sólabs Passionate about Quality Automation

DEVIATION | APP-P0014
Overview

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Developed for companies in the following industries:

BIOTECH

MED DEVICE

PHARMA

R&D

VIRTUAL

ABOUT THIS QM APP

"This Deviation process has all that we recommend—detailed reporting is robust and easily available; impact assessments are evaluated and approved, and they target risk management, accuracy in details and full consensus.

Investigations are launched where required; extension requests are made to, and administered by, QA; and both planned and unplanned deviations can be managed through this process.

If the deviation is unplanned, users can choose to conduct a full investigation to define the root cause and impact."

— Philippe Gaudreau, Founder & CEO, SOLABS

HIGHLIGHTS

- During impact and risk assessment stages, fields are available and targeted questions are asked that can support a material disposition if required
- Manager evaluations are done in parallel with QA assessments for better efficiency
- QA may reject or ask for clarification from the initiator in order to clarify the deviation
- Process starts with reporting, where users may have various deviation types: equipment, test methods, validation protocols, etc.
- Ability to categorize deviation as critical versus minor, for example, and Deviation category can be reviewed and changed after review of investigation
- Users can initiate a dependent or related CAPA process where required, before it is closed out by QA

DEVELOPED BY SOLABS

solabs DEVELOPED BY

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.

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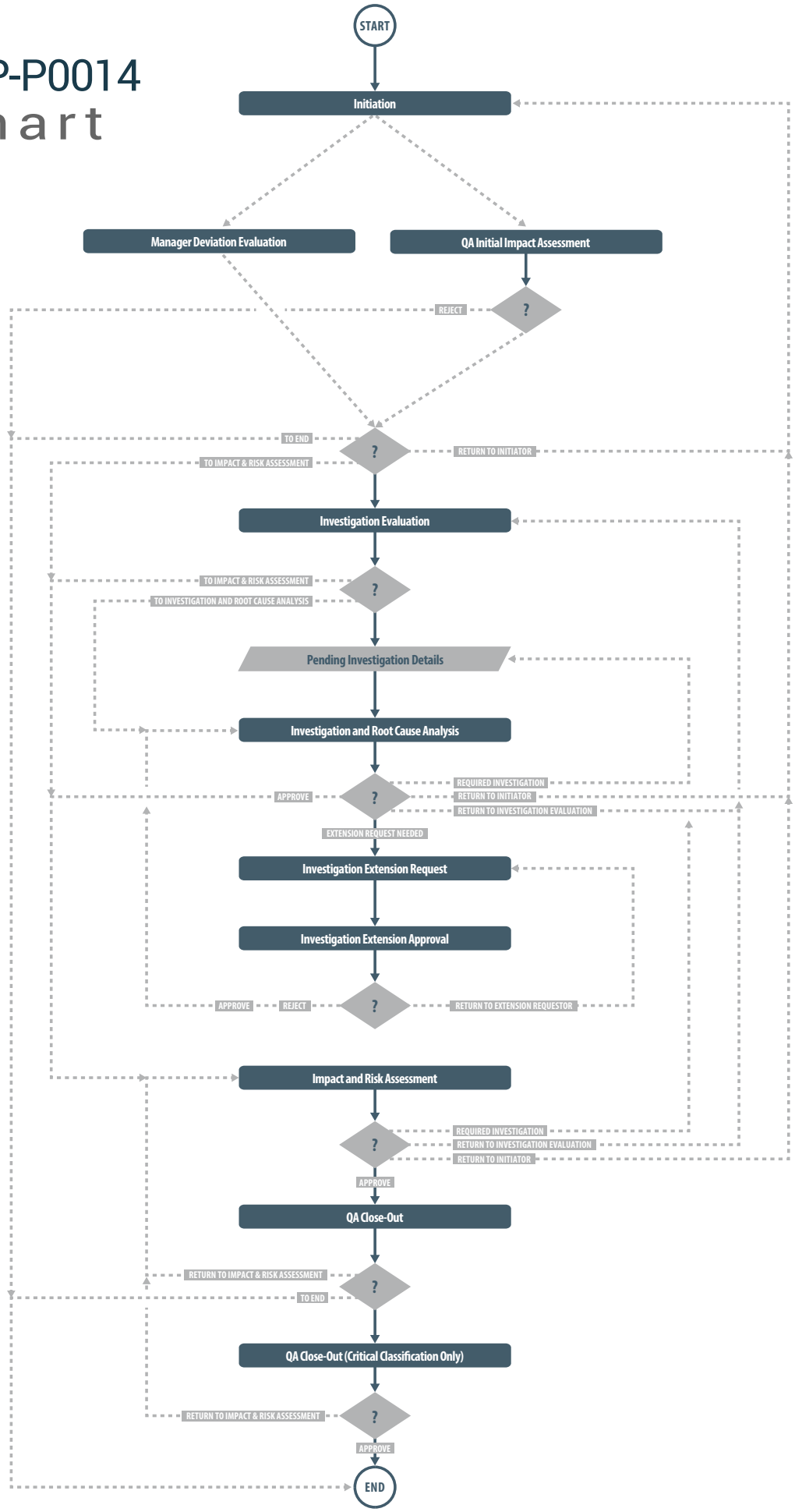
Flowchart



PHILIPPE GAUDREAU SAYS

QA's ability to categorize the Deviation as minor, major or critical is a central component of a Deviation Process. The categorization can be defined at initiation, but can also be changed later in the process should an issue escalate or be downgraded, the information changes over time, etc.

Deviation types being flagged as Test Method, Equipment, or Validation Protocol, for example, enable more granular reporting and specific routing. This is added value with this APP, as it allows for specificity, pertinence and valuable details to be entered or highlighted, which ensures the right task goes to the right user or department.

? = Decision

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