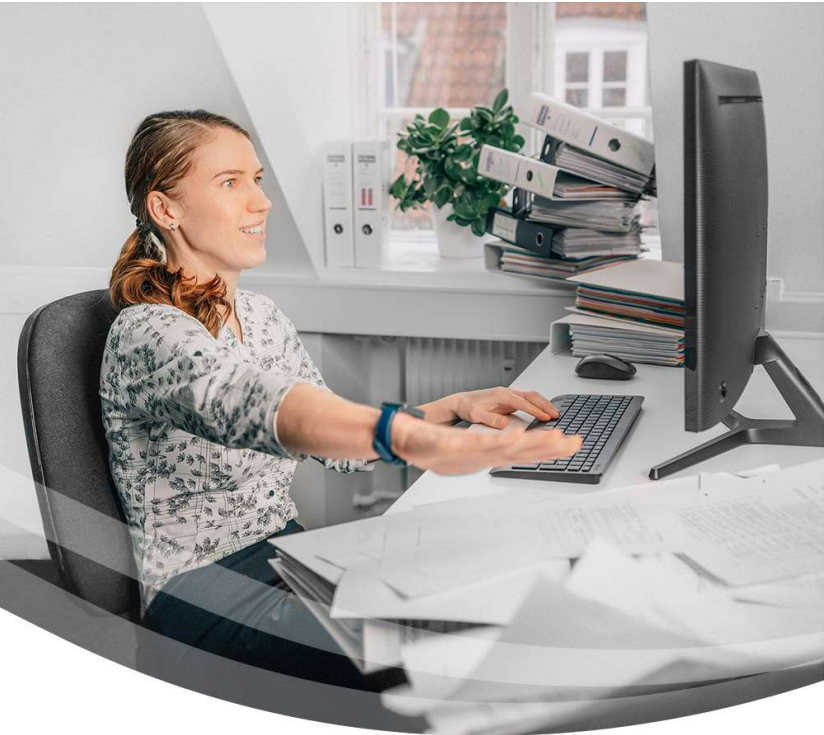


# SimplerQMS

Workflows in SimplerQMS

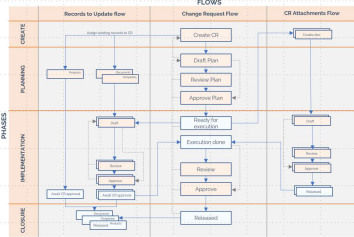


# SimplerQMS workflows

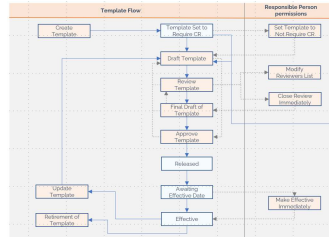
Tailored for processes in Life Science companies



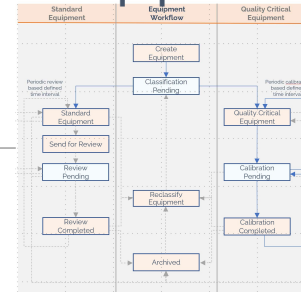
## Change Requests



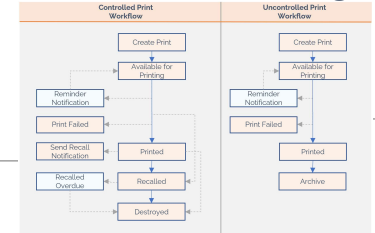
## Templates



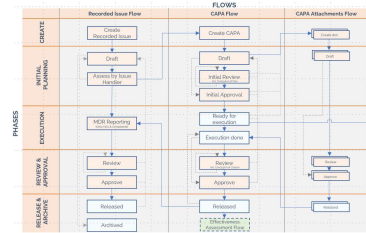
## Equipment



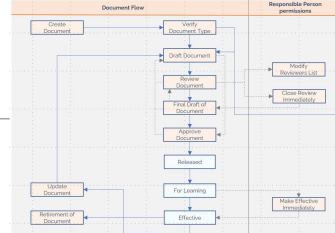
## Controlled Printing



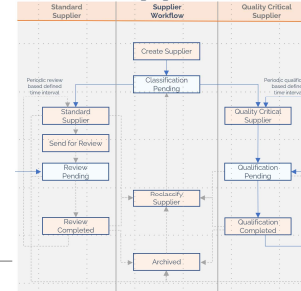
## Recorded Issues & CAPAs



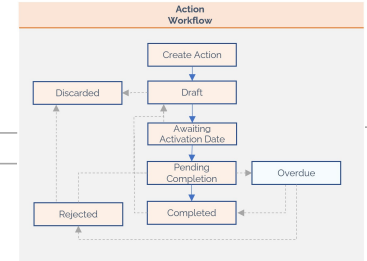
## Quality Documents



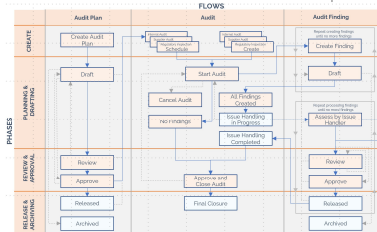
## Suppliers



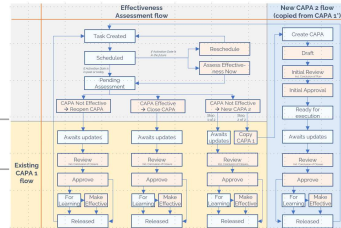
## Actions



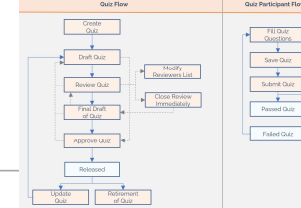
## Audits



## CAPA Effectiveness



## Quizzes





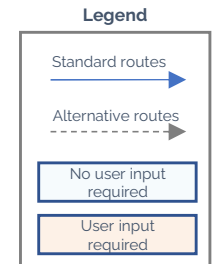
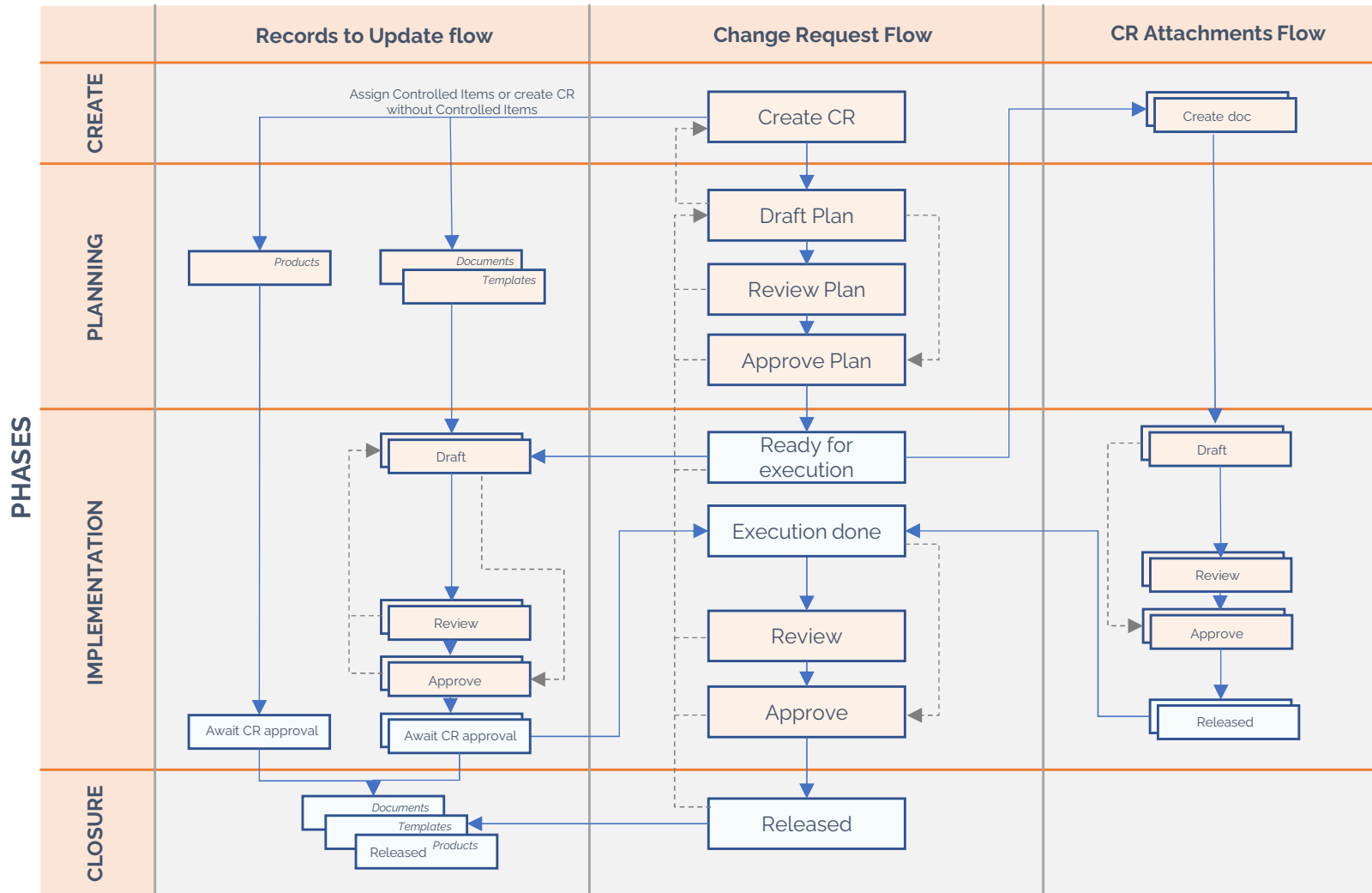
# Workflow overview

Slide	Workflows	Work Instructions
4	Change Requests	WI-00035 Managing Change Requests
5	Recorded Issues & CAPAs	WI-00046 Managing Recorded Issues and CAPAs
6	CAPA Effectiveness Assessment	WI-00047 Assessing Effectiveness of CAPA
7	Quality Documents	WI-00037 Managing Quality Documents
8	Templates	WI-00036 Managing Templates
9	Training - Quizzes	WI-01055 Creating and Managing Quiz WI-01056 Quiz Participation
10	Audits incl. Plans & Findings	WI-00045 Managing Audits
11	Equipment	WI-00042 Managing Equipment
12	Suppliers	WI-00041 Managing Suppliers
13	Controlled & Uncontrolled Printing	WI-02238 Controlled Printing
14	Action	WI-00039 Actions, Periodic Tasks and Reminder Rule

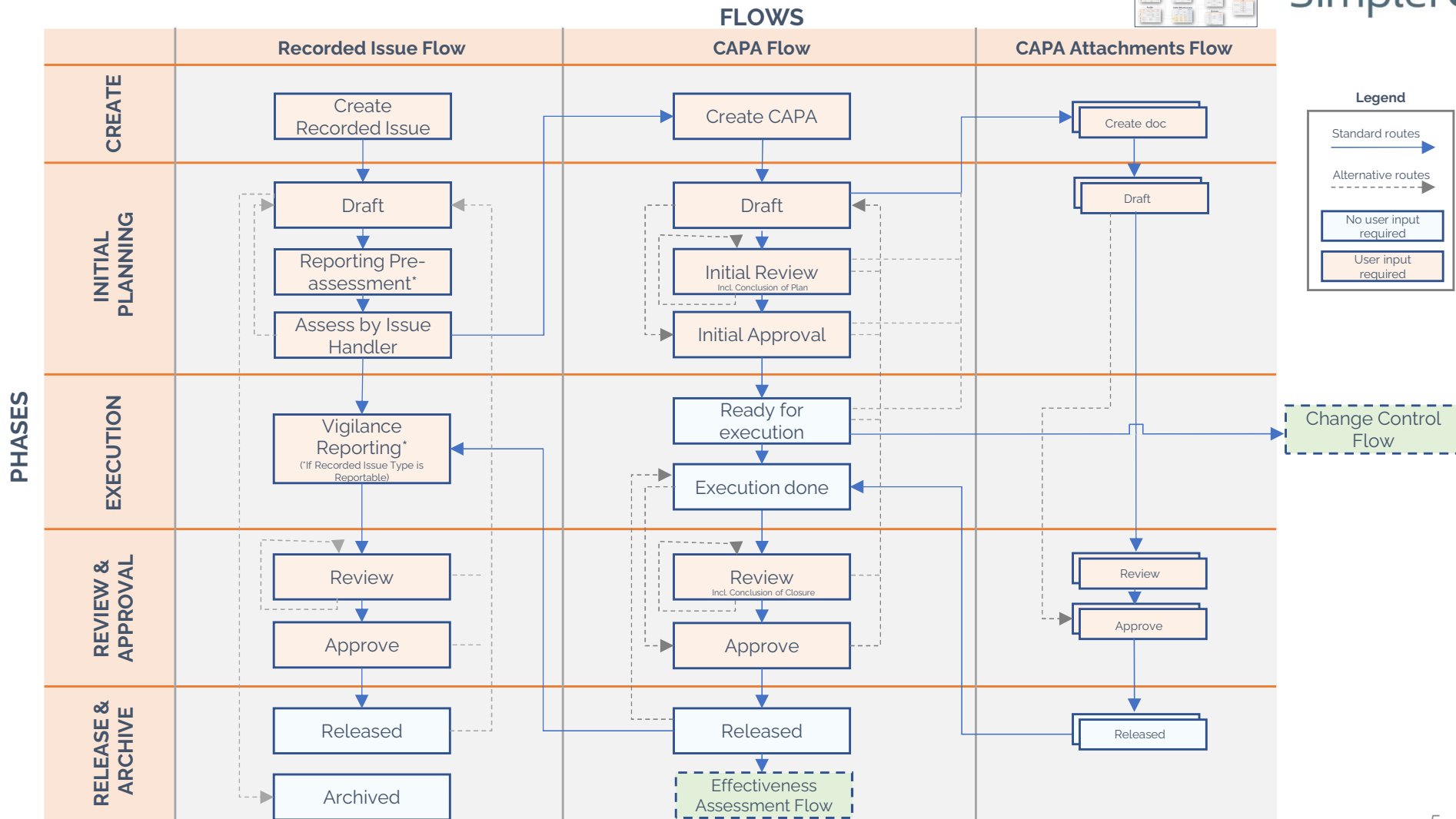
# Change Request (CR) and CR Attachments



## FLOWS



# Recorded Issues\* with CAPAs and CAPA Attachments

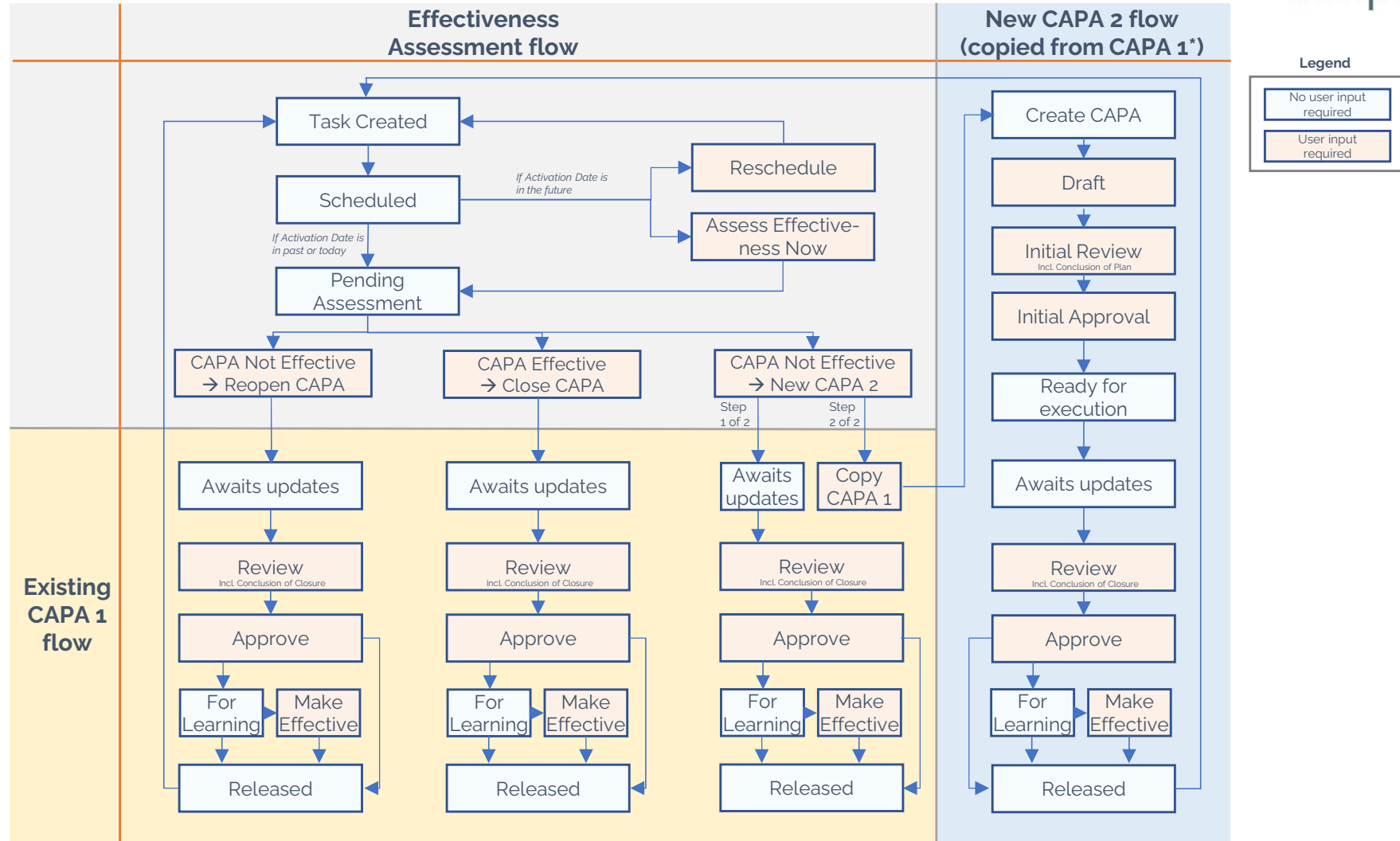


**Legend**

- Standard routes (solid blue arrow)
- Alternative routes (dashed blue arrow)
- No user input required (light blue box)
- User input required (light orange box)

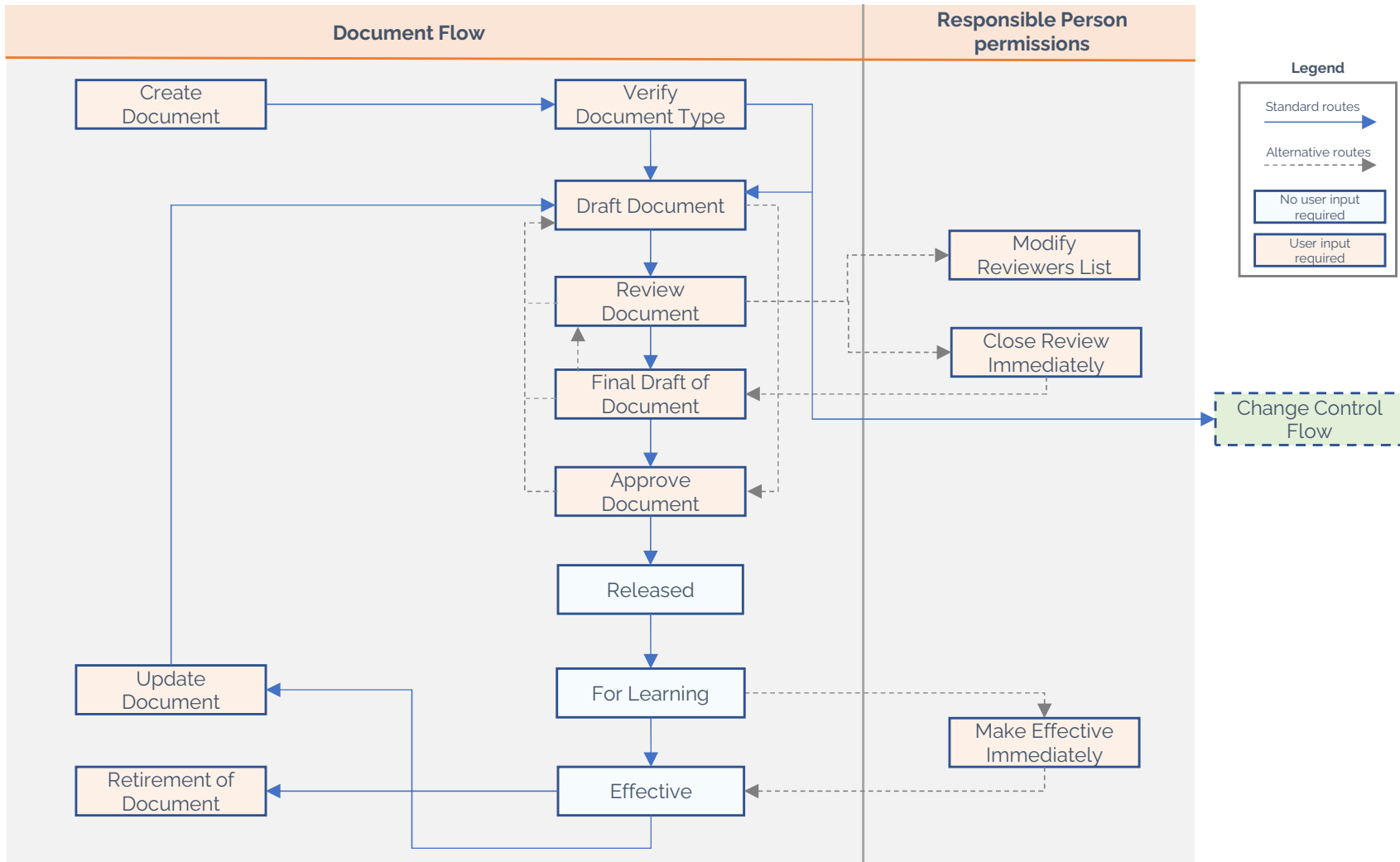
\*Recorded Issues include: Complaints, Nonconformances, Supplier Issues and Continuous Improvements

# Effectiveness Assessment of CAPAs

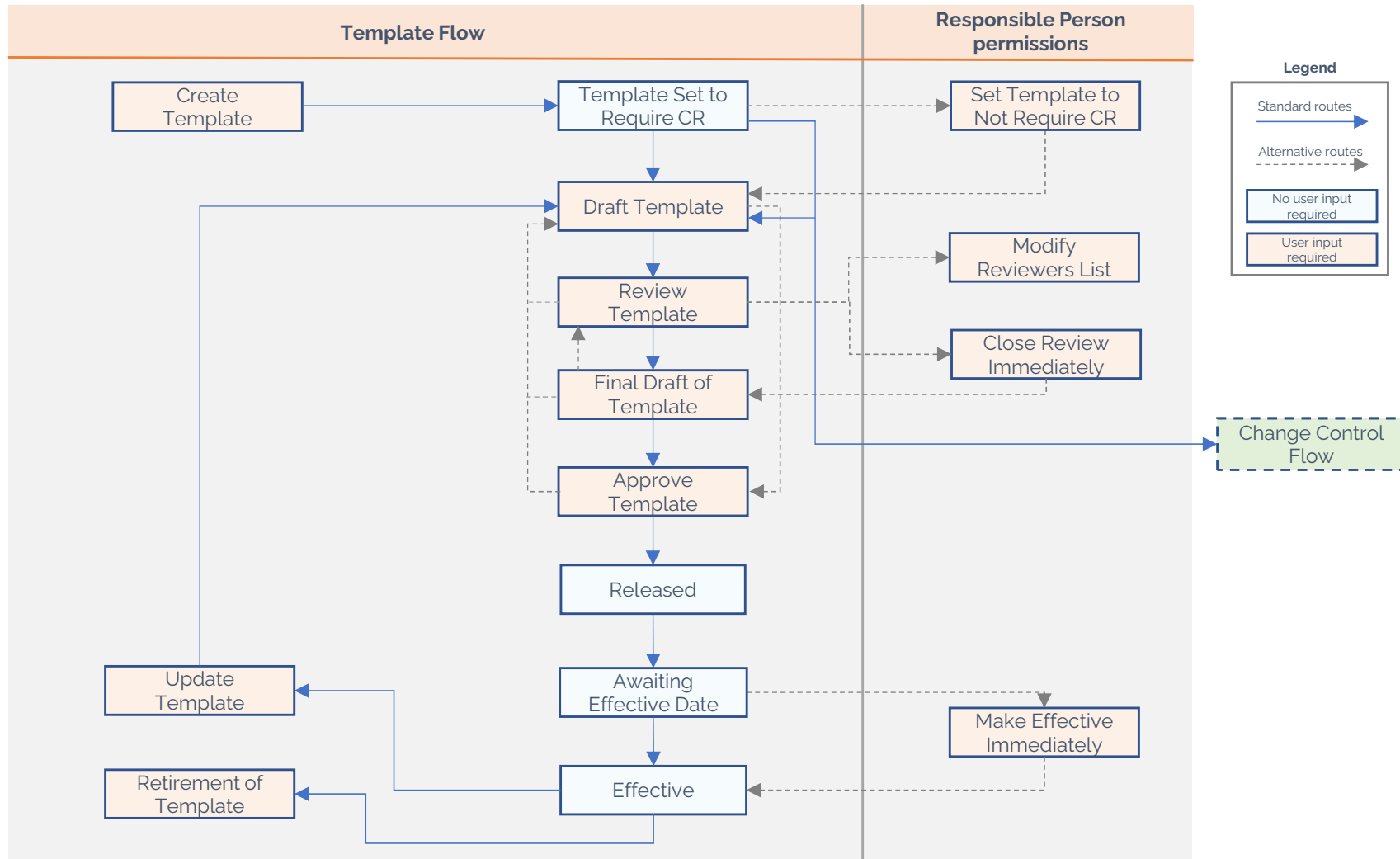


\*Go to the workflow "Recorded Issue" flow with CAPA and CAPA attachments flow" to view the full CAPA workflow incl. CAPA Attachments

# Quality Documents without Change Requests

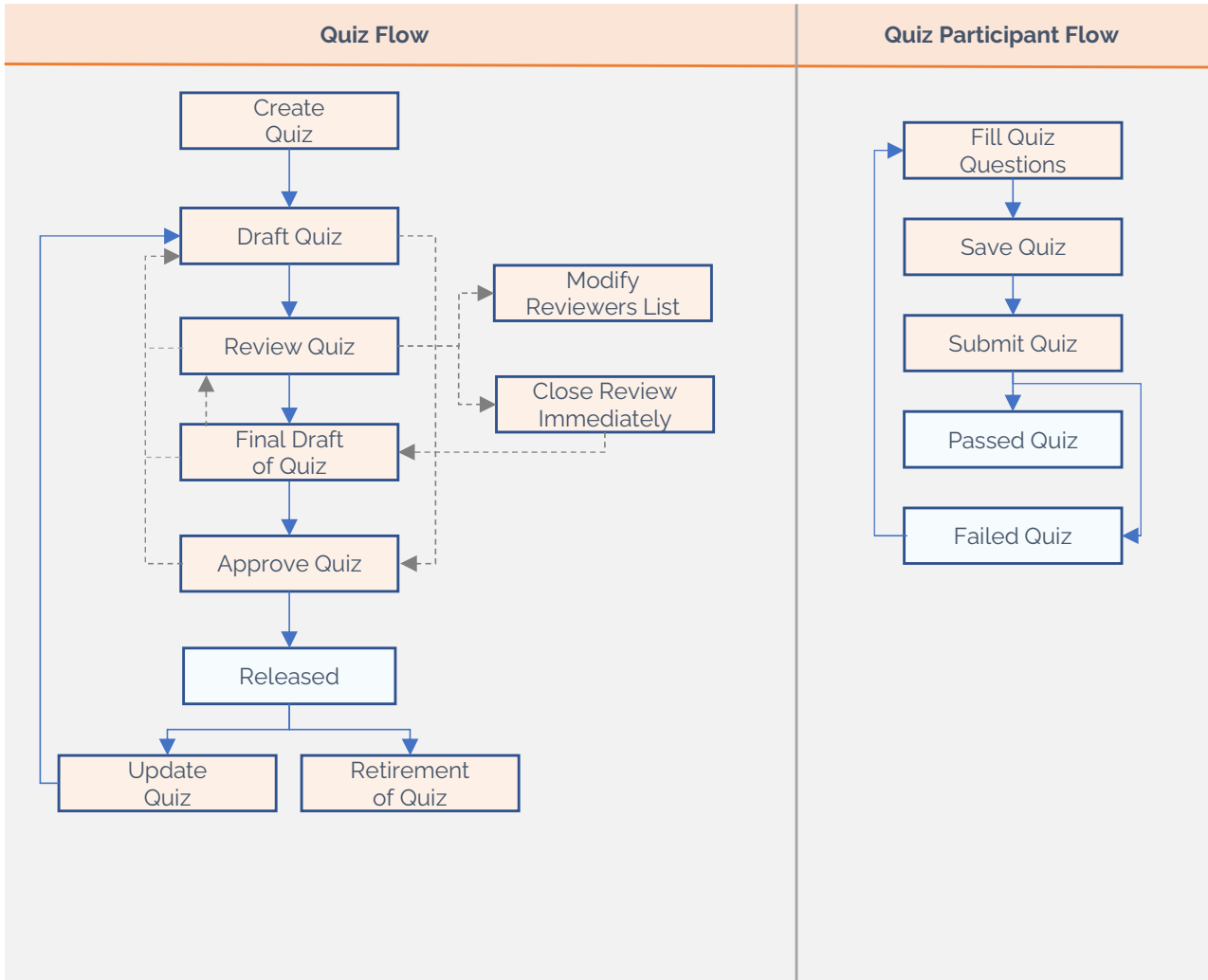


# Templates without Change Requests





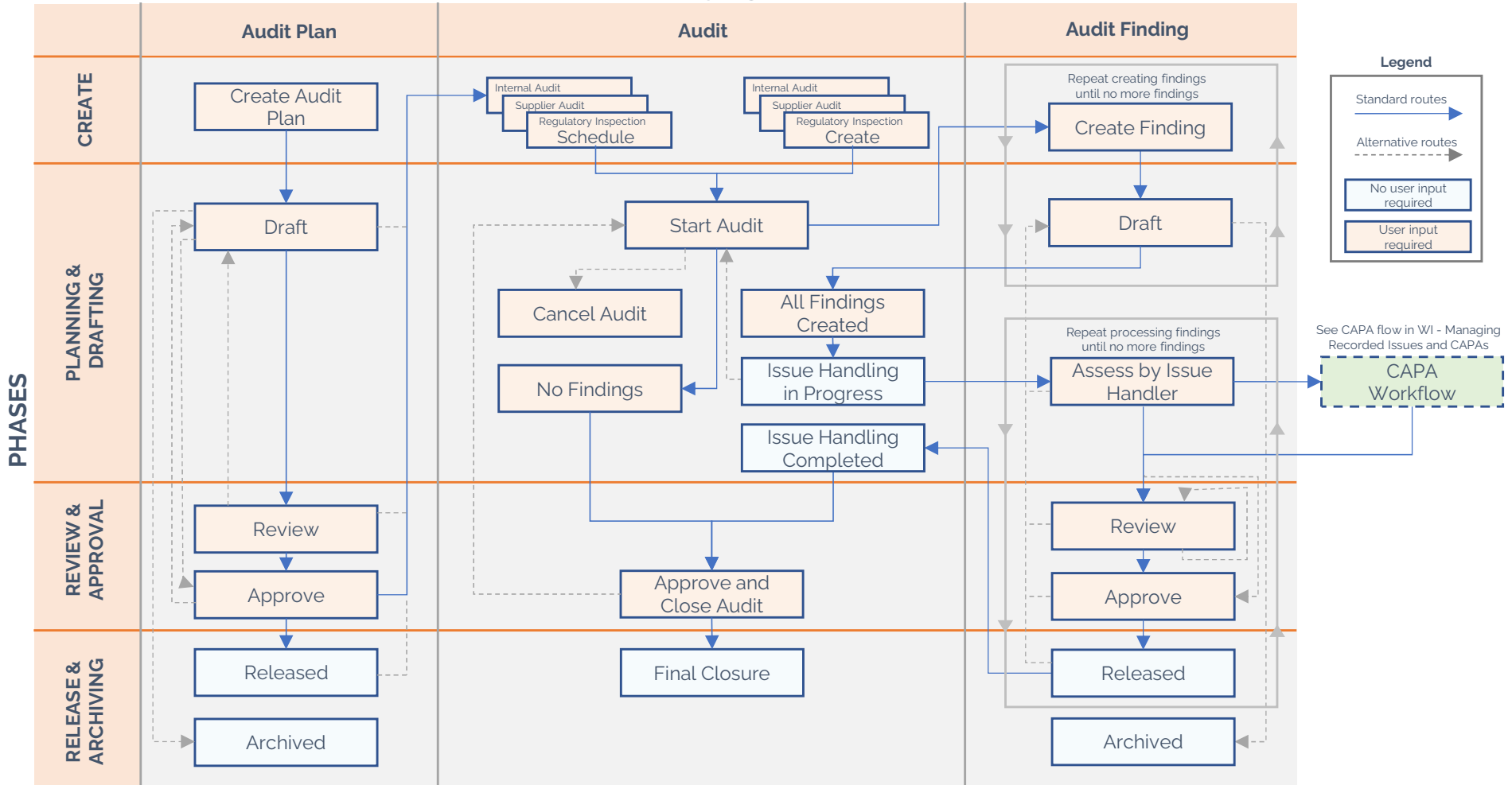
# Quizzes – creating and taking quizzes



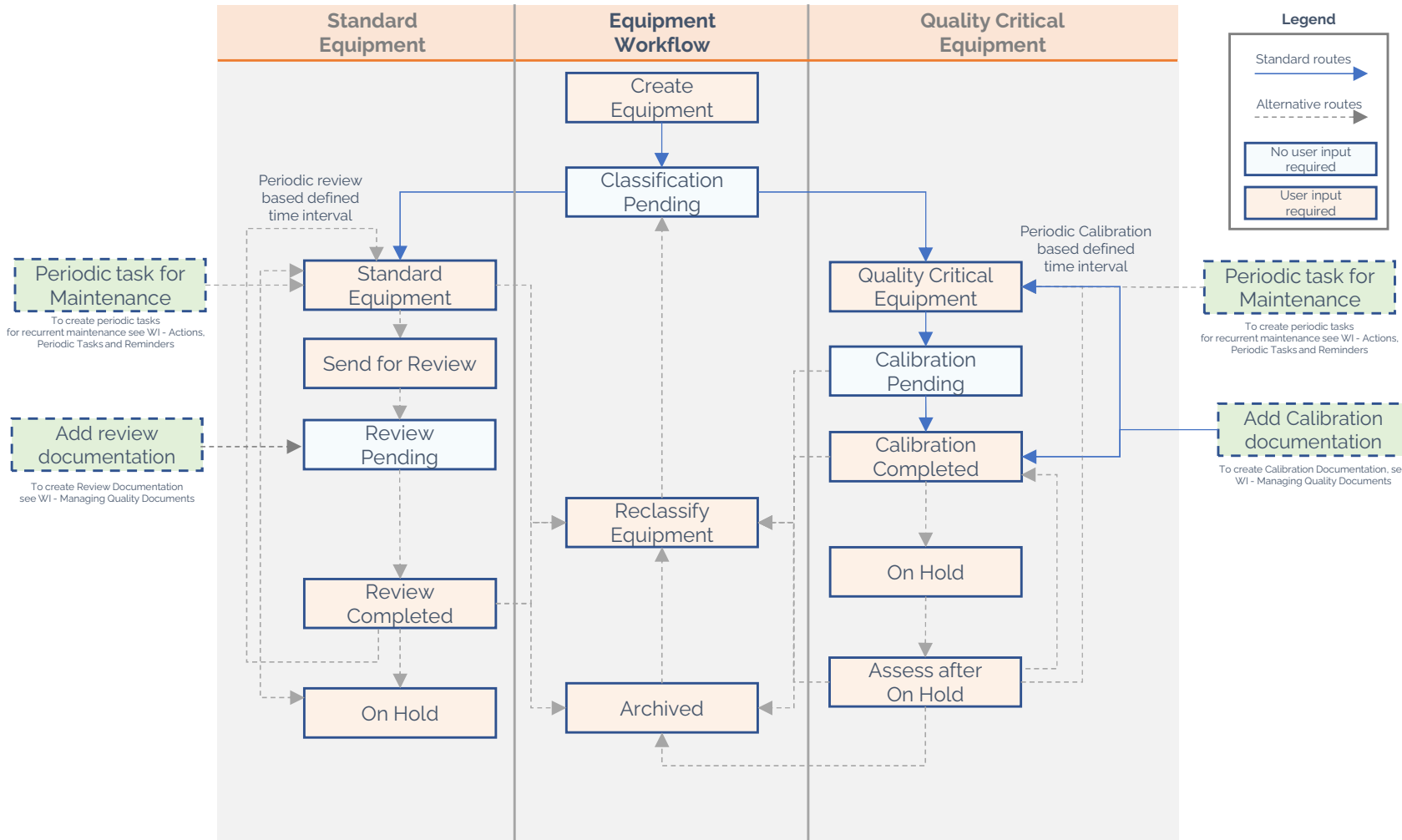
# Audits including Audit Plans and Audit Findings



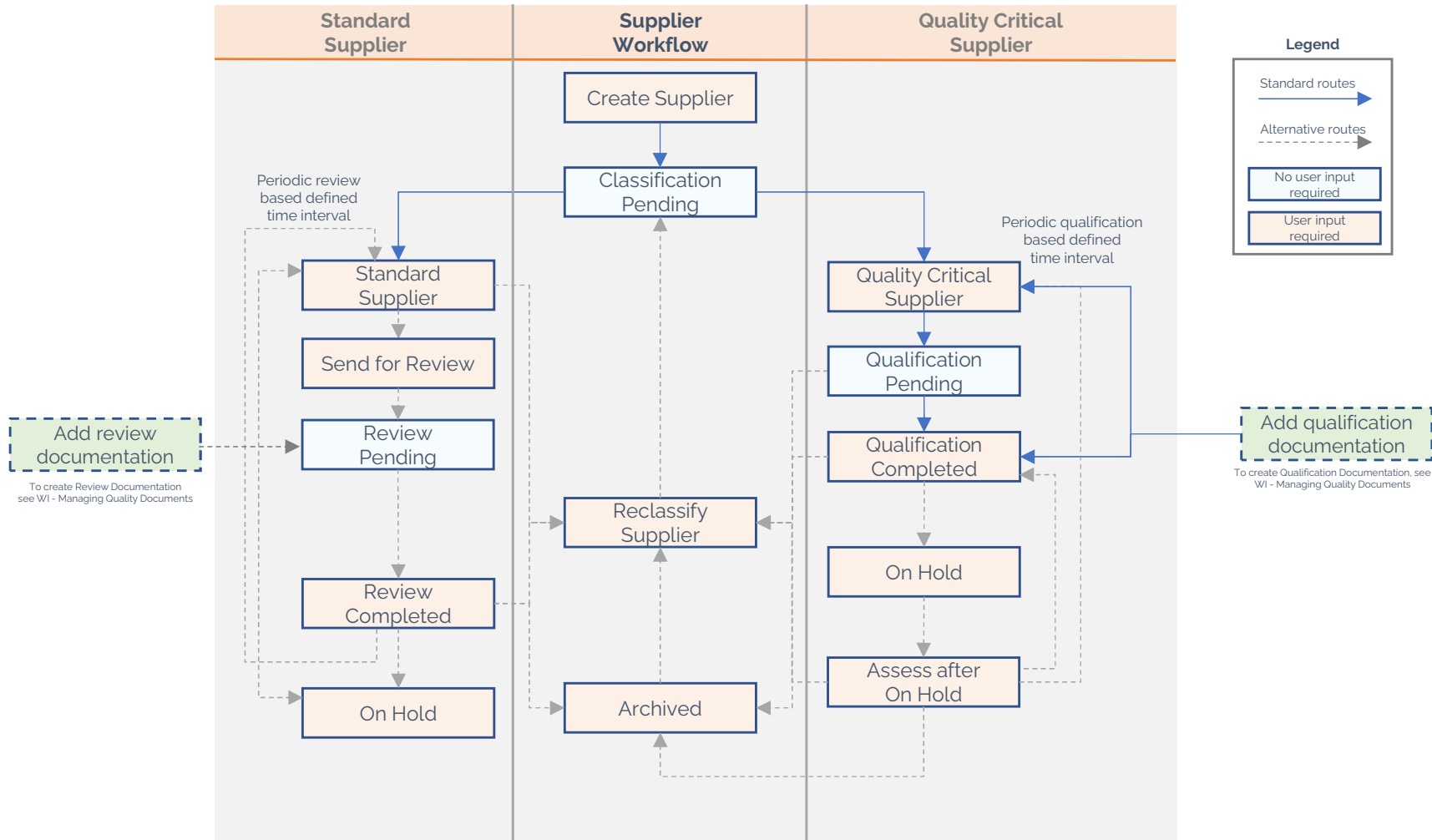
## FLOWS



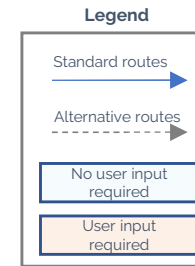
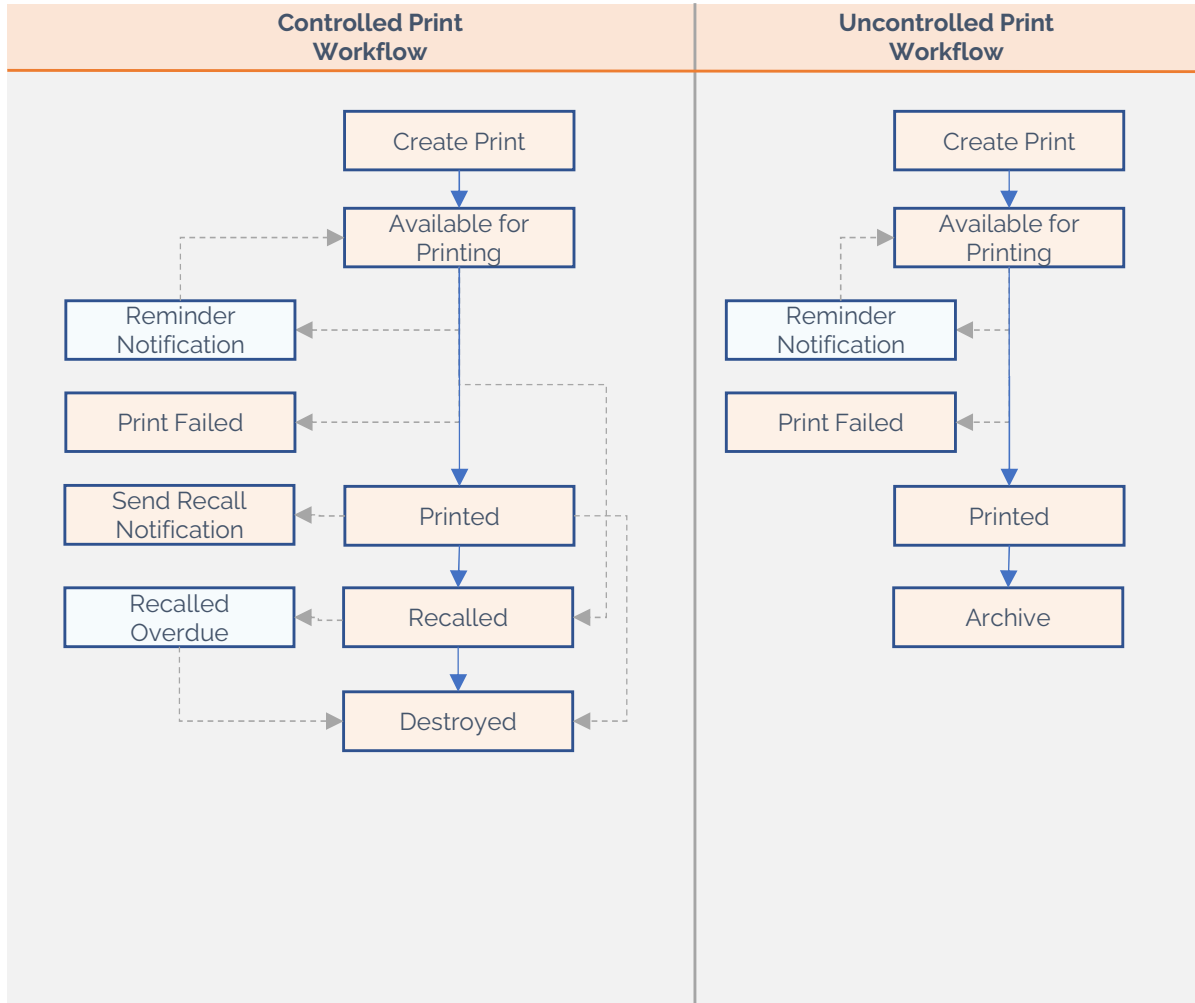
# Equipment (Standard & Quality Critical)



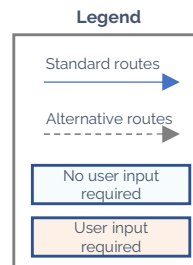
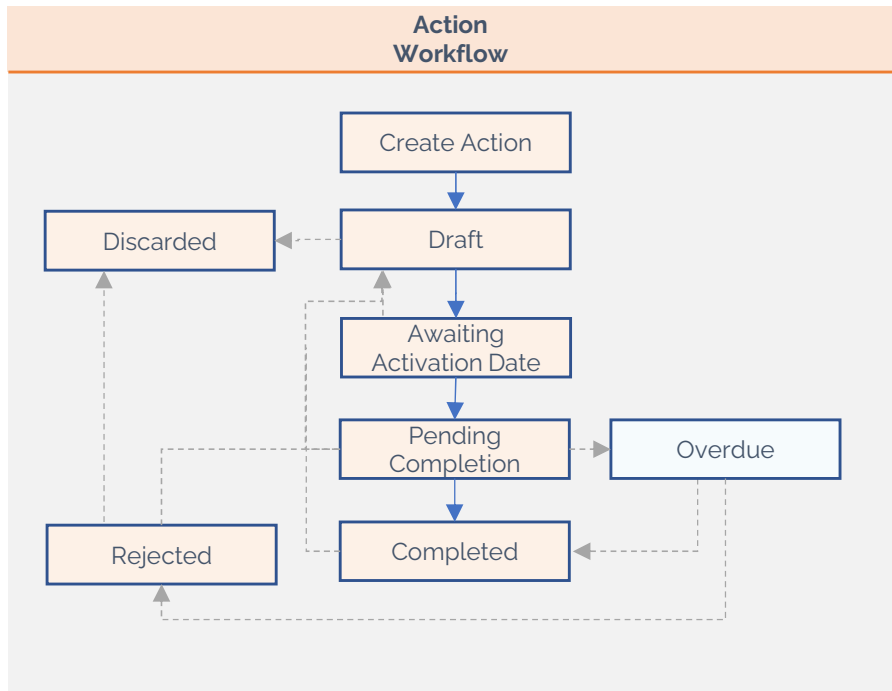
# Suppliers (Standard & Quality Critical)



# Controlled & Uncontrolled Printing



# Action



## Guide for what Task and Action feature to use

	Reminder Task	Periodic Task	Action <small>(Replaces Assignments)</small>
Frequency of task	Recurrent or One-time	Recurrent	One-time / ad-hoc
Assignment triggered	By document release	On Activation date based on scheduling values	On Activation date based on scheduling values
Location of feature	Create -> Periodic Task -> Reminder Task	Create -> Periodic Task -> Periodic Task	Create -> Action
Requires e-signature to complete	Yes	Yes	Determined by initiator
Mandatory for all assignees to complete	No, only one	No, only one	Determined by initiator
Examples / Use cases	Reminder task to print and replace a work instruction in a binder when a new is released	Recurrent task to calibrate equipment with a given time interval	Action to do x based on a conclusion of a CAPA
Notes		The "Periodic Document Review" and "Effective Assessment" is based on the Periodic Task	Will block CAPAs and CRs from being released until action is completed

## Revision History

Version	Date	Description of Change	Reason	Author
1	2022-12-05	Migrated to SimplerQMS Production	2.9 Update	MMB
2	2023-03-23	Added workflows for Controlled Printing and Actions, updated workflows for Supplier, Equipment, Recorded Issues and updated overview	3.0 Update	MMB, RF