

AUDIT | APP-P003

Overview

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Developed for
companies in
the following
industries:



BIOTECH



MED DEVICE



PHARMA



R&D



VIRTUAL

ABOUT THIS QM APP

*"This audit process is unique and innovative for SOLABS. All of the previous audit processes we built had 8-10 steps and were quite complex. So we took a step back and wondered, can we simplify an audit process without loss of detail or flexibility? We had to be absolutely certain: did it circulate, process, and fulfill all of the promised functionalities? The answer was yes—so we built it, deployed it and, since then, clients have given us great feedback! This process is sophisticated in terms of what it demands from our EQMS, **SOLABS QM**, yet very simple to use from an end-user standpoint." --Philippe Gaudreau, Founder & CEO, SOLABS*

HIGHLIGHTS

- The process starts with either actual audit findings, or with anticipated points the company wants to address to prepare for an upcoming audit
- At Step 2, called **Action Plan**, there may be several action plans, assigned to multiple users, with one or more **Plan** (made up of **Tasks**) per user, running **in parallel**
 - Each of these **Action Plans** are assigned simultaneously, and each can be sent independently for **QA Review at Step 3**, and loop until the action plan is approved
 - Further **Parallel Tasks** are assigned to users, one by one, as a way of incrementally completing the actions required to address the findings
- Users report back their **Findings**, and these are submitted, independent of one another, until the resolutions are implemented
- The **Audit | APP-P003** is linked to the **Document Control** functionality in **SOLABS QM**, where you can create, review, approve, and link Audit Agendas, Audit Reports, etc.
- Companies can take advantage of the ease of integrating off-site and/or out-of-country consultants, clients, suppliers, etc., by using **External** user accounts in **SOLABS QM**

AUTHORS

Martine Boire, QA Director, SOLABS



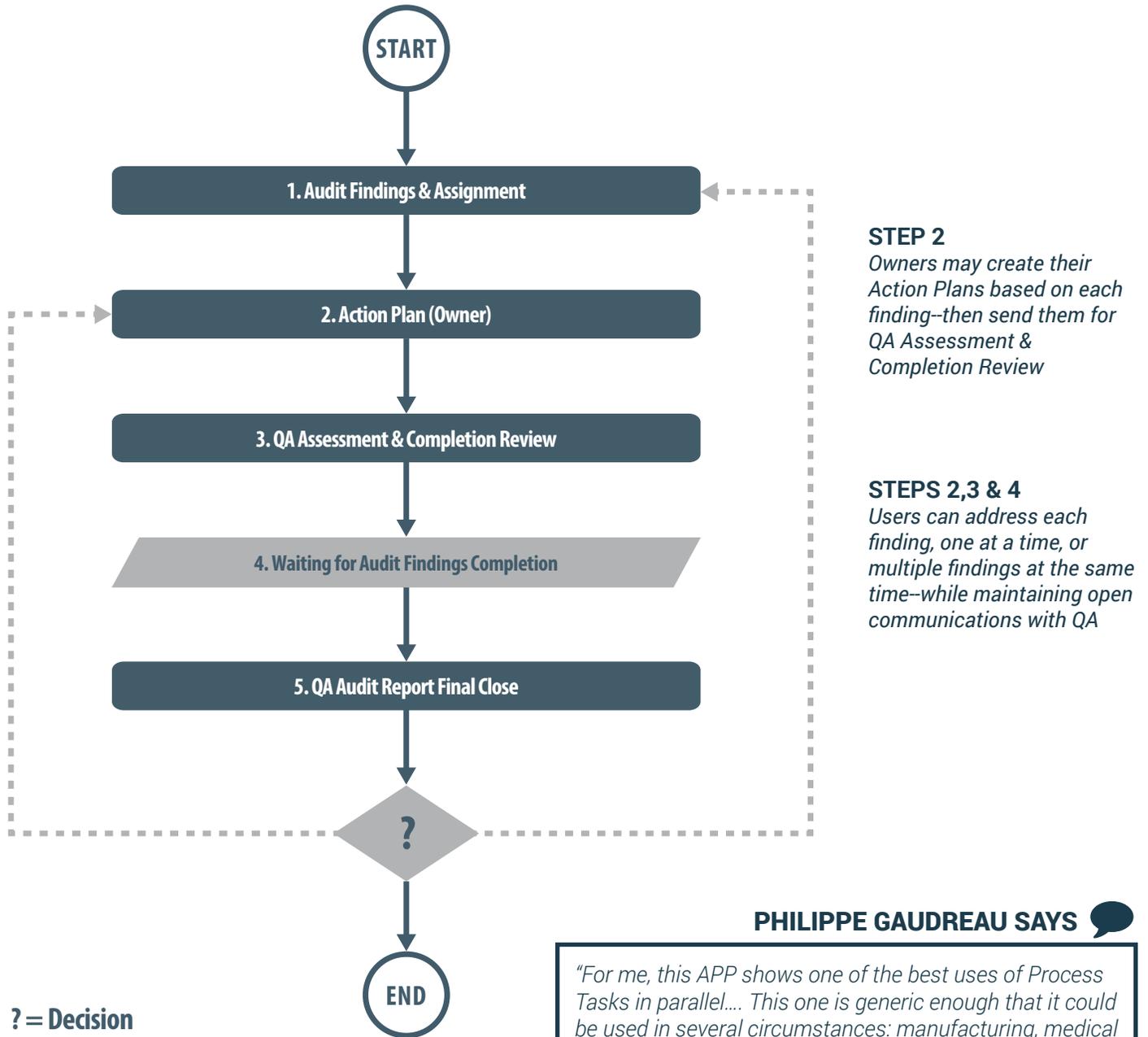
With a BSc in Nutrition, and originally a Nutritionist by discipline, Martine's career path changed when she accepted a job in the Pharmaceutical Industry as a Compliance Auditor for Document Batch Records. She worked in the Pharmaceutical and Medical Device Industries for 12 years prior to joining **SOLABS**. With almost 10 years at **SOLABS**, Martine, our Director of Quality Assurance, is a force to be reckoned with, overseeing Quality Assurance, Product Development and Validation activities for an ever-growing client base.

Philippe Gaudreau, Founder & CEO, SOLABS



As CEO of **SOLABS**, and almost 17 years after co-founding the company, Philippe Gaudreau continues to grow an avid interest in quality management and compliance practices in the Life Sciences. He is passionate about finding best in class solutions, with the goal of helping our Life Sciences clients automate their quality operations without losing the flexibility they have with their manual systems. He offers his expertise through his devotion to software development, his deep knowledge of business process management and optimization, and his expertise in document life cycle management.

AUDIT | APP-P003 Flowchart



PHILIPPE GAUDREAU SAYS

"For me, this APP shows one of the best uses of Process Tasks in parallel.... This one is generic enough that it could be used in several circumstances: manufacturing, medical device, contract manufacturing, etc.... The SOLABS Quality Best Practices Unit, along with our SMEs and the rest of our Development team, will be creating more targeted flavors of the Audit process in the months to come.... But this one will remain core, because of the great structure, the flexibility, and ease of use."