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Process-Based Procedures, Enhancing QMS

Presented by: Keith Williams

Formpipe.GxP
Simply Compliant

Introducing the speaker

- I am an entrepreneur, director, and business manager with UK, European and US experience. I have over 25 years of Life Sciences experience, particularly in the pragmatic approach to getting computerised systems compliant and keeping them compliant.
- I have worked in a manufacturing, laboratory and clinical environment and more recently focused this experience to build a compliant set of highly configurable electronic products for content and document management.
- I have a BSc in Microbiology and an MSc (Eng.) in Biochemical Engineering.

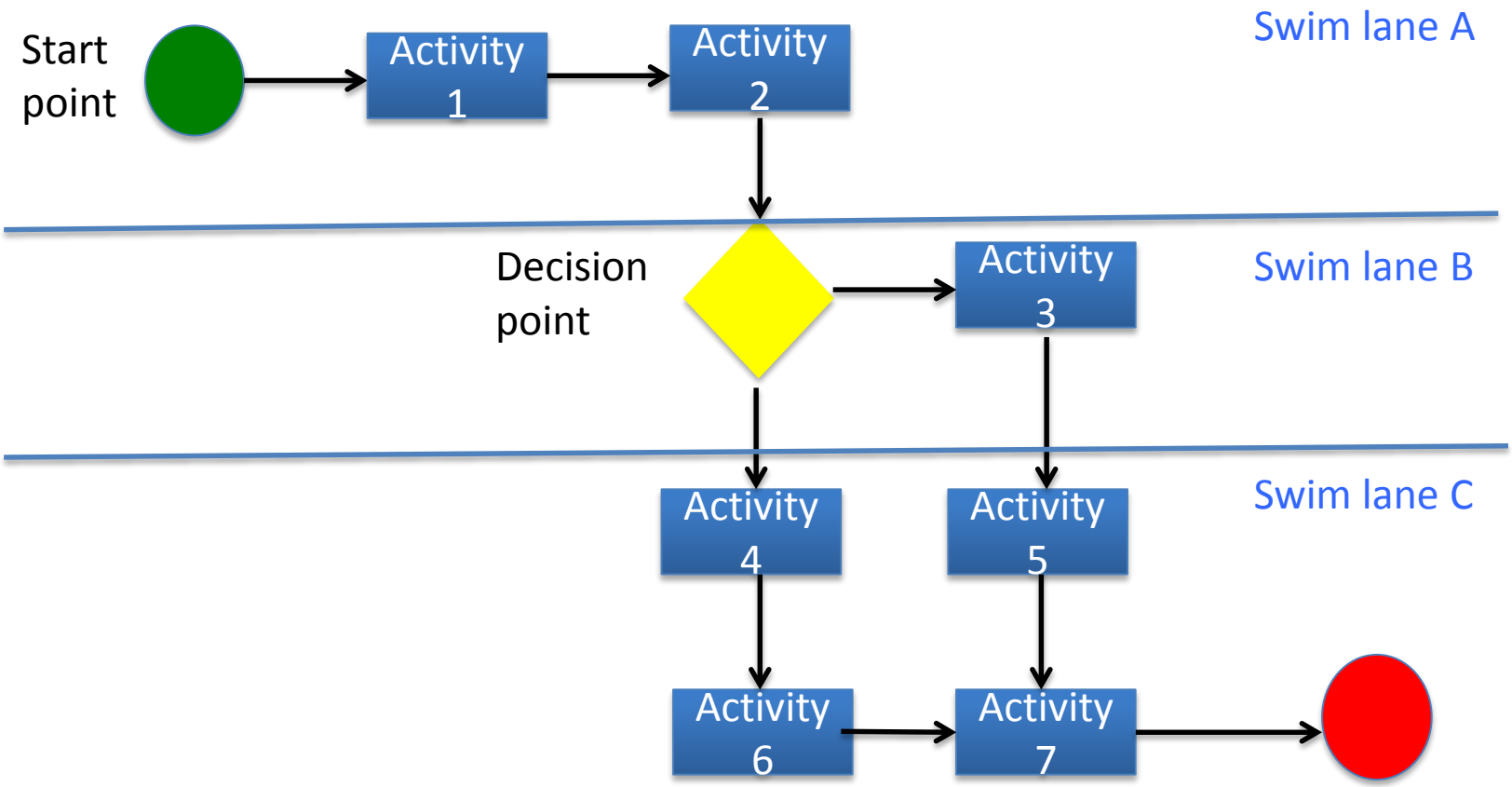
Agenda

- Why?- bother to analyze the process
- How? Do the Process Analysis
- A couple of examples
- Batch record example
- Enhanced eQMS Structure
- Benefits
- Conclusion

Why?

- QMS based on Paper, Shared Files, Spreadsheets….
- QMS partly electronic but fragmented over multiple systems e.g. DMS, LMS, Forms…..
- Cant find anything! Too many SOPs! Local optimization! Frustration! Non-compliance! Time wasted!

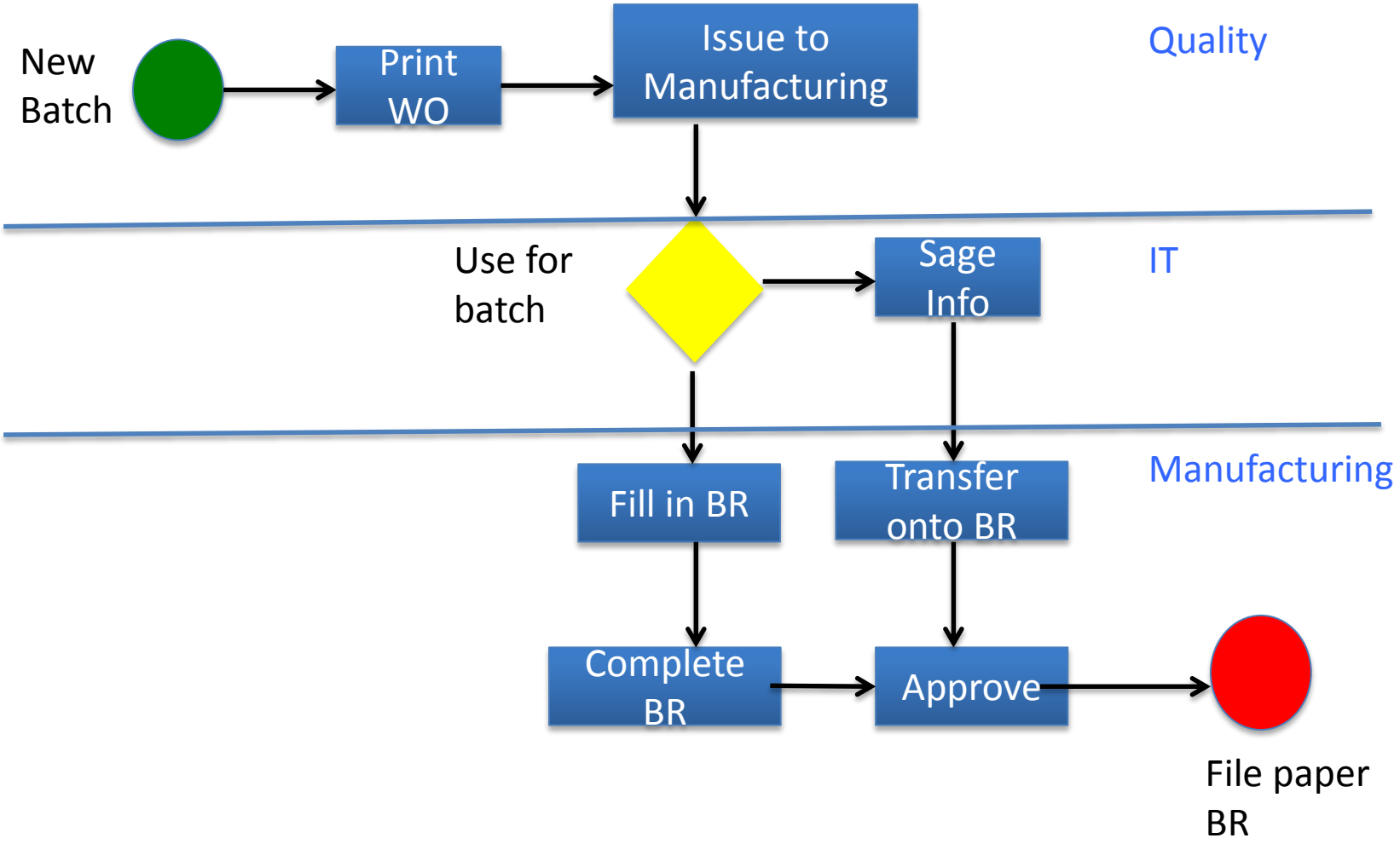
How?-Process Map Construction



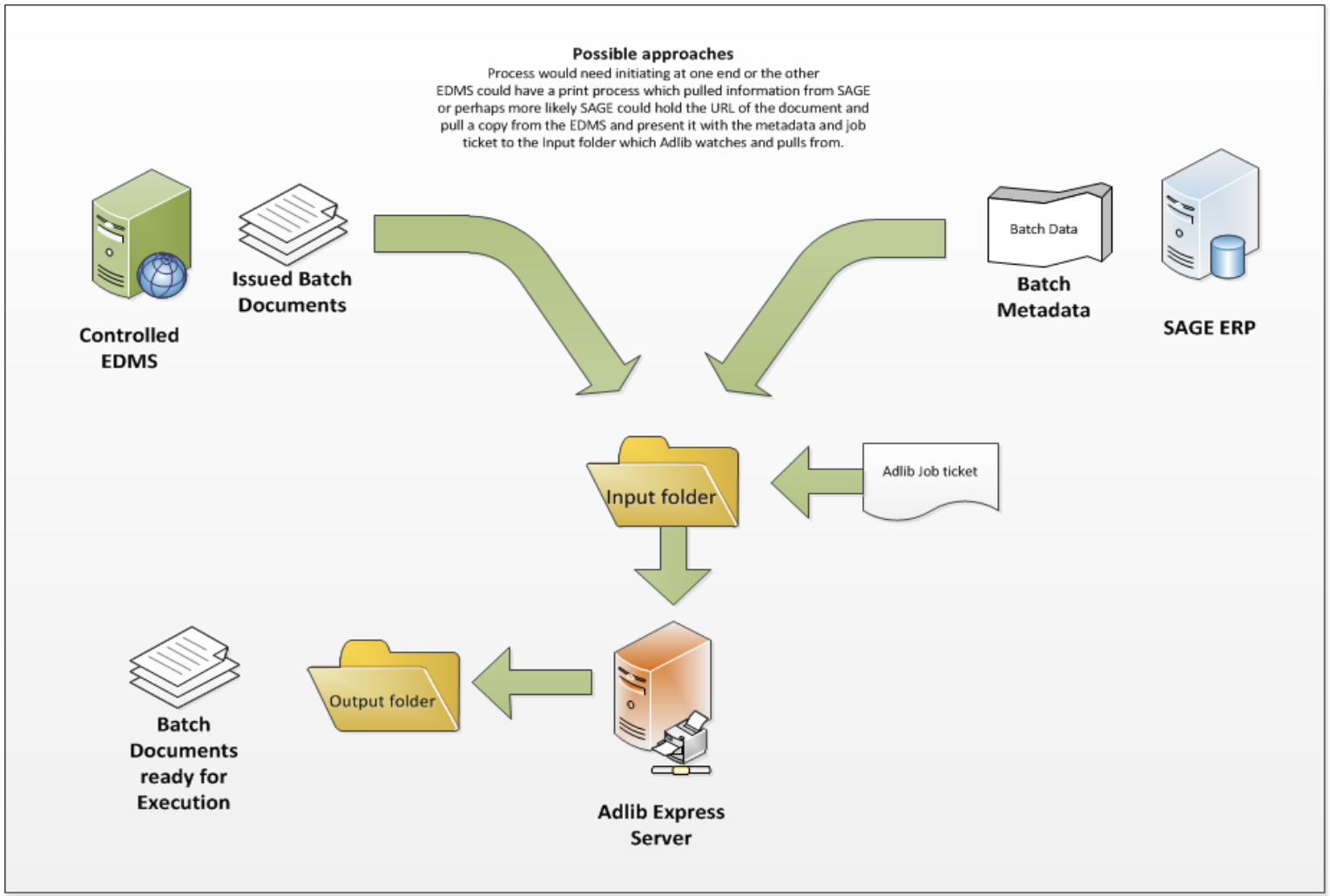
The Value of Process Maps

- Processes applied across the whole enterprise, not just one department, consistency
- Holistic view of inputs and outputs
- Clear distinction between Activities and Decision Points
- Clarity of responsibilities e.g. via Swimlanes
- Facilitates process improvements e.g. Lean Six Sigma

Study 1-Batch Record (BR) Process



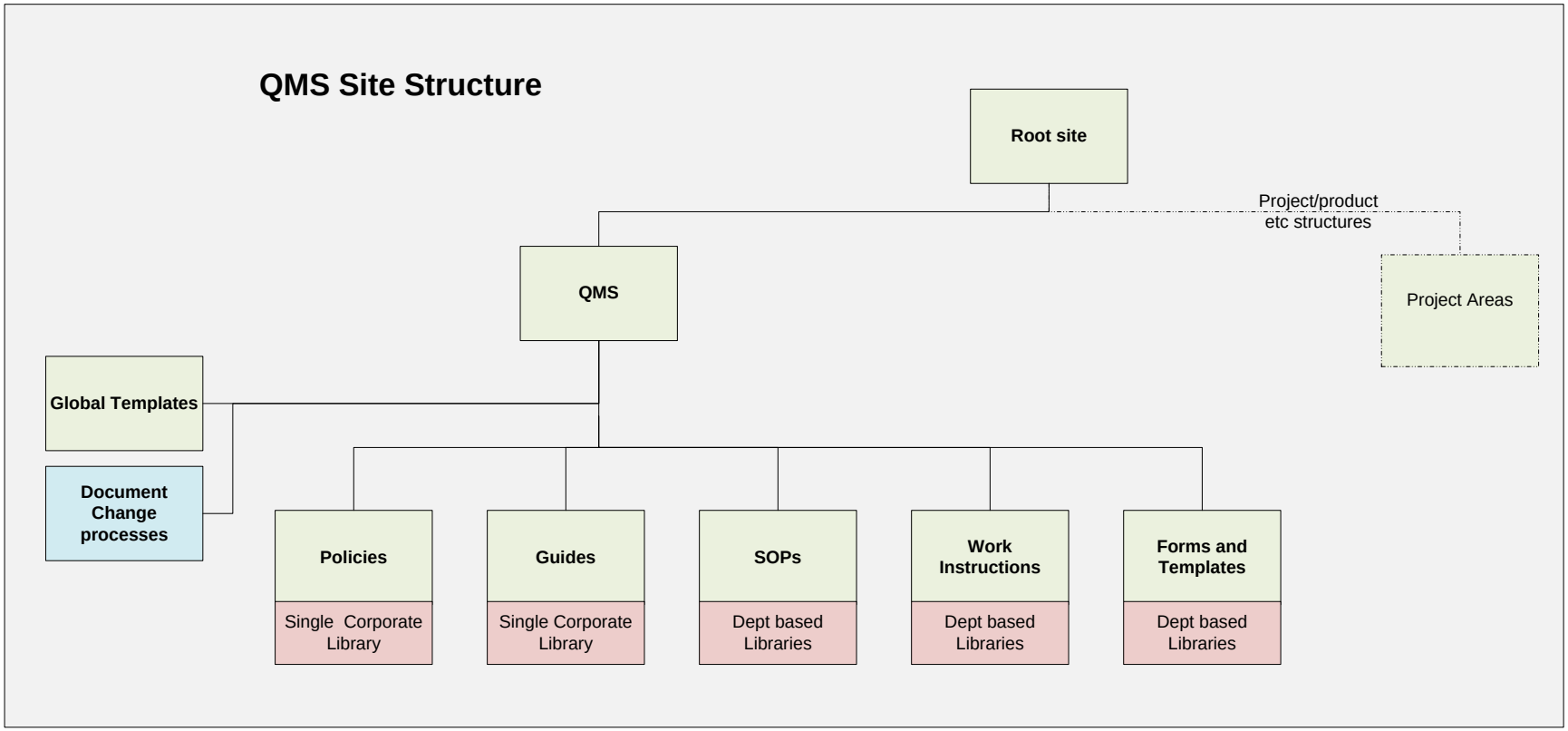
Study 1- Mapping aided Automate BR Process



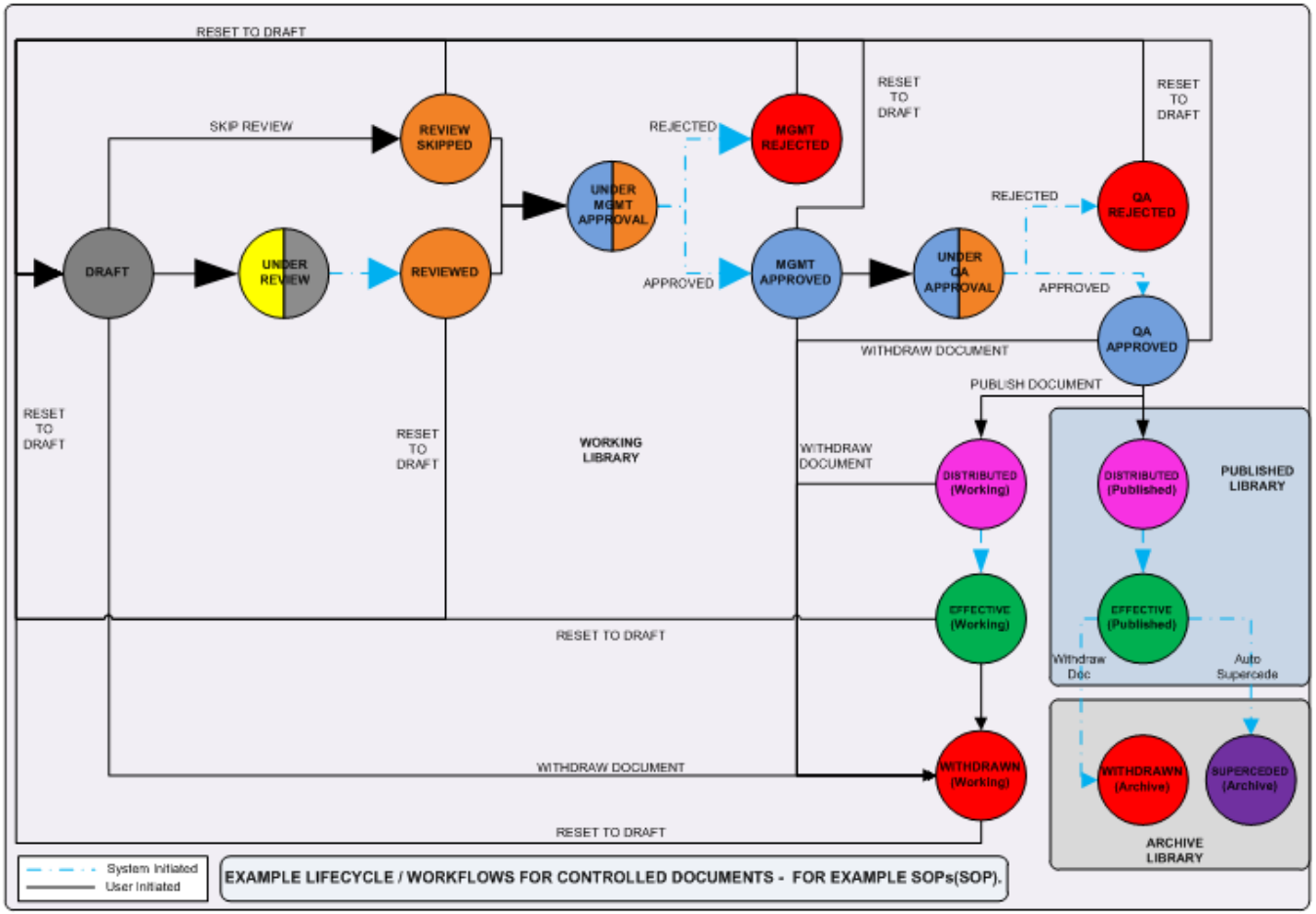
Processes, Procedures & eQMS

- Use Process Maps to define your eQMS processes (Forms, SOPs, Training)
- Process Maps are part of a hierarchical framework and can be part of the QMS
- Process Maps can be ‘navigable’ via hyperlinks within a document or between processes
- Processes can be used to define structure, workflows and metadata in eQMS and EDMS

Example eQMS Site Hierarchy



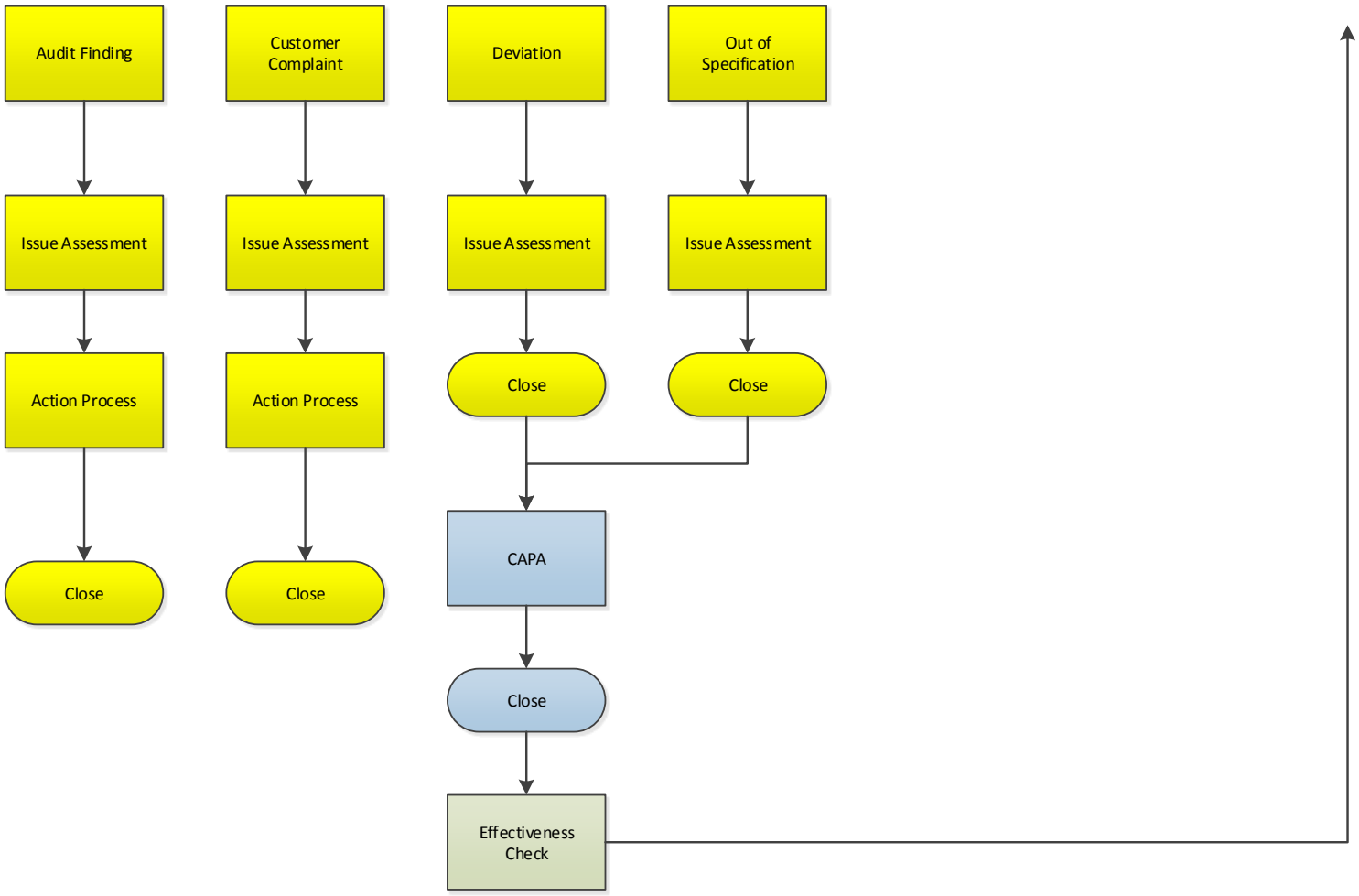
Example eQMS Workflow



Study 2- multiple issue management in QMS

- Several processes, managed separately but each compliant
- lifecycle is largely manually driven
- there are a number of templates and forms associated with each process
- Issue assessment done with each process and issue close out

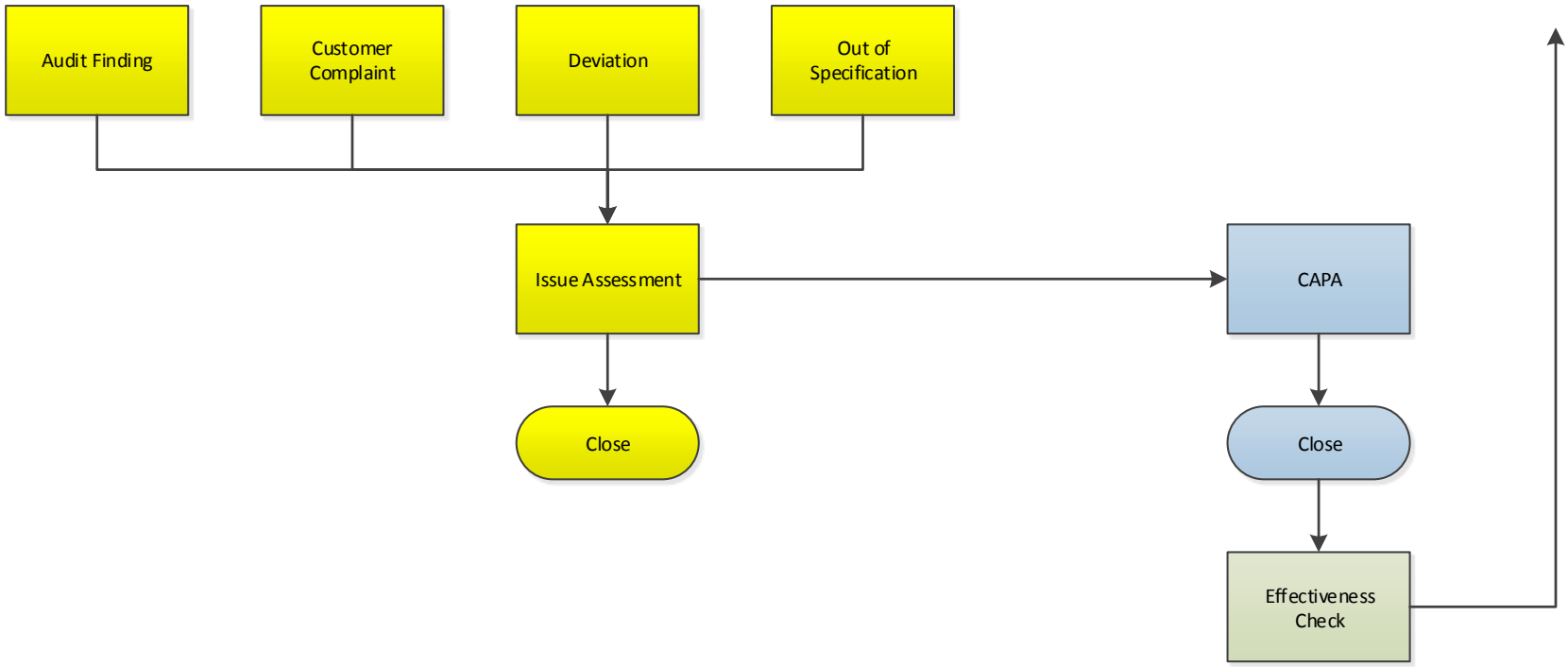
Multiple managed Quality processes for issue assessment and management



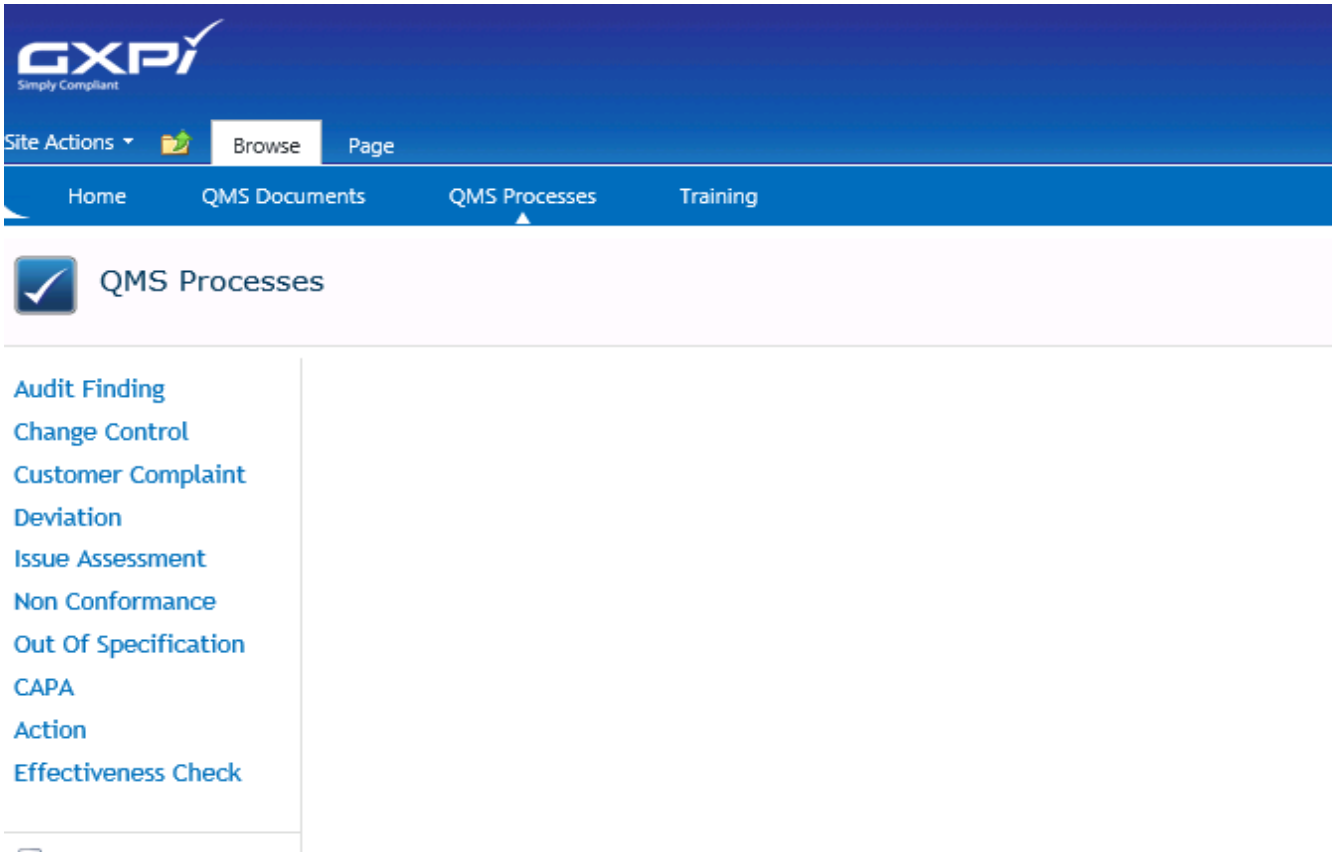
Study 2- Blend into a single eQMS unified process

- Analysis indicated rationalisation possible
- Multiple processes reduced to single Issue assessment
- Simplified process for management using Risk analysis process
- also allowed all forms processes in QMS to be managed in eQMS

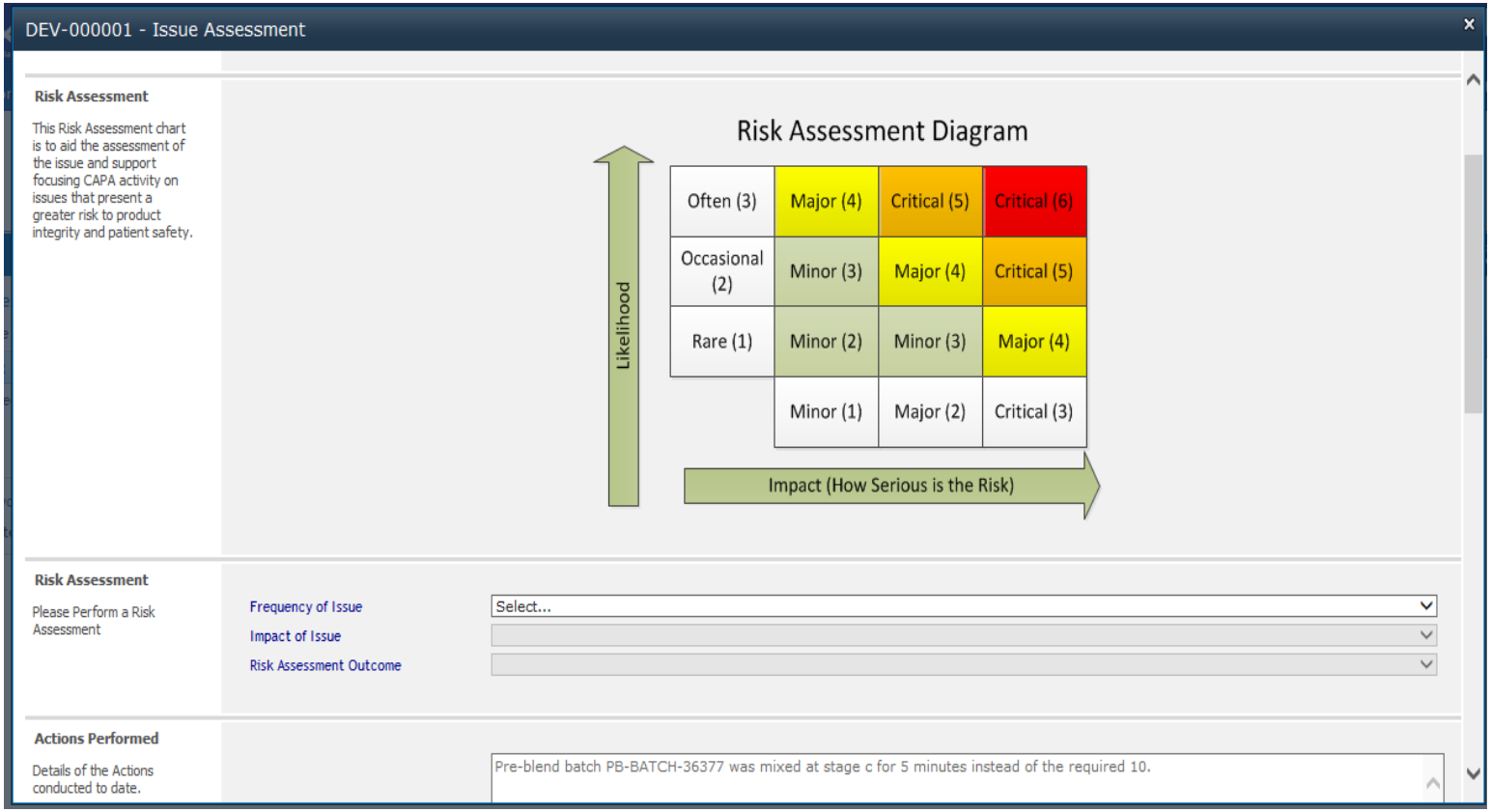
Single processes for issue assessment and management post analysis



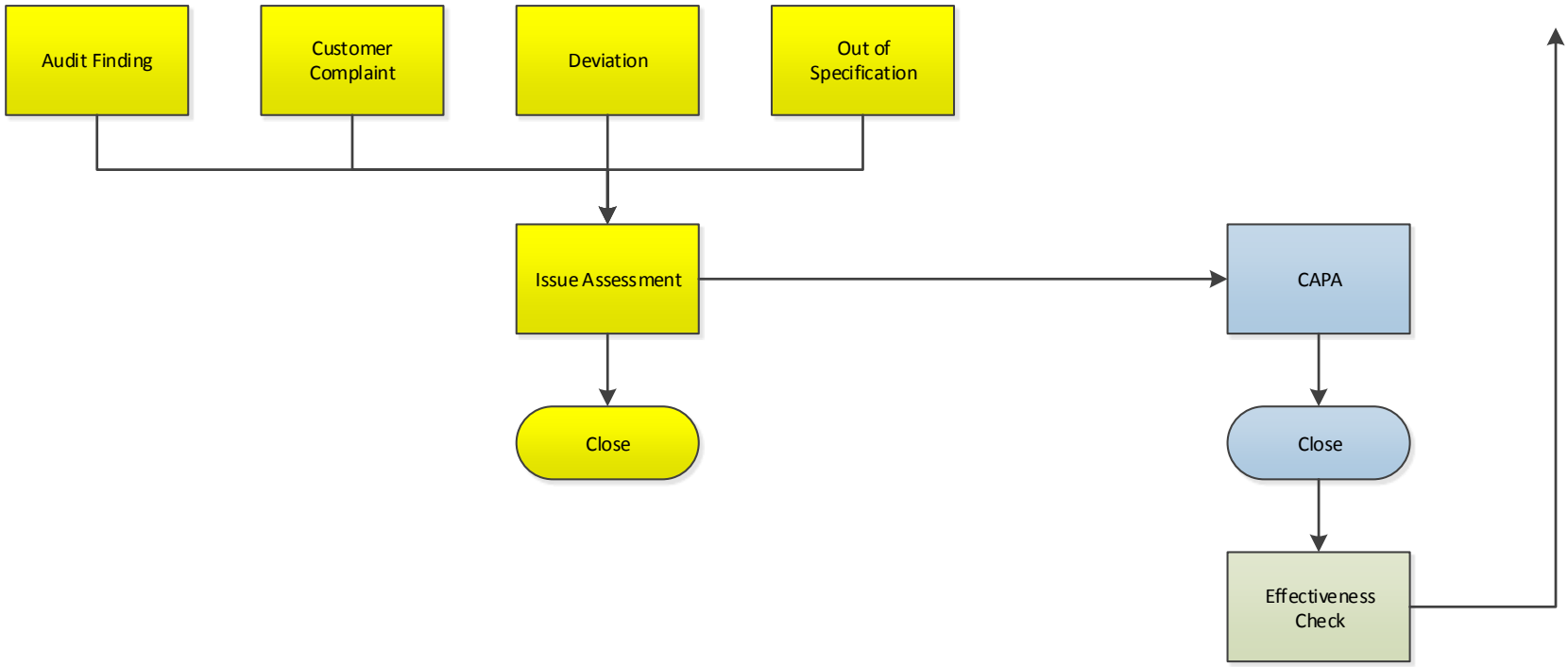
Entry of data by process managed in simple menu



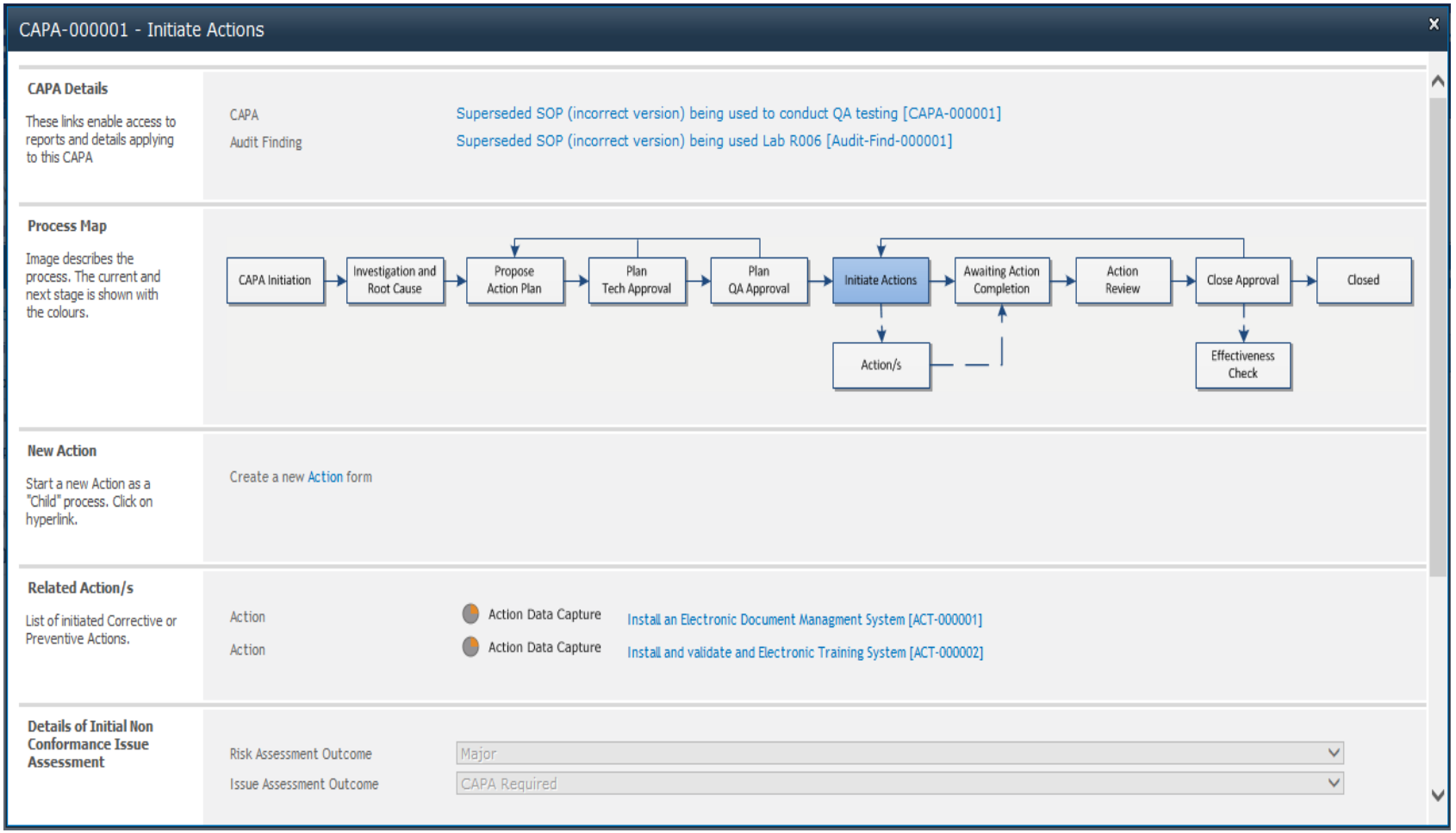
Issue assessment combined into standard Risk Assessment



CAPA initiated from audit findings



CAPA generated from an Audit finding



Benefits

- Improved access to procedural information
- Improved compliance efficiency
- Basis for performance measurement (KPIs) easier to manage all processes can be interrogated
- Good basis for continuous improvement as reporting on all processes

Conclusion

- Process Analysis is critical in order to find out what is really going on in the organisation, and to facilitate genuine improvement
- Processes mapping can improve your eQMS
- Well-defined processes are vital in order to get the most from your eQMS or EDMS

Thank you!

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