solabs Passionate about Quality Automation

CAPA | APP-P0026
Overview

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Overview

Developed for companies in the following industries:

BIOTECH

MED DEVICE

PHARMA

R&D

VIRTUAL

ABOUT THIS QM APP

"We apply our combined decades of life science sector experience when we talk to clients. A CAPA is a challenging thing for any client, so we build in—as with this one—the latest and greatest CAPA advances, if you will.

*Specifically **four** new areas keep us more closely aligned with current and evolving industry expectations, and reflect our accumulated knowledge in this area.*

These are:

***i)** Risk Assessments*
***ii)** Categorizations of CAPAs*
***iii)** Effectiveness Checks*
***iv)** Extension Requests*

The difference between a CAPA that can be handled internally and one that has to be escalated to, say, deal with regulators or customers is severity or criticality—something that affects the product's SISPQ, or Safety, Integrity, Strength, Purity and Quality.

This CAPA is, in my opinion, the evolution of CAPAs: it covers all the bases, and integrates considerable best practices and some future-proofing as well."

--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.

CAPA | APP-P0026
Flowchart

STEPS 1-3

Allows a multi-step assessment for Definition, Evaluation and Acceptance—judging the severity or gravity of the CAPA, and categorizing it accurately is crucial for appropriate follow-through and resolution.

Risk Assessment and CAPA Categorization occur during these steps, adding a level of scoped specificity and severity evaluation at the start, with the aim of better, more targeted solutions, and directed focus from the CAPA's inception.

STEPS 4-7

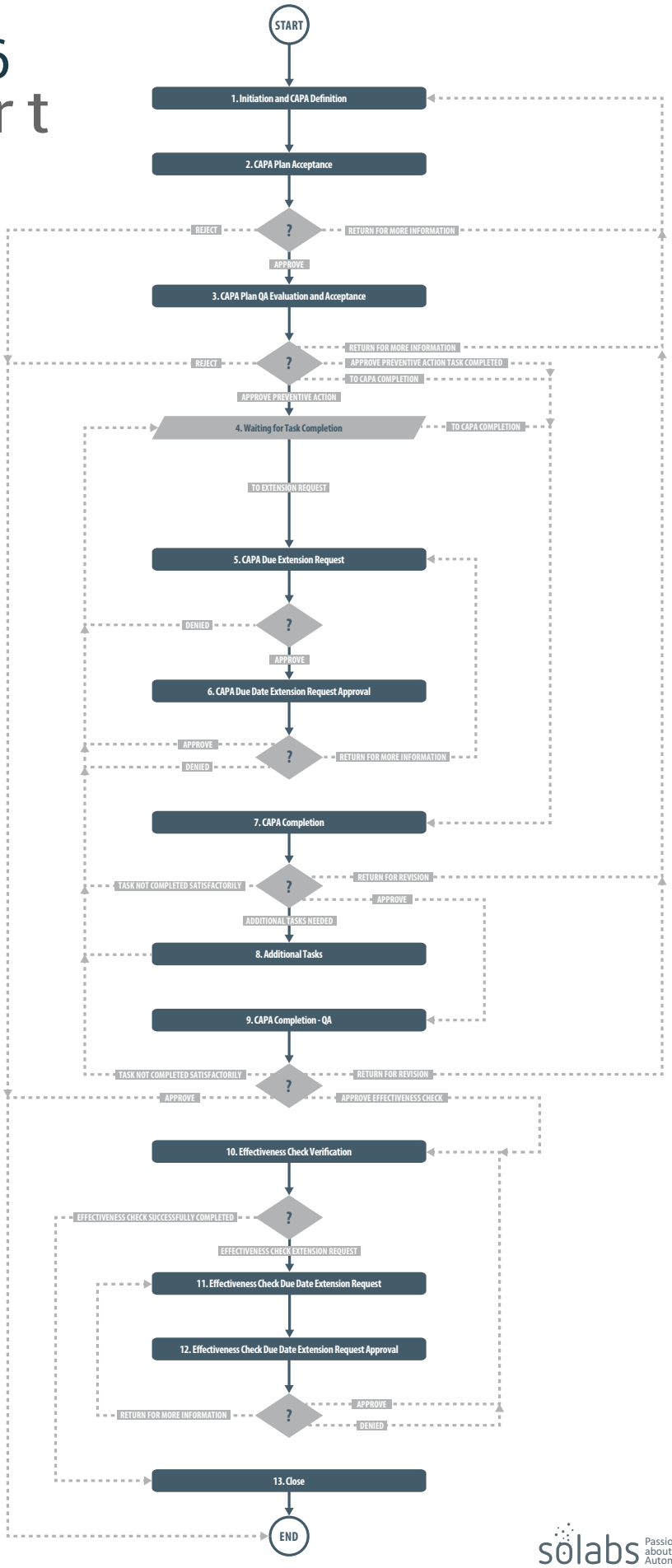
Extension Requests (QA-administered; must be tracked) and Additional Tasks (dependent tasks upon which the completion of the CAPA depends) are both features of the enhanced CAPA, as mentioned above, and both appear between Steps 4 and 7.

STEP 9

An Effectiveness Check step additionally makes sure that the preventative action emerging from the corrective action—which triggered this process—has had measurable and reproducible effects.

BRIAN GRAEFF SAYS

"Regardless of which industry customers are in, or how their company is organized, they all need Quality sub-systems, like our QM APPS, because they're all subject to the same regulatory requirements. This CAPA has been built to reflect current best practices in several distinct and important ways—as well as to keep abreast of regulatory advisories, so that we help our clients to stay a step ahead wherever possible as well."



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