## **Recorded Issues\*\* with CAPAs and CAPA Attachments** Simpler **QMS FLOWS Recorded Issue Flow CAPA Flow CAPA Attachments Flow** CREATE Legend Create Create CAPA Create doc Recorded Issue Standard routes Alternative routes Draft Draft Draft INITIAL PLANNING No user input required -----Initial Review User input Initial Review required Reporting Preassessment\* Initial Approval Assess by Issue Handler **PHASES** Vigilance **EXECUTION** Ready for Change Control Reporting' execution Flow **CAPA Process** Closed **Execution done** REVIEW & APPROVAL Review Review Review Approve Approve

Released

Effectiveness

Assessment Flow

Released

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RELEASE & ARCHIVE

Archived

Released

<sup>\*</sup> If Reportability on the Recorded Issue Type is set to Yes

<sup>&</sup>quot;Recorded Issues include Complaints, Nonconformances, Supplier Issues and Continuous Improvements