solabs Passionate about Quality Automation

CHANGE CONTROL | APP-P016
Overview

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Overview

Developed for the following company types:

CONTRACT MANUFACTURING

FULLY INTEGRATED

GEOGRAPHICALLY DECENTRALIZED

MULTIPLE FOREIGN MARKETS

VIRTUAL

ABOUT THIS QM APP

"Among the chief advantages of this QM APP are the parallel secondary tasks, used in this case to allow the company to have multiple products in legislative approval pipelines with various countries' regulatory agencies at the same time. The progress of each pipeline is completely independent of the others, and can progress, leaving the others unimpeded. This is a very powerful workflow tool as, in this scenario, the more products and agencies, the increasingly complex the situation."

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

HIGHLIGHTS

- This is a fairly complex change management process: a company with a virtual business model would typically find this process to be very useful, as would any company that requires approvals from multiple regulatory agencies
- Approvals of changes by multiple Regulatory Authorities complicate the process exponentially. For example, with virtual companies, although they may use Contract Manufacturers, they, as the Product Owner, are ultimately responsible for approvals with all regulatory authorities
- Not all Regulatory Authorities assess the impact of a change the same way. They each have different risk tolerances, and therefore different approval processes and timelines—this was the genesis of the multiple, independent approval pipelines approach
- The ability to release a product in one market (while not in others) is critical: cycle times can be very long, and can vary widely from one market to the next
- Between **Steps 8 and 9**, a loop has been created for **Pre-Implementation Tasks**: in-context examples of this may include a change of test methods, and the validation involved in doing so; or the making of a production test batch as proof of concept

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.

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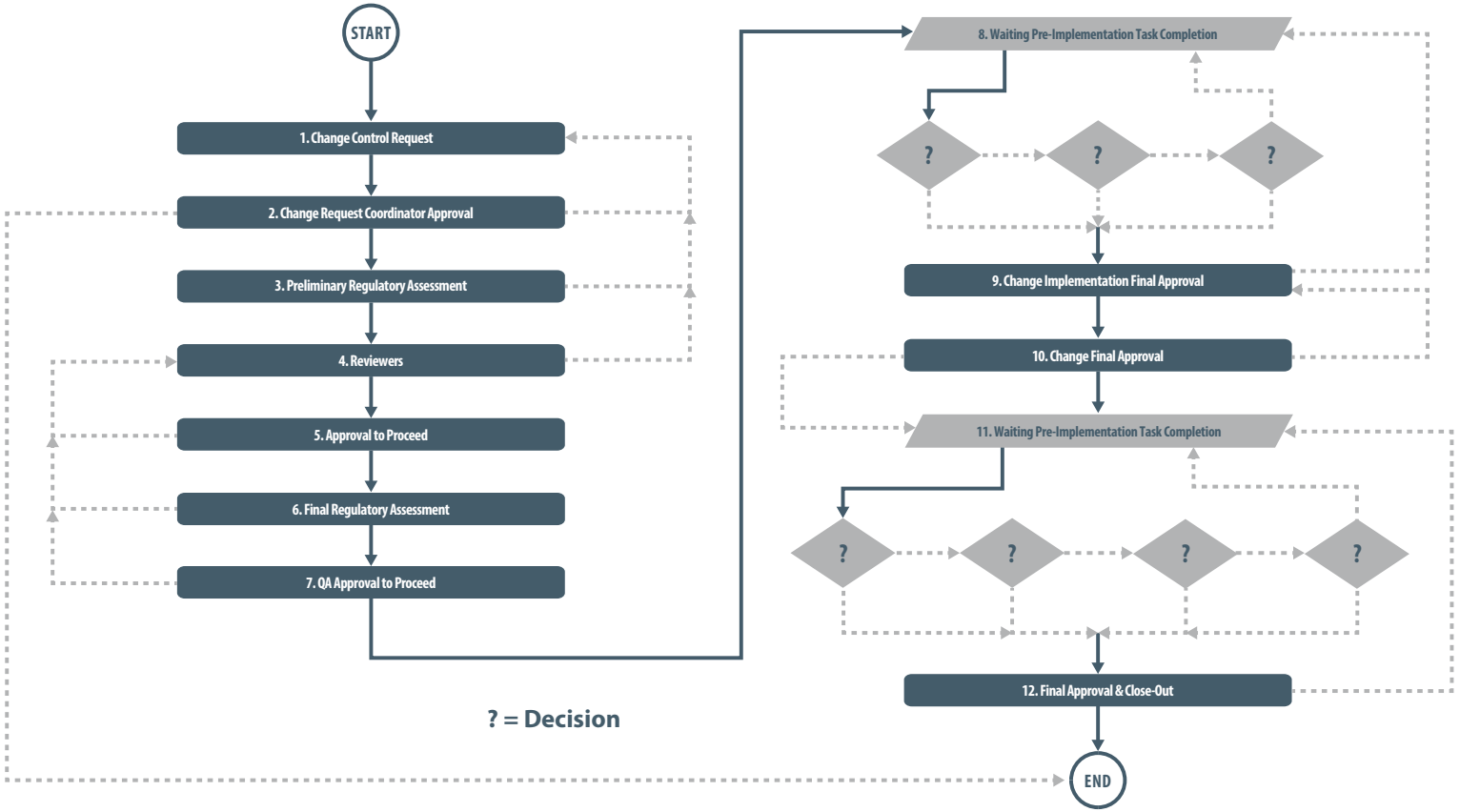
Flowchart



STEP 3

*A **Preliminary Regulatory Assessment** can take place if desired. There is also the option to return the process to the Initiator for modification*

STEP 8

*A **Post-QA Pass** allows a verification that all Pre-Implementation tasks are complete before Change Implementation final approval: this leverages the power of secondary tasks*

STEP 11

*A **Waiting Post-Implementation Task Completion** step occurs that facilitates independent handling of tasks*

STEP 11 & 12

The looping between Steps 11 and 12 enables the 'multiple products, multiple countries pipeline' with each being independently managed, and able to emerge with regulatory approval independently

BRIAN GRAEFF SAYS

"When a drug, for example, is being approved in multiple markets—with all the associated paperwork--the challenges add up rapidly. If you're passing one change by one regulatory agency, that's one thing. But if you're trying to shepherd four products through four countries' regulatory agencies, it gets extremely complex very quickly. This APP helps mitigate, anticipate and manage some of those uncertainties."