Effectiveness Assessment of CAPAs

SimplerQMS

Effectiveness Assessment flow

New CAPA 2 flow (copied from CAPA 1*)

Legend
- No user input required
- User input required

Task Created

Scheduled

If Activation Date is in the future → Reschedule

Assess Effectiveness Now

If Activation Date is in past or today

Pending Assessment

- CAPA Not Effective → Reopen CAPA
- CAPA Effective → Close CAPA
- CAPA Not Effective → New CAPA 2

Step 1 of 2 — Step 2 of 2

Existing CAPA 1 flow

CAPA Not Effective → Reopen CAPA
Awaits updates → Review (Incl. Conclusion of Closure) → Approve → For Learning / Make Effective → Released

CAPA Effective → Close CAPA
Awaits updates → Review (Incl. Conclusion of Closure) → Approve → For Learning / Make Effective → Released

CAPA Not Effective → New CAPA 2
Awaits updates / Copy CAPA 1 → Review (Incl. Conclusion of Closure) → Approve → For Learning / Make Effective → Released

New CAPA 2 flow
Create CAPA → Draft → Initial Review (Incl. Conclusion of Plan) → Initial Approval → Ready for execution → Awaits updates → Review (Incl. Conclusion of Closure) → Approve → For Learning / Make Effective → Released
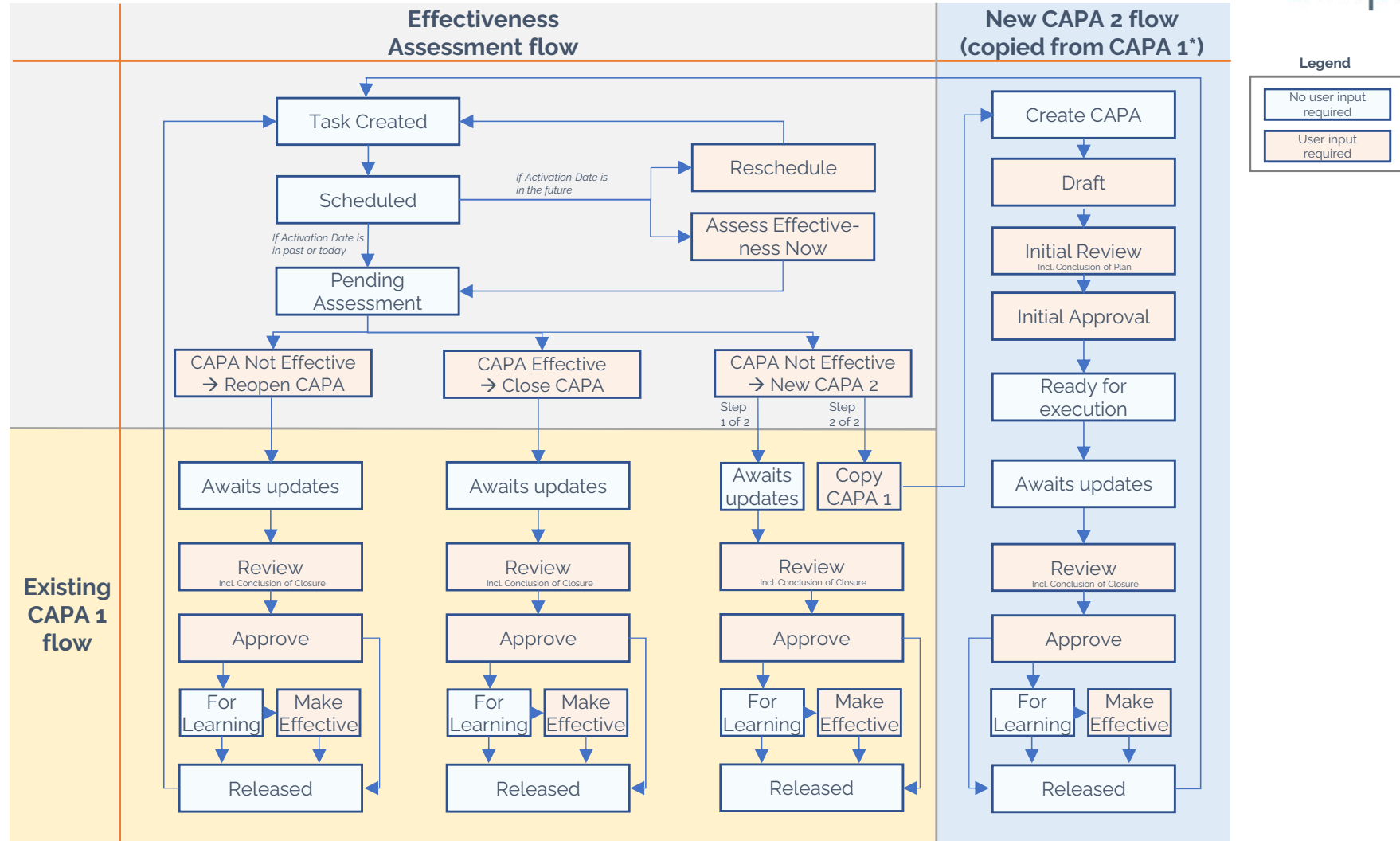
*Go to the workflow "Recorded Issue" flow with CAPA and CAPA attachments flow" to view the full CAPA workflow incl. CAPA Attachments

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