



# COMPLAINT | APP-P028

## Overview

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Developed for companies in the following industries:



BIOTECH



MED DEVICE



PHARMA



R&D



VIRTUAL

### ABOUT THIS QM APP

*"Complaints themselves are not inherently complex, but this process routes the complaints **for a Virtual Company through a CMO** (Contract Manufacturing Organization)—someone else manufactures their products, even though their name is on the label, and the administrative work is theirs. Even this fairly specific situation can change a lot depending on whether, say, you're a pharmaceutical company or a medical device company, both of which are cases we've dealt with lately. Above all, though, this APP is very good at tracking complaints across the complexities of outsourced manufacturing and virtual landscapes."* --Brian Graeff, Head of the Quality & Best Practices Unit

### HIGHLIGHTS

- From **Step 4 Investigation**, Additional Tasks that arise as a result of the main investigation can be launched, permitting users to run tasks until they are completed: these are peripheral but related items required for the Complaint to be closed
- At **Step 4, Extension Requests** on assigned tasks may be made and approved/rejected as required. QA is almost uniformly tasked with the approval/rejection of these requests
- A child **CAPA Process** can be launched from this APP if this is seen as a resulting requirement of the Complaint Process

### AUTHORS



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

Brian Graeff's career in the Pharmaceutical industry spans over 39 years. He has held various management positions in Quality Assurance, Quality Control and Production. Brian brings a wealth of experience in pharmaceutical manufacturing, quality management, and CGMP interpretation and implementation to SOLABS. He believes that "focusing on the fundamentals" is the key to product quality, compliance and maintaining a company's license to operate.



#### Anne-Marie Pinet, Product Analyst, SOLABS

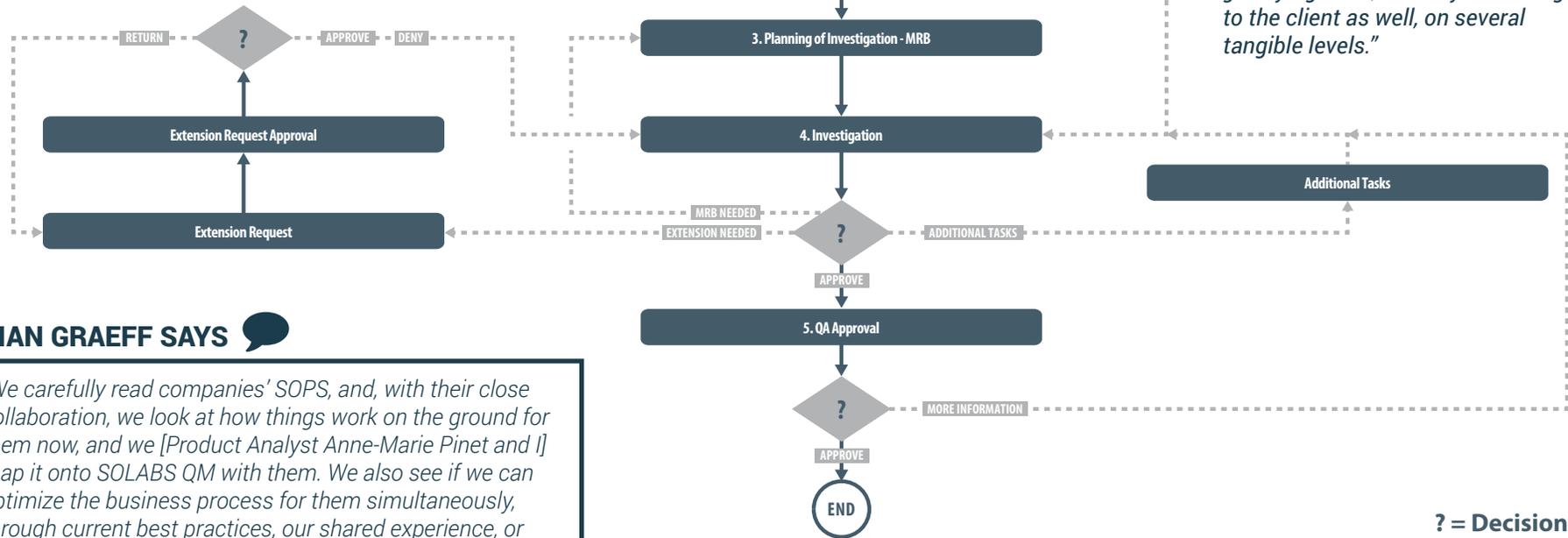
Anne-Marie Pinet is passionate about being among the first points of contact for many SOLABS QM clients and implementations. As a Business Analyst with over 25 years of experience in computer science, mainly acquired in the Life Science Industry, Anne-Marie is known for her strong analytical skills and for her ability to think outside of the box. Some of her key drivers are team spirit and customer/end-user satisfaction.

# COMPLAINT | APP-P028 Flowchart

We've built some features into this Complaint APP that endeavor to keep clients current with evolving Best Practices:

## STEP 2

The QA Assessment in Step 2 is meant to determine the severity of the Complaint. QA is obliged to record every complaint received, so this step is also used to triage them.



*"We've reached the point with several clients where we've been able to streamline and consolidate processes to the point where, for example, they might need to re-draft their current SOP, which is gratifying to us, but very rewarding to the client as well, on several tangible levels."*

### BRIAN GRAEFF SAYS

*"We carefully read companies' SOPs, and, with their close collaboration, we look at how things work on the ground for them now, and we [Product Analyst Anne-Marie Pinet and I] map it onto SOLABS QM with them. We also see if we can optimize the business process for them simultaneously, through current best practices, our shared experience, or streamlining & other strategies. This process is the result of a very thorough Complaint APP workflow, with consideration taken into account for off-site or contract manufacturing."*