM - CAPABILITIES	HOW CAN THIS BE DONE WITH PAPER?	HOW CAN THIS BE DONE WITH SOLABS QM?
12. Supervisor acknowledgement, notification based on the identity of the initiator	Easy (assuming your supervisor's desk is not too far)	**Easy** (Automated)
13. Delegation of tasks	Cumbersome: Always difficult to notify everyone just before you leave.	**Easy:** So easy it's tempting to use delegation while you are at work…
14. Initiation from an external source ex: scanning a form can start processes automatically	N/A	**Easy:** Processes can be integrated with external applications to be initiated automatically.
15. Integration with an ERP system ex: extract lot numbers	Challenge: Manual and error prone	**Easy:** Enter a batch number, and extract all related information to populate fields in SOLABS QM.
16. Only publishes the approved & effective document, cannot be deleted	Cumbersome: Publishing is a based on procedural mechanism (manual)	**Easy:** Publishing is automated.
17. Converts every document in a PDF format with an electronic signature stamp on the PDF	Easy (with a good scanner)	**Easy** (Automated)
18. SharePoint Interface	Challenge (a manual one): Scanned paper copy can sent to SharePoint	**Easy** (Automated): Approved and effective documents are automatically published in Document Libraries.
19. Training records are linked to documents requiring training	Cumbersome: Training forms can get lost.	**Easy:** Training records are electronic and real-time information on training gaps is available.
20. Stores the history of training records	Easy (with binders)	**Easy** (with a database)
21. Search tool: find a document by content or attribute	N/A	**Easy:** You can search in document contents (e.g. Word documents) and/or in Metadata (Title, Author, etc.).
22. An inventory of all active documents is available at all times	Cumbersome (Labor-intensive)	**Easy** (Real-time)
23. A Document Control process, manages all document management steps from A to Z from a change request to publishing, and including training if applicable	Cumbersome: Once a document number has been assigned, document specialists and/or coordinators have limited visibility on the review and approval processes.	**Easy:** Document specialists and/or coordinators have clear visibility on the amount of documents they have in process at all time.

SOLABS QM - CAPABILITIES	HOW CAN THIS BE DONE WITH PAPER?	HOW CAN THIS BE DONE WITH SOLABS QM?
24. 100% web-based, no installation on your pc	N/A	**Easy:** As long as you have access to your network, you have access to SOLABS QM.
25. Accesses to documents are controlled by groups	Easy *but…*: You must have the key...	**Easy:** Security is granular to specific documents or processes.

INTRODUCTION TO PROCESSES IN SOLABS QM

As SOLABS QM's Processes are being referred to extensively in the previous section of this document, you will find here a small introduction to SOLABS QM's PROCESS module.

The Process module is used for processing forms electronically and also monitoring the progress of secondary tasks related to those processes. Forms are filled-out within what is referred to as a Process in SOLABS. A process consists of various process steps (or process tasks) assigned to users or roles, as shown on a process flowchart. SOLABS' Process module is used to electronically circulate Change Control forms, Deviation forms, CAPA forms, and other forms linked to controlled business processes.
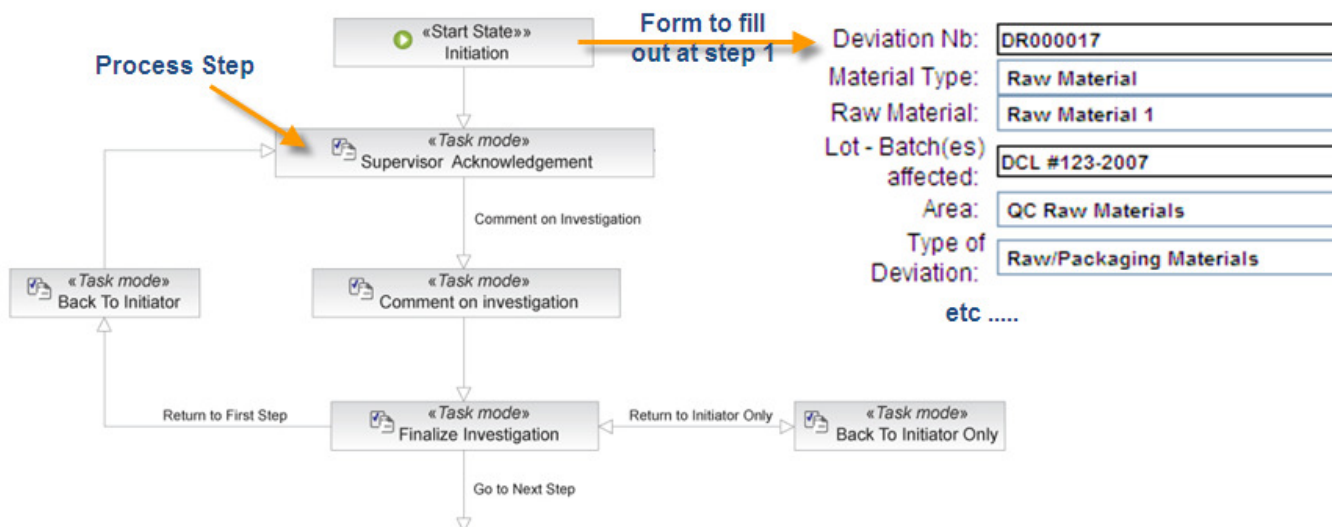

FIGURE 1. A process consists of various process steps (or process tasks) assigned to users or roles, as shown on a process flowchart.

For more information on our typical quality processes, e.g. CAPA, OOS, Change Control, etc. – please visit our Web site at www.solabs.com.

CONCLUSION

If you are considering going from a paper-based or hybrid (Paper combined with Excel, Access, etc.) to a QMS Software Solution, we'd be interested to explain our hypothesis and conception about paper in more details.

ABOUT SOLABS

SOLABS offers a QMS Software for GxP regulated organizations. The system has proven to be the Easiest QMS software to Operate in the market. The company founded 10 years ago has gained a leadership position in Canada. SOLABS addresses the needs of mid-size Life Science companies by offering a simple & well priced solution. Many clients using SOLABS QM have successfully been audited by Health Canada and/or FDA.

For more information, please visit our website at www.solabs.com or contact us at info@solabs.com.