



Controlled Documents

- SOPs
- Test Methods
- Specs
- Protocols
- And more



Quality Processes

- CAPA
- Change Control
- Deviations
- Complaints
- And more



Training records and Profiles

- Courses
- SOPs
- On-the-job
- And more

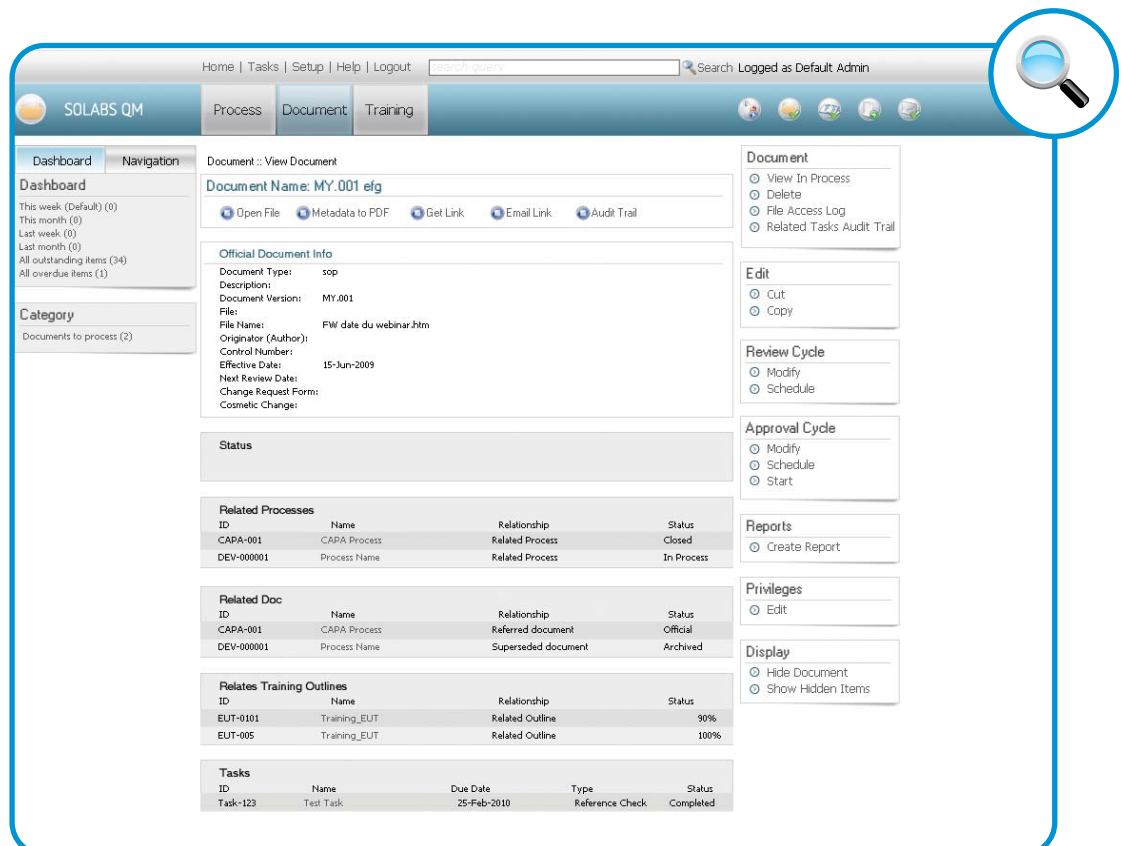
E-QMS system specifically for Life Sciences companies

ONE core software system validated once.

SOLABS offers an integrated software solution which helps improve Quality operations and processes, and provides critical compliance with 21 CFR part 11 and other regulatory requirements. The SOLABS solution has proven to be easy to use, operate and maintain. SOLABS has been a market leader in Canada by deploying best in class Quality solutions exclusively for the Life Sciences market for more than ten years. SOLABS delivers a complete solution including software, services and support in a simple, cost-effective manner.

Companies choose SOLABS because:

- We understand regulations and best practices related to Life Sciences organizations
- We adapt processes such as CAPA and Change Control to their practice and not vice-versa
- We manage implementation projects and actively support validation efforts
- We offer data migration services
- We train coordinators and system administrators



The screenshot displays the SOLABS QM software interface. The top navigation bar includes 'Home | Tasks | Setup | Help | Logout' and a search field. The main content area is divided into several sections:

- Dashboard:** Shows summary statistics for 'This week (Default) (0)', 'This month (0)', 'Last week (0)', 'Last month (0)', 'All outstanding items (34)', and 'All overdue items (1)'. It also includes a 'Category' section for 'Documents to process (2)'.
- Document View:** Displays 'Document Name: MY.001 efg' with options to 'Open File', 'Metadata to PDF', 'Get Link', 'Email Link', and 'Audit Trail'.
- Official Document Info:** Lists details such as Document Type (sop), Description, Document Version (MY.001), File Name (FW date du webinar.htm), Originator (Author), Control Number, Effective Date (15-Jun-2009), Next Review Date, Change Request Form, and Cosmetic Change.
- Status:** A section for document status.
- Related Processes:** A table showing CAPA-001 (CAPA Process, Closed) and DEV-00001 (Process Name, In Process).
- Related Doc:** A table showing CAPA-001 (CAPA Process, Official) and DEV-00001 (Process Name, Superseded document, Archived).
- Relates Training Outlines:** A table showing EUT-0101 (Training_EUT, 90%) and EUT-005 (Training_EUT, 100%).
- Tasks:** A table showing Task-123 (Test Task, Due Date: 25-Feb-2010, Type: Reference Check, Status: Completed).
- Document Actions:** Includes 'View In Process', 'Delete', 'File Access Log', and 'Related Tasks Audit Trail'.
- Edit:** Includes 'Cut' and 'Copy'.
- Review Cycle:** Includes 'Modify' and 'Schedule'.
- Approval Cycle:** Includes 'Modify', 'Schedule', and 'Start'.
- Reports:** Includes 'Create Report'.
- Privileges:** Includes 'Edit'.
- Display:** Includes 'Hide Document' and 'Show Hidden Items'.

Integrated system to manage Quality Processes, Controlled Documents and Trainings Records in one user-friendly interface.

Quality processes management



(CAPA, Change Control, Deviations, Complaints and more)

- Processes have a life; they are opened or closed (visibility)
- Reporting is easy, reports are clear (annual product review)
- The electronic form builds itself as you fill in the data, in sync with the advancement of the process.
- Workflows are graphically represented in a flowchart real time indication of where the process is at.
- You only see what you need to fill out in forms.
- Return to initiator for changes instead of having to do it yourself (JBPM-real business process engine)
- From the moment a process is created it is indexed-searchable
- Integration with an ERP system ex: extract lot numbers
- Initiation from an external source ex: scan form starts process automatically
- Attach documents to processes + secondary tasks (not planned at first) all linked together
- Assign tasks to individuals, groups of your choice for each process. Processes are not pre-configured in advance (investigator, reviewer and approver)
- Notification on particular events to individuals that are not involved in the process
- Supervisor acknowledgement, approval based on the identity of the initiator
- Delegation of tasks

Controlled documents management



(SOPs, Test Methods, Specs, Protocols and more)

- Only publishes the approved & effective document
- Converts every document in a PDF format with an electronic signature stamp on the PDF
- Part 11 compliance to control documents. All stays in 1 system, no more scanning after signing
- Review cycle is open: reviewers can add comments on the previous reviewers commented version
- Search tool: find a document by content or attribute
- An inventory of all active documents is available at all times
- Can be interface with SharePoint
- The document change control process, manages from A to Z all the steps of the change request to publishing including training if applicable
- Data migration services, allows to upload batches of data with a simple excel template

Training records and profiles management

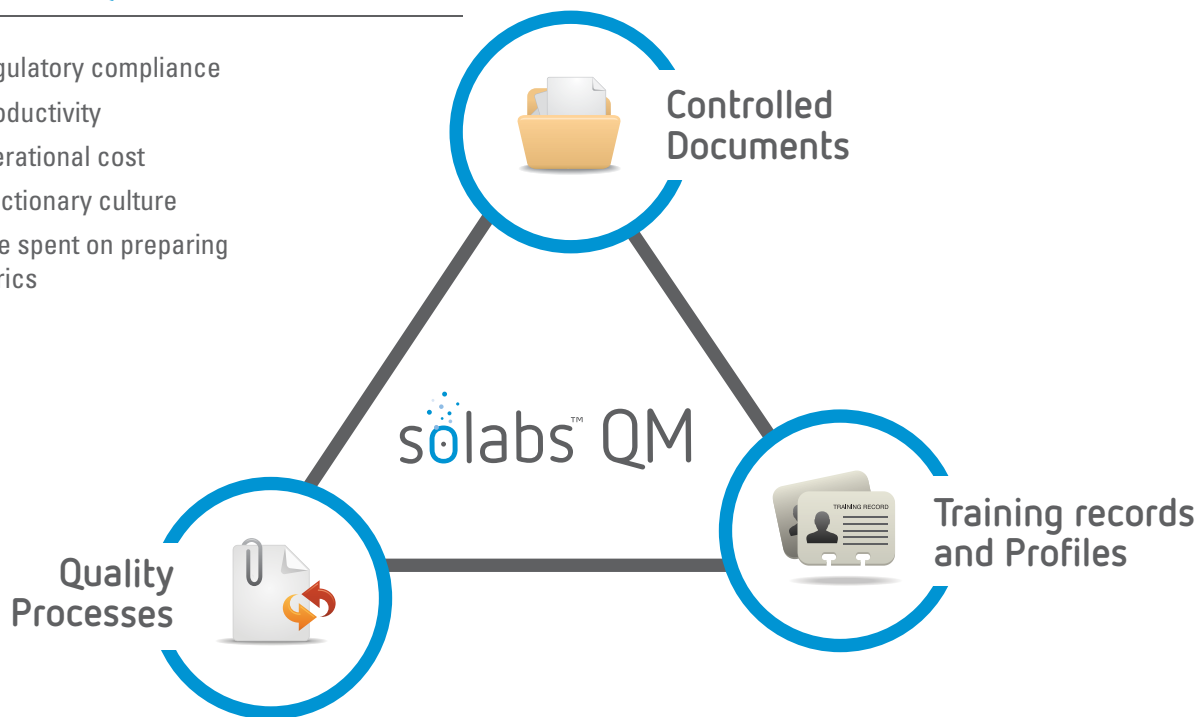


(Courses, SOPs, On-the-job and more)

- Training records are integrated with documents requiring training
- Training profiles based on job functions
- Stores the history of training records
- Electronic confirmation of training for trainees & trainers

With SOLABS QM

- Improve regulatory compliance
- Improve productivity
- Reduce operational cost
- Reduce reactionary culture
- Reduce time spent on preparing quality metrics



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