

# COMPLAINT | APP-P032

## Overview

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Developed for companies in the following industries:



BIOTECH



MED DEVICE



PHARMA



R&D



VIRTUAL

### ABOUT THIS QM APP

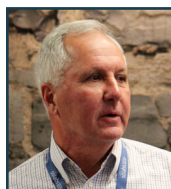
*"In our opinion, a Complaint process itself doesn't have to be terribly complex. Once, however, our clients start dealing with third parties (customers, suppliers, merchandisers, manufacturers), it all becomes harder to track and administer, and to get and keep everyone on the same page.*

*This Complaint process was originally developed for a Medical Device manufacturer, and is fairly linear, but it can be configured to feed in/out of other legacy systems or paper-based processes, or it can trigger a CAPA, say, if required. Clients usually recognize themselves in processes, but we optimize the flow for them during our on-site workshop, as our APPS are always configurable.*

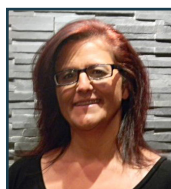
*It's also worth keeping in mind that our clients' customers may be medical service providers, i.e., hospitals, surgery departments, and health centers. Depending on what they produce or provide, they may be accountable to their customers who, in turn, are accountable to theirs--and the stakes can be high; lives could be at risk."*

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

### 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-P0032

## Flowchart

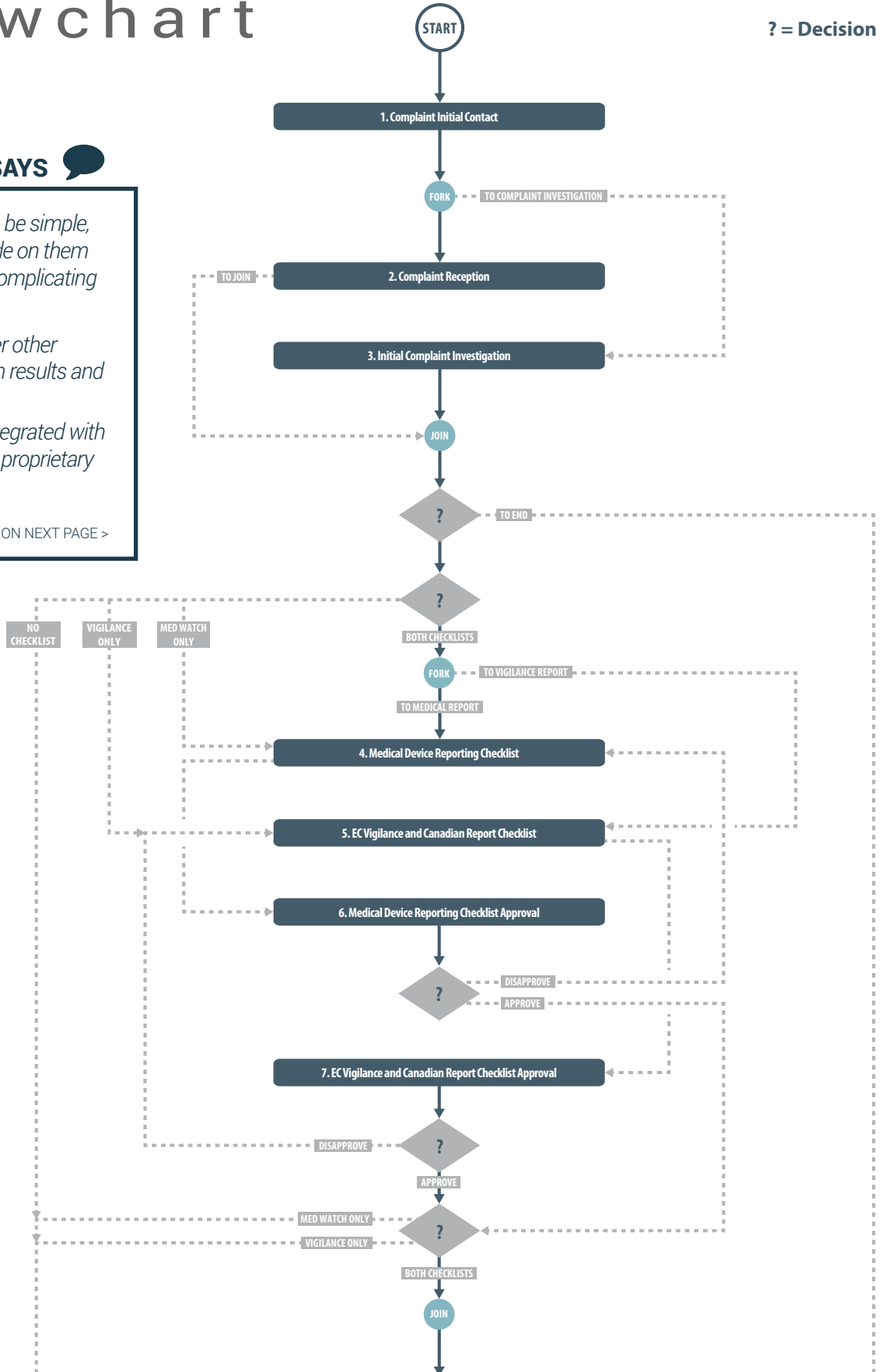
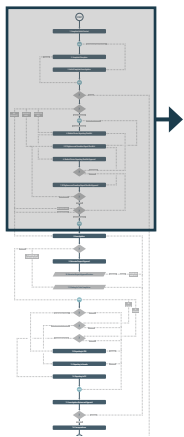
? = Decision

### ANNE MARIE PINET SAYS

*"Complaint processes can be simple, but demands may be made on them depending on dozens of complicating factors:*

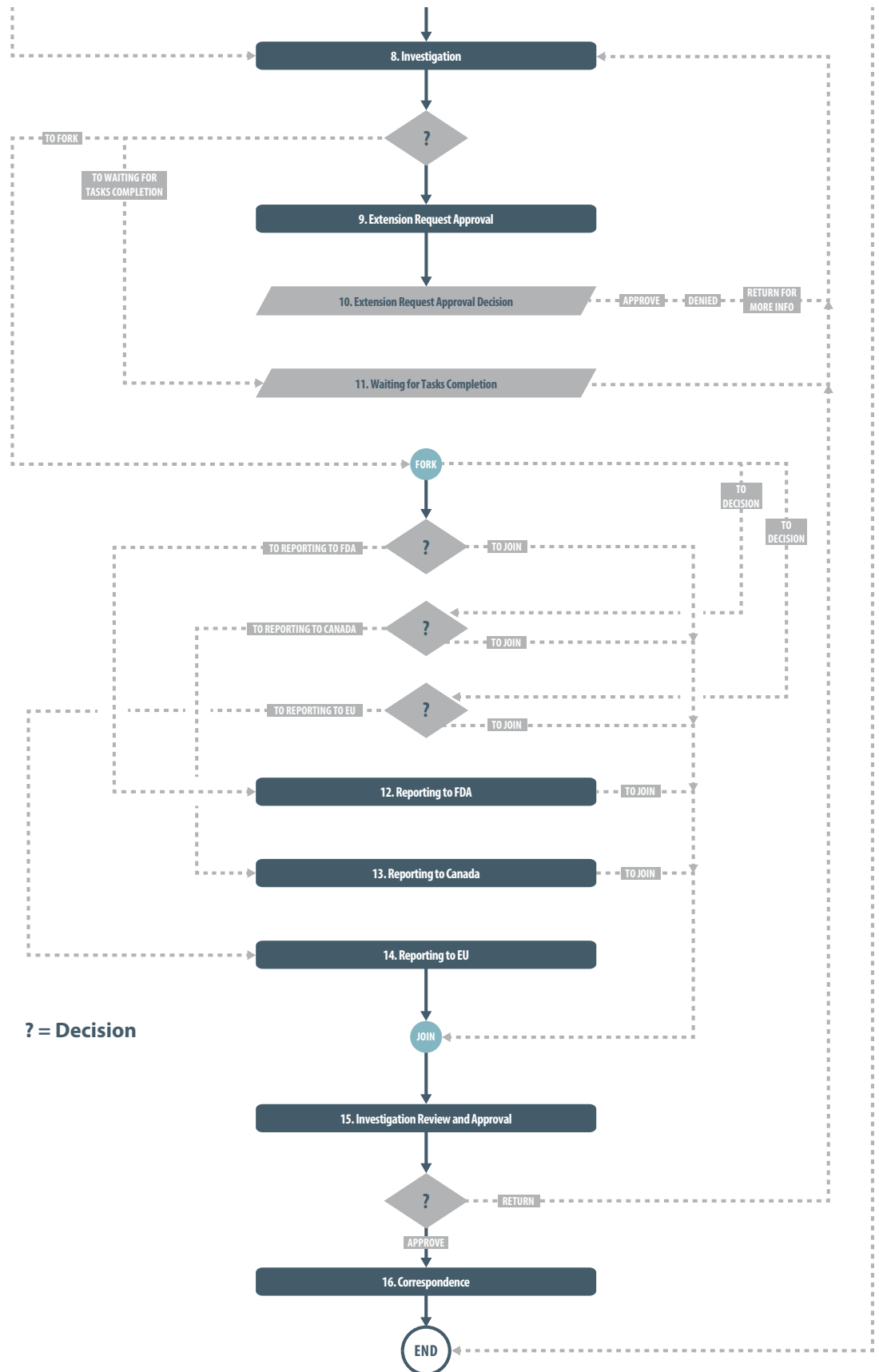
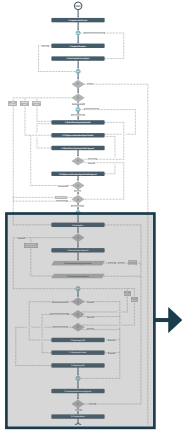
- They may need to trigger other processes depending on results and outcomes
- They may need to be integrated with legacy, manual, or other proprietary systems

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# COMPLAINT | APP-P0032

## Flowchart



### ANNE MARIE PINET SAYS

CONTINUED >

- If another company handles your manufacturing, complaints will need to be gathered, triaged and routed across geographic and time zones, and potentially international borders
- If you sell to consumer end-users or to a professional audience, you will find your Complaints may differ widely
- You will also want to consider how the Complaint process itself is handled at your facility, and how its integration fits into the larger Quality picture."