



**solabs**

Passionate  
about Quality  
Automation

# CAPA | APP-P0013 Overview

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## Overview

Developed for companies in the following industries:



BIOTECH



CONTRACT  
MANUFACTURING



INTEGRATED  
PHARMA



R&D



VIRTUAL

### ABOUT THIS QM APP

*"This is a fairly straightforward, but thorough, CAPA Process—with the ownership of the Action Plan by department heads or stakeholders as one of its chief differentiators.*

*This CAPA would be ideal for a Contract Manufacturing Organization, a fully-integrated Pharmaceutical company, or one with Manufacturing operations.*

*The number of steps places it somewhere in the middle of the spectrum in terms of complexity, and makes it suitable for an organization with multiple departments and of a certain size.*

*In terms of industry, this CAPA would suit the needs of those who need absolutely unambiguous buy-in from department heads or stakeholders."*

– Philippe Gaudreau, Founder & CEO, SOLABS

### HIGHLIGHTS

- The Action Plan is created at Step 1, along with the secondary tasks that address the component parts of the Plan
- The Department Head then either approves it and the process moves forwards, or sends it back to the Initiator where required for more information
- A QA evaluation is then conducted to ensure approval from Quality
- Further Assignments at this stage may involve work from various stakeholders and/or departments
- Acceptance of the Action Plan is required, in parallel, by different departmental stakeholders
- A more formal QA approval follows before any secondary tasks are created or assigned
- Users can then decide if they're implementing a voluntary effectiveness check or not, before close-out by QA

### DEVELOPED BY SOLABS

The SOLABS QM APPS team have assembled a range of powerful and contextually-indispensable workflow APPS to manage Life Sciences Quality Processes, all powered by the SOLABS QM 10 Business Process Engine.

These proprietary workflows have been assembled and tested over 10 years, and with the combined expertise and resources of our staff, many of whom have spent part or all of their careers in pharmaceutical, medical device, and biotechnology companies. Their tested and true arsenal of business workflow processes are used daily by users all over the world.

The SOLABS team constantly continues to grow our APPS library. If we don't currently have an APP that fits 100% of your requirements, it's a safe bet it's currently being developed—and all of our APPS remain fully configurable.

# CAPA | APP-P0013 Flowchart

## PHILIPPE GAUDREAU SAYS

*"Our full-featured CAPA processes built around recommendations from our Best Practices Unit all include: i) secondary tasks, ii) extension requests, iii) CAPA categorization, and iv) an effectiveness check. These, respectively, introduce iterative looping of all dependent tasks; accountable and tracked flexibility; tightly defined and articulated scoping; and a clear, unambiguous reading of the stakes."*

? = Decision

