SOLABS QM APPS
Overview

Developed for companies in the following industries:

BIOTECH

MED DEVICE

PHARMA

R&D

VIRTUAL

INTRODUCTION

With SOLABS QM, you manage quality processes, controlled documents and employee training under the same user interface. We like to refer to this as the holistic approach to managing quality operations.

SOLABS has developed choices of individual APPS to manage each quality process rather than following the legacy module approach. Modules are not user friendly, they don't speak to each other, require extensive configuration, and extensive user training. Most of all, modules aren't linked out of the box with the rest of the quality management system. SOLABS QM **is** a single integrated EQMS system.

SOLABS QUALITY & BEST PRACTICES UNIT

"I've had about 40 combined years of experience in the pharmaceutical industry. I retired from Sunovion Pharmaceuticals almost four years ago, after serving as their VP of Quality Operations, and soon afterwards, Philippe Gaudreau [SOLABS Founder & CEO] approached me about joining to help with SOLABS' Quality Processes, or QM APPS.

My role at SOLABS, for the past few years, has been Head of the Quality and Best Practices Unit, and my job is to develop the Quality APPS, which are basically various flavors of business processes such as Change Control, CAPA, Non-Conformance, and Complaints, for example. I work with the SOLABS team to develop these APPS to such a point that they meet clients' needs out of the box.

The part I really enjoy is working directly with clients by hosting on-site workshops to customize the APPS, to meet their specific business requirements, goals and terminology. It provides me an opportunity to share my experience with the clients, and to help them optimize their Quality Processes."

- Brian Graeff, Head of the Quality & Best Practices Unit, SOLABS

Clear Benefits of the SOLABS APPS MODEL

APPS are easily deployed within SOLABS QM under the same user interface with the same menu actions

APPS are available in several flavors for each process--the only common denominator being that they must respect regulatory requirements and guidelines

APPS benefit from the integrated support of the Document and Training sections, *e.g., a CAPA process can monitor completion of a Training activity, or an Audit process may incorporate the use of standard response letters*

APPS flavors allow for a close-to-perfect fit for most life sciences companies

APPS can be deployed out of the box without the need for never-ending configuration exercises

APPS can easily be tweaked to fulfill specific requirements or business models

APPS have been built through 10 years of R&D efforts, conducted in partnership with the life sciences: pharmaceutical, medical device, and biotechnology companies

APPS are aligned with standard industry requirements. They follow guidance from the FDA, EMA and Health Canada

APPS can be deployed in SOLABS QM at any time, allowing for short phased implementations

APPS are being developed, built, and deployed constantly, and our goal is to have over 100 flavors of APPS to choose from. They can also be completely client-specific. If we don't have the APP you are looking for, we can easily build it from one of our templates

APPS are flexible enough to support any configuration, e.g., having two distinct Change Control processes (Internal and Vendor for instance), or extracting Investigations from Quality Events processes, such as Deviations or Complaints

APPS can easily be retired and replaced. If your APP no longer fits your company's culture/maturity level, simply retire it, archive the data, and start using a new APP

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Features Common to All
SOLABS QM APPS

APPS are based on roles and privileges: Users need to be assigned the appropriate role or rights to initiate and/or act in a Process

Users receive both email and homepage notifications when they have an action to perform in the system

Follow-up on ongoing tasks and activities is automatic through extensive views and reporting capabilities

Metrics can be extracted to demonstrate adherence to certain established completion delays

Critical and required data is captured in the Audit Trail. The audit trail may never be deactivated or turned off

e-Signature with username and password is mandatory to fill-out and submit a form

Progress may be tracked in real time to ensure completion

All completed Process forms can be returned to initiator for modifications

In most processes, approval to proceed is done by Supervisor, Department Head or SME

Search can be conducted across all Processes by process name or keyword contained within each one

A unique ID Number is automatically assigned to each process

Supporting documentation, such as pictures, documents, or videos, can be attached at any step of the process

Trending and reporting on process statuses is accessible at any time

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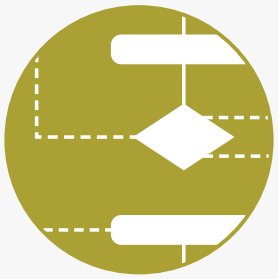

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CHANGE CONTROL | COMMON FEATURES

- ☑ At initiation, you can select change types or categories (Facility, Equipment, Computerized System, etc.)
- ☑ The choice of Change Type will impact which fields are displayed and flow of the process
- ☑ Change description, justification, and proposed implementation dates are captured within the process
- ☑ Change Control coordinators or SMEs are responsible for reviewing changes and selecting approvers. Approvals are done in parallel for greater efficiency
- ☑ Pre- and post-implementation tasks can be included by initiators, SMEs and Supervisors
- ☑ Clear priority levels to choose from: Major, moderate or minor
- ☑ Impacted documents and changes to these documents are taken into consideration, and follow-up actions may be assigned if needed
- ☑ At time of implementation, impacted documents can all be set effective at the same time
- ☑ Extension delays need to be approved and documented
- ☑ Effectiveness Check Verifications may be built into each Change Control process
- ☑ Completion of Pre- and Post-Implementation Tasks is recorded by the assigned users
- ☑ Regulatory Assessment may be built into each process
- ☑ Change Control form, Pre- and Post- Actions, related processes and attachments are all visible on the same page
- ☑ Change Controls can be triggered from other current processes to create a parent-child relationship
- ☑ Seamless integration with ERP systems to auto-populate or validate information, such as lot number, product, supplier, equipment, etc., is available
- ☑ The final step in most Change Control processes is closure by QA

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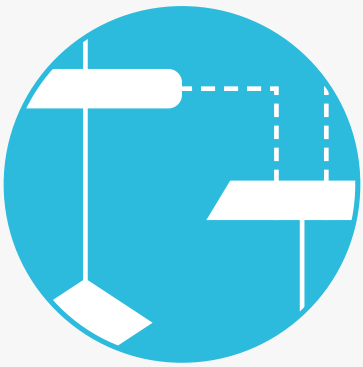
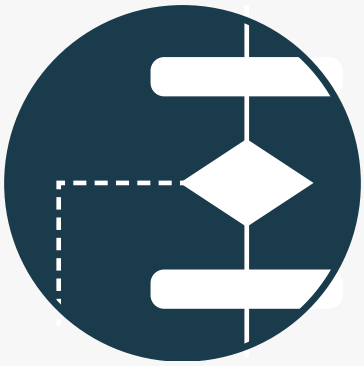


CAPA | COMMON FEATURES

- ☑ At the minimum: CAPA Type (CA/PA), person responsible, Source, Due Date, and CAPA Plan are captured at initiation
- ☑ CAPA Risk Management Category is captured at initiation and may be changed by Quality
- ☑ Quality approves the CAPA Plan before it is released and made official
- ☑ The CAPA Plan automatically creates Actions (tasks), which are assigned to users after the plan is approved
- ☑ Extension delays need to be approved and documented
- ☑ Effectiveness Check Verifications are built into each CAPA
- ☑ Completion of Training Activities can be monitored by managers, training administrators or document coordinators
- ☑ The CAPA form, CAPA actions, related processes and attachments are all visible on the same page
- ☑ CAPAs can be triggered from other ongoing processes, such as Deviations, to create a parent-child relationship



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QUALITY EVENTS (COMPLAINTS, DEVIATIONS, NON-CONFORMANCE) | COMMON FEATURES

- ☑ Fields exist to capture investigations, root cause and conclusions
- ☑ Review/Approval is done by Supervisor or Department Head
- ☑ Ability to have links established between processes to create a dependency
- ☑ Ability to record remedial actions assigned to specific users
- ☑ Disposition decision on any affected material is included as released, rejected or partial release
- ☑ Option to initiate an investigation that remains linked to the event
- ☑ Ability to perform & track events per supplier
- ☑ Seamless integration with ERP system to auto-populate or validate information such as lot number, product, supplier, equipment information, etc.
- ☑ Seamless integration with CRM system to validate information such as client information, complaint summary, etc.