

DOCUMENT CONTROL | APP-P0007 Overview

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Overview

Developed for companies in the following industries:



BIOTECH



MED DEVICE



PHARMA



R&D



VIRTUAL

ABOUT THIS QM APP

"This APP provides high levels of efficiency to the document control group by automating all clerical tasks such as expediting, routing, triaging, and division of tasks. It also facilitates sorting and grouping of documents by type, owner, status or version, etc. I like to compare it to the use of the hub approach by large shipping companies, in the sense that it centralizes critical elements of document control: tracking, triage, follow-up, training, data integrity, and process efficiency..."

*This APP is built using a true Business Process Engine, which ensures no steps are skipped, the process keeps advancing, triggers are closely monitored and compliance is always retained. Document Control groups often refer to this APP as an automated administrative assistant that comes with a flexible and powerful super-set of features, which work in concert across all three SOLABS QM sections (**Document, Training and Process**)."*

--Philippe Gaudreau, Founder & CEO, SOLABS

HIGHLIGHTS

- Step 1 is key in this process as it allows any user company-wide to make a Document Control request, based on permissions and roles in the system
- The two '**Waiting**' steps, Steps 3 and 5, are not 'wasted' time: the SOLABS QM Business Process Engine monitors the process periodically, to ensure whether pre-specified conditions have been met, i.e., trainings have been triggered and completed, documents have been approved, etc.
- Outstanding or incomplete Document Control requests can be obsoleted after a pre-defined period of time (with notifications) as a way of limiting administrative delays and establishing priorities and benchmarks
- At **Step 4**, a Training Completion step ensures that user training is completed before a document is made effective
- Overall, the Process facilitates volume of work, automation of disparate tasks spread between users and offices, and standardizes and expedites routine tasks

AUTHORS



Martine Boire, QA Director, SOLABS

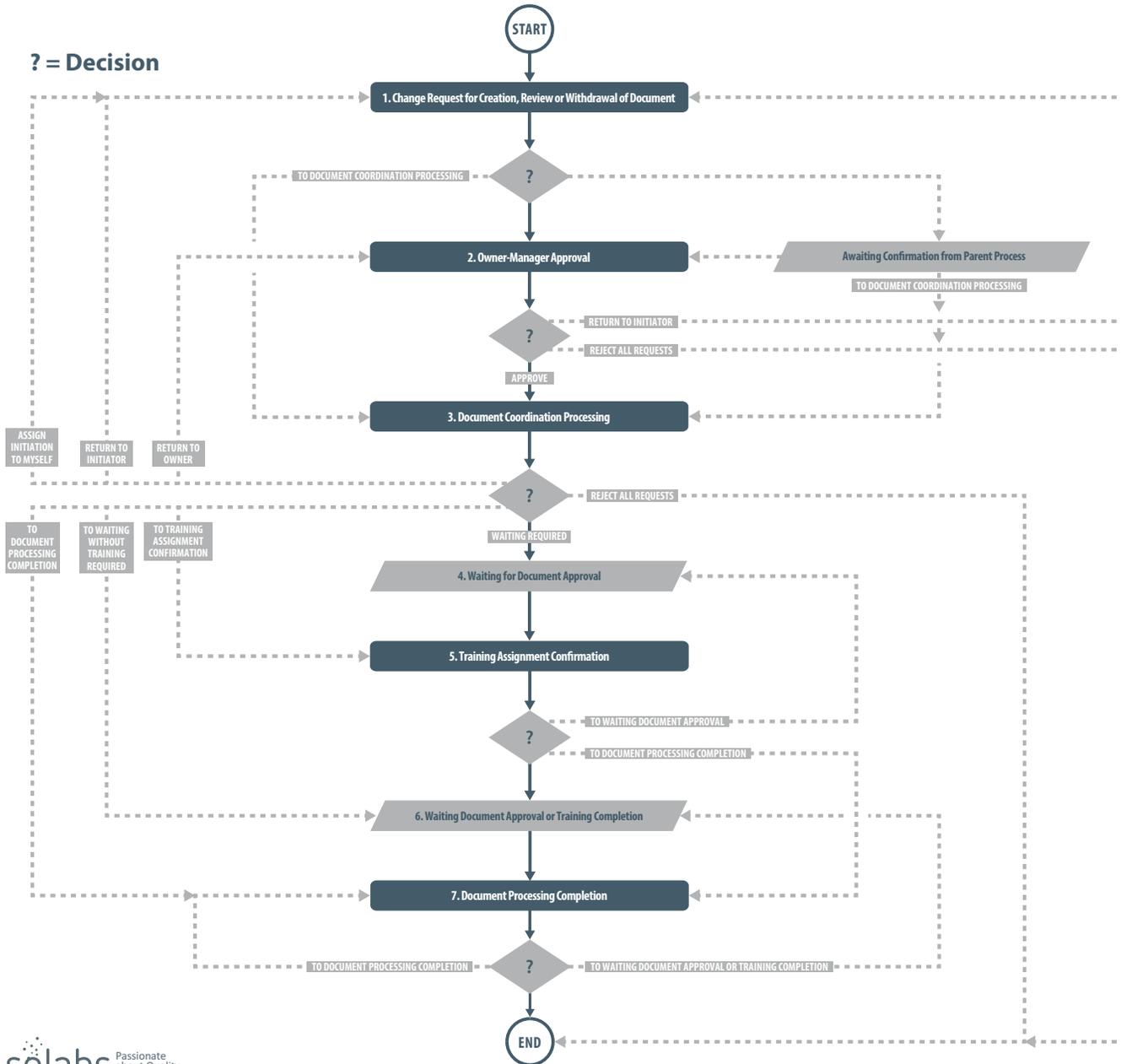
With a BSc in Nutrition, and originally a Nutritionist by discipline, Martine's career path changed when she accepted a job in the Pharmaceutical Industry as a Compliance Auditor for Document Batch Records. She worked in the Pharmaceutical and Medical Device Industries for 12 years prior to joining **SOLABS**. 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.

DOCUMENT CONTROL | APP-P0007 Flowchart



MARTINE BOIRE SAYS

"If you have a manual routing system—that doesn't route tasks between people, keep things moving, perform updates, and trigger subsequent events—then you are at risk of non-compliance. This particular app has been optimized from our years of R&D experience, our observations and best practices unit, and it leverages the SOLABS QM Business Process Engine at its most powerful. This APP also, as with others, exploits our accumulated expertise and strengths, and touches the Document, Training and Process sections—the three pillars of any Quality Management System.

As complex and powerful as it is, it shows only its most straightforward features to most users, and reserves its specialized, most powerful functions for those who do Document Coordination for a living, or who've been tasked with it. These Document Control units are what I like to refer to our Super Users, they're in the system regularly, and are the ultimate experts when it comes to advanced functionalities. Since they only represent a very small portion of employees in any given company, training them is quite simple and very straightforward. This process has been used for many years now and, although we have every reason to be really proud of it, we're always excited to receive feedback, which helps us to make small yet important improvements over time."