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Annual Meeting
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The
Leading Edge
of Pharmaceutical
Innovation

Process-Based Procedures, Enhancing QMS

Presented by: Keith Williams



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.

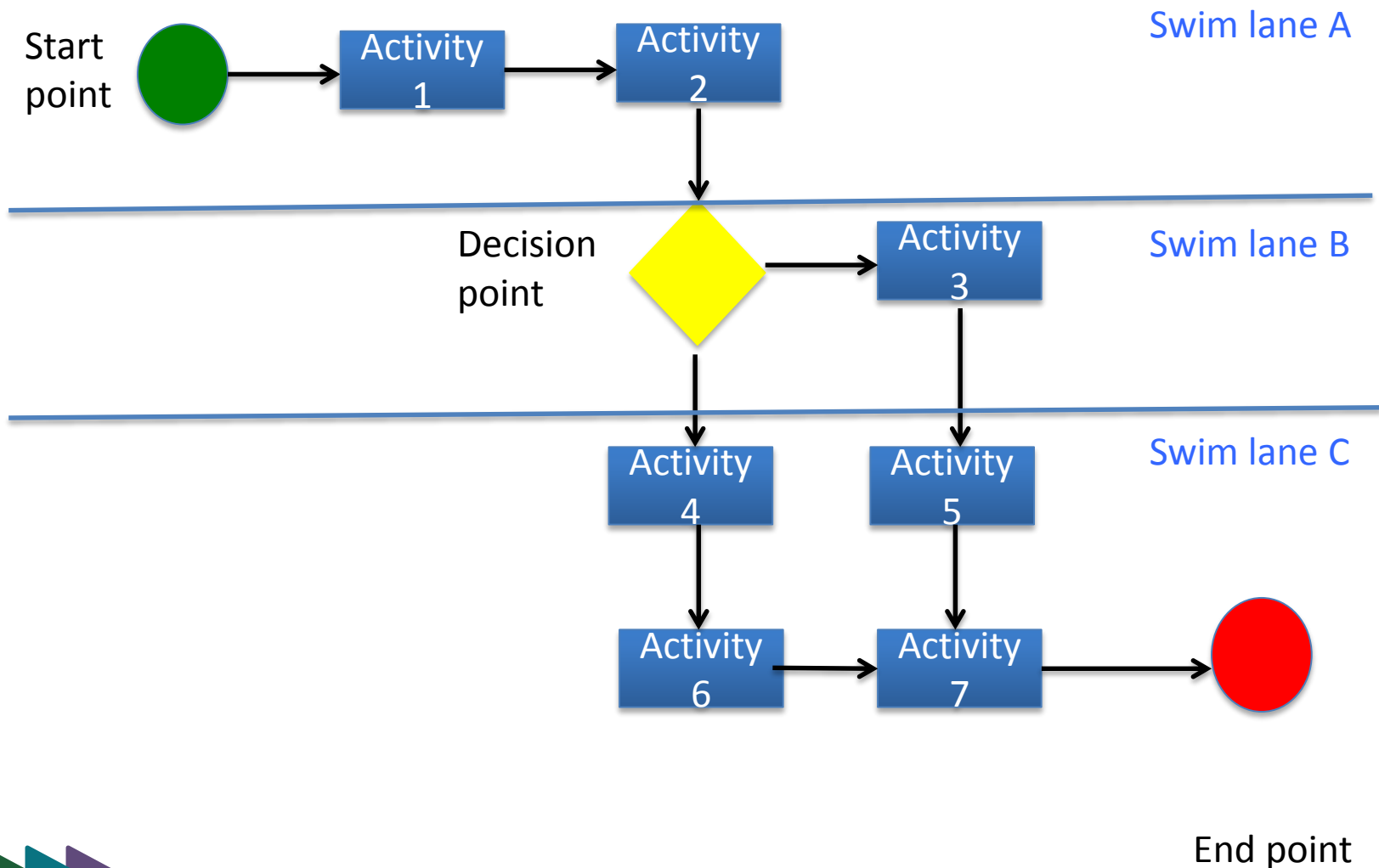
Agenda

- 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!

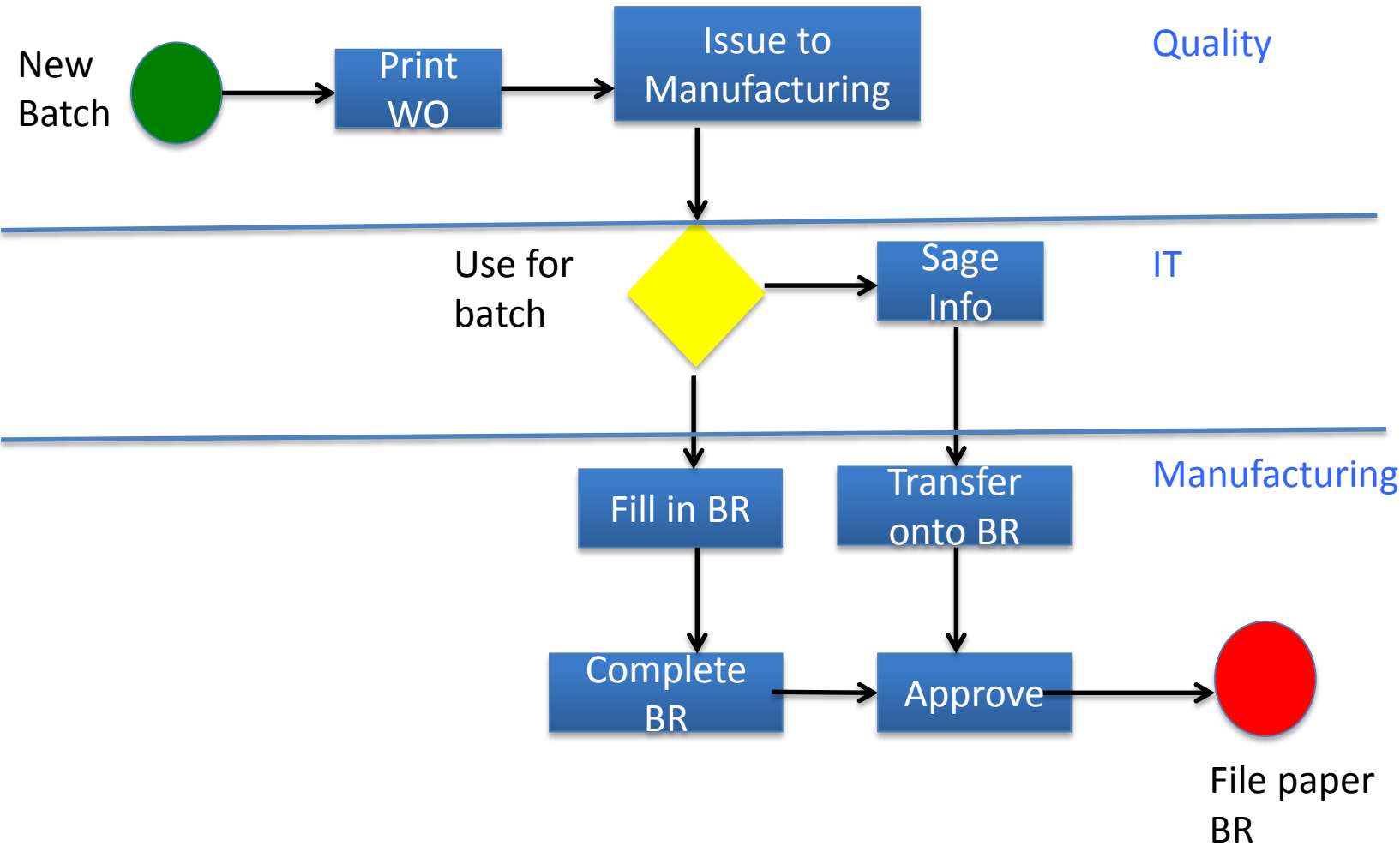
How?-Process Map Construction



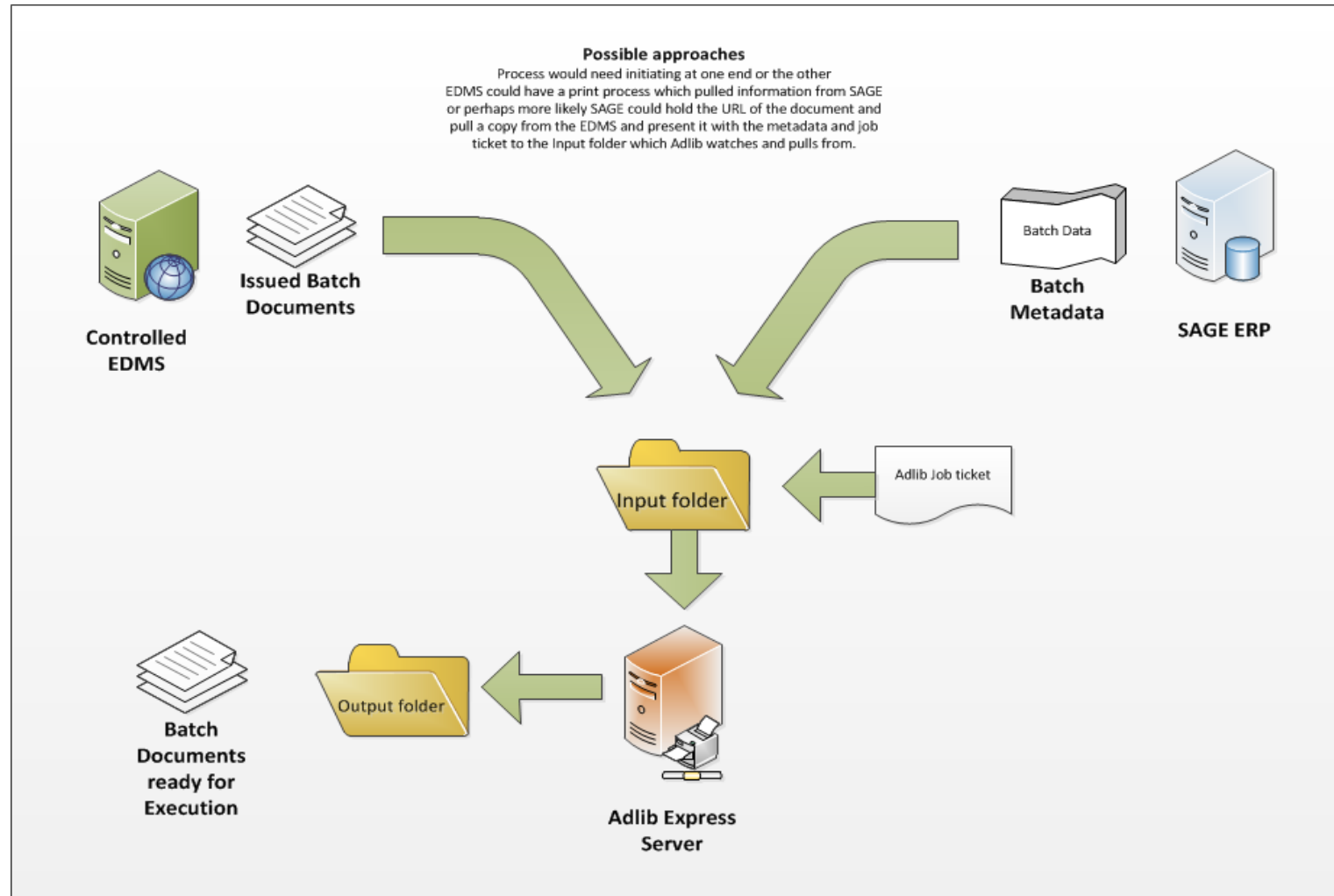
The Value of Process Maps

- 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



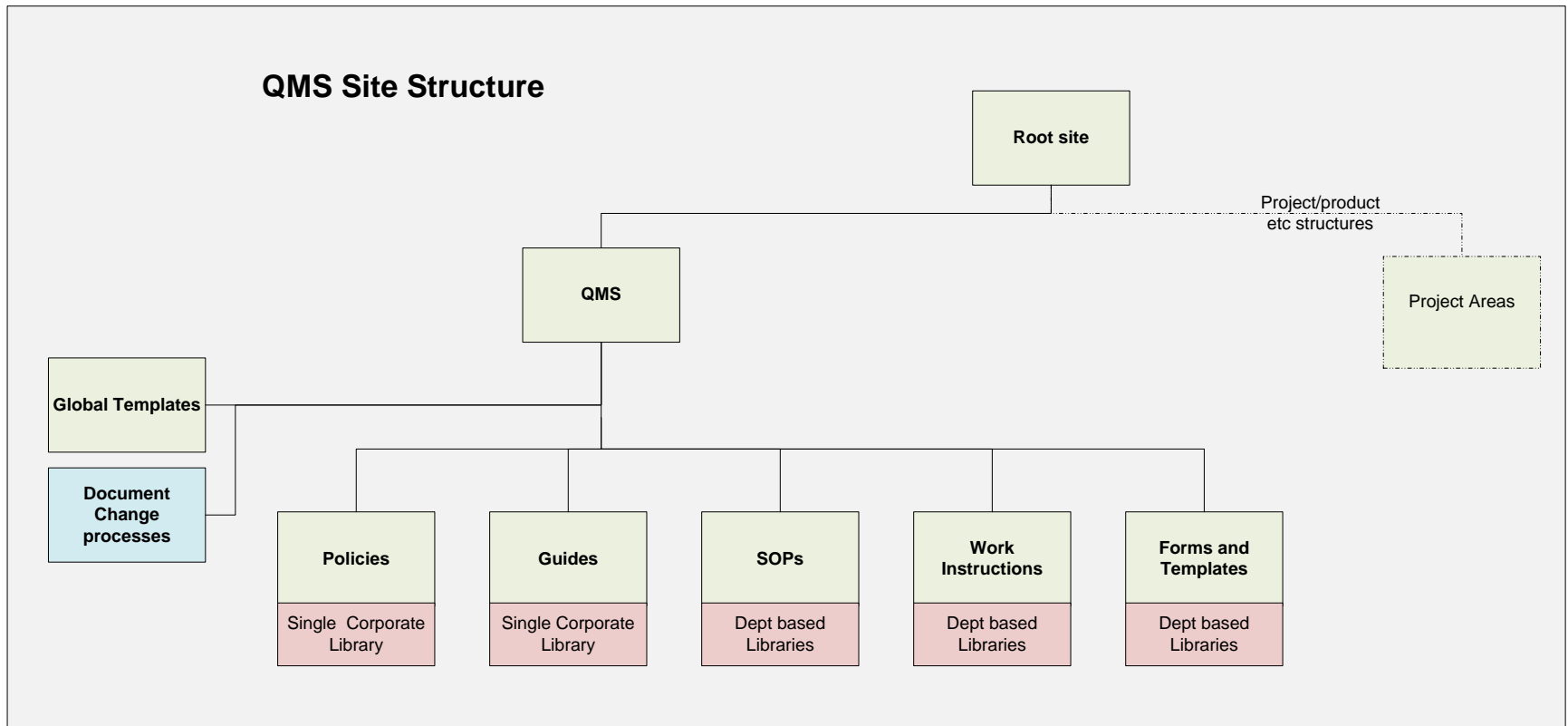
Study 1- Mapping aided Automate BR Process



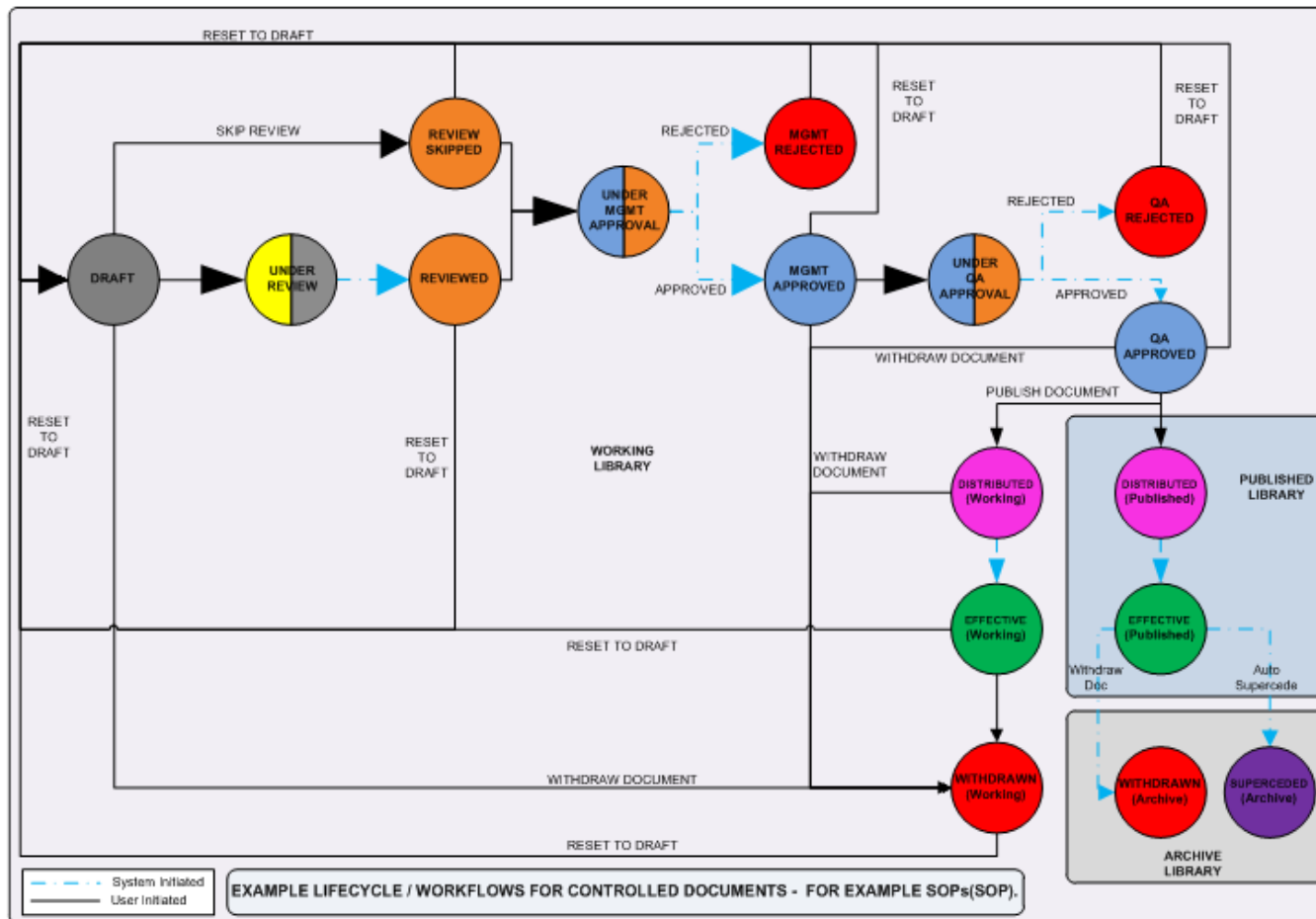
Processes, Procedures & eQMS

- 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



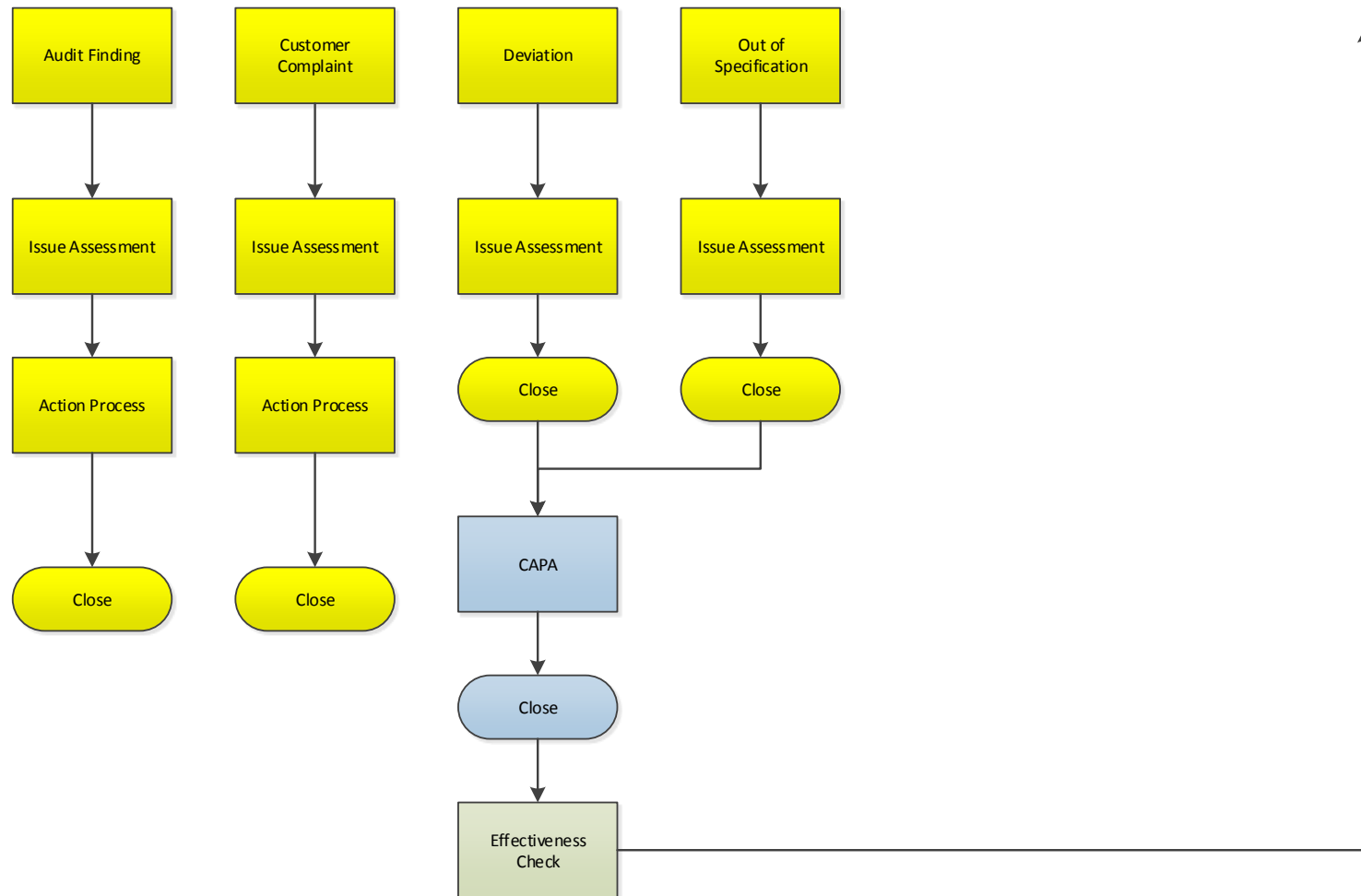
Example eQMS Workflow



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

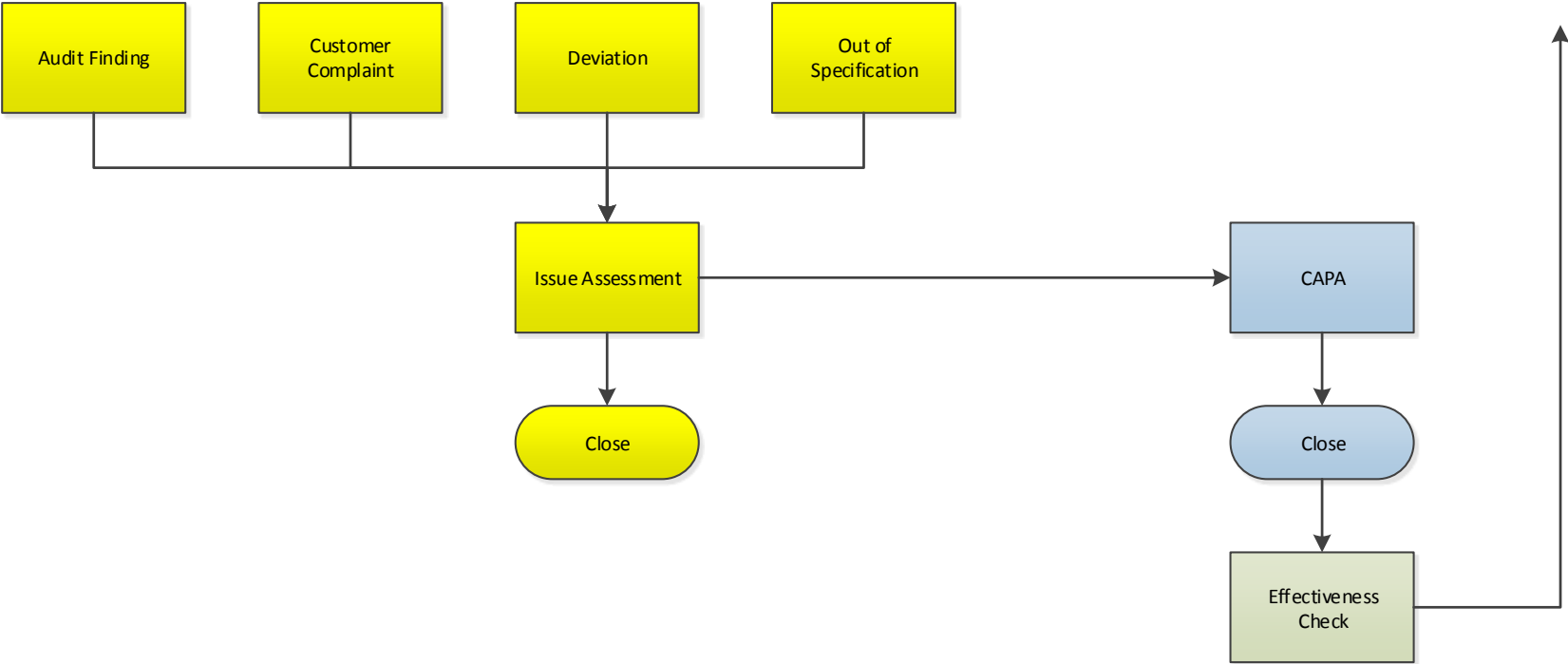
Multiple managed Quality processes for issue assessment and management



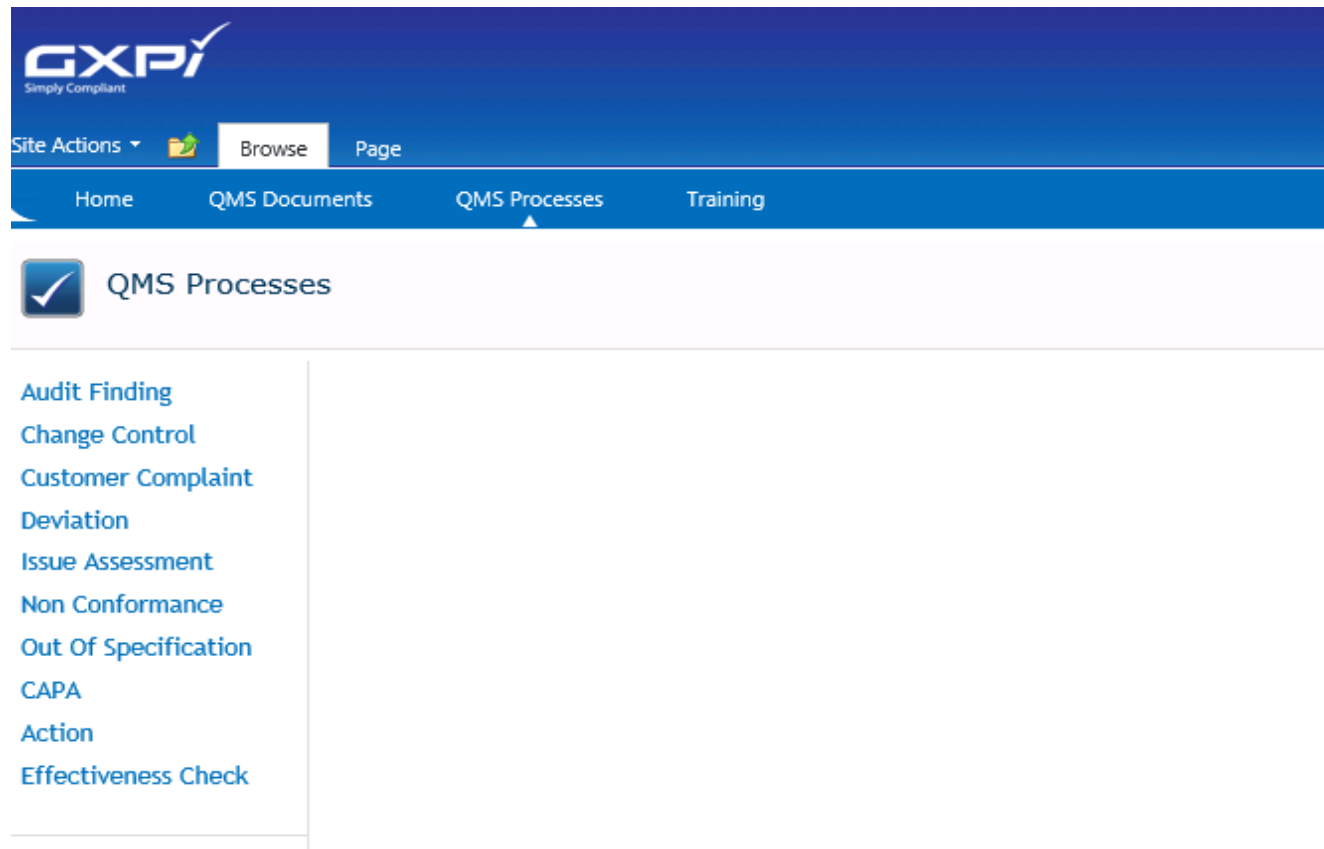
Study 2- Blend into a single eQMS unified process

- 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



The screenshot displays the GXPI web application interface. At the top left is the GXPI logo with the tagline "Simply Compliant". Below the logo is a navigation bar with "Site Actions" (a dropdown menu), a "Browse" button, and a "Page" label. A secondary navigation bar contains links for "Home", "QMS Documents", "QMS Processes" (which is highlighted with a mouse cursor), and "Training". Below this, a section titled "QMS Processes" is shown with a checkmark icon. A list of process categories is displayed in a sidebar:

- Audit Finding
- Change Control
- Customer Complaint
- Deviation
- Issue Assessment
- Non Conformance
- Out Of Specification
- CAPA
- Action
- Effectiveness Check

Issue assessment combined into standard Risk Assessment

DEV-000001 - Issue Assessment

Risk Assessment

This Risk Assessment chart is to aid the assessment of the issue and support focusing CAPA activity on issues that present a greater risk to product integrity and patient safety.

Risk Assessment Diagram

The diagram is a 4x4 matrix with 'Likelihood' on the vertical axis and 'Impact (How Serious is the Risk)' on the horizontal axis. The cells contain risk levels and scores in parentheses. The colors of the cells are: Red (Critical 6), Orange (Critical 5), Yellow (Major 4), Green (Minor 3), and Light Green (Minor 2). The bottom row is partially missing.

Often (3)	Major (4)	Critical (5)	Critical (6)
Occasional (2)	Minor (3)	Major (4)	Critical (5)
Rare (1)	Minor (2)	Minor (3)	Major (4)
	Minor (1)	Major (2)	Critical (3)

Risk Assessment

Please Perform a Risk Assessment

Frequency of Issue

Impact of Issue

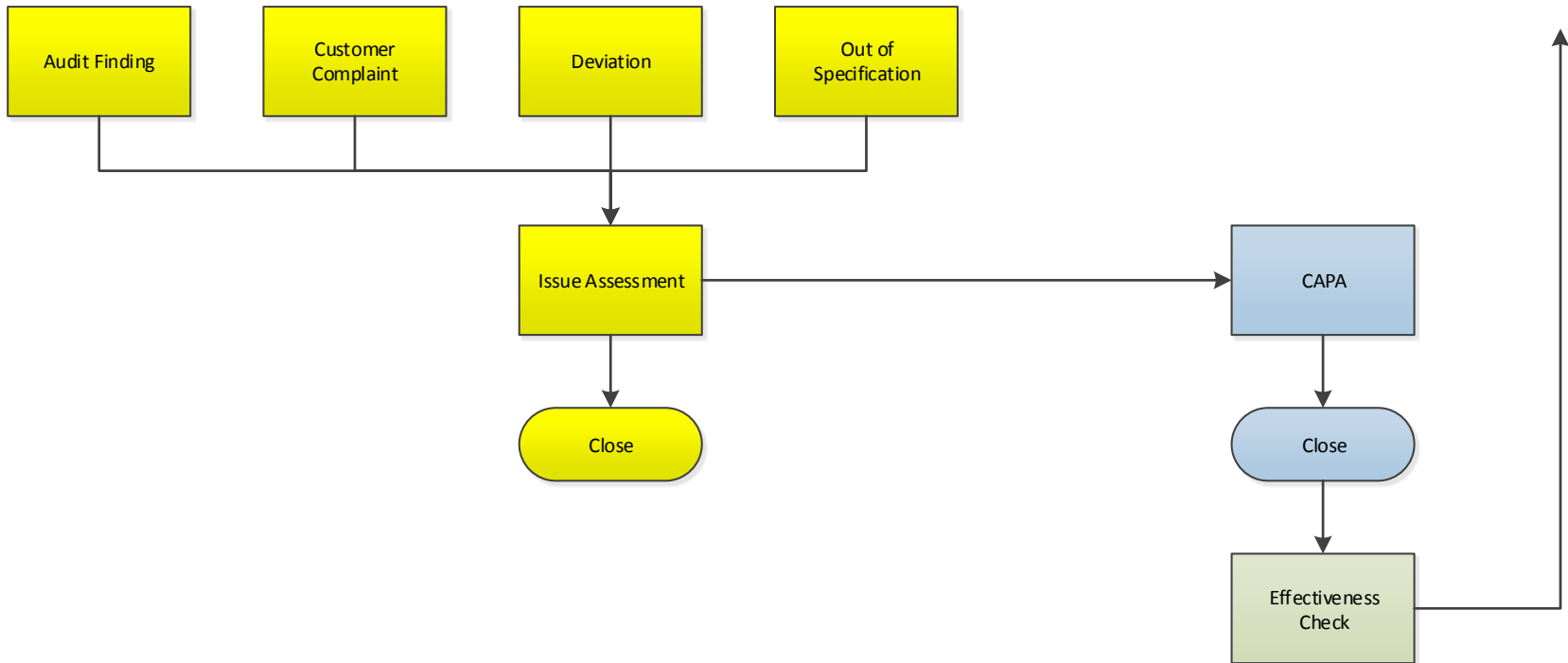
Risk Assessment Outcome

Actions Performed

Details of the Actions conducted to date.

Pre-blend batch PB-BATCH-36377 was mixed at stage c for 5 minutes instead of the required 10.

CAPA initiated from audit findings



CAPA generated from an Audit finding

CAPA-000001 - Initiate Actions

CAPA Details
 These links enable access to reports and details applying to this CAPA

CAPA	Superseded SOP (incorrect version) being used to conduct QA testing [CAPA-000001]
Audit Finding	Superseded SOP (incorrect version) being used Lab R006 [Audit-Find-000001]

Process Map
 Image describes the process. The current and next stage is shown with the colours.

```

    graph LR
      A[CAPA Initiation] --> B[Investigation and Root Cause]
      B --> C[Propose Action Plan]
      C --> D[Plan Tech Approval]
      D --> E[Plan QA Approval]
      E --> F[Initiate Actions]
      F --> G[Awaiting Action Completion]
      G --> H[Action Review]
      H --> I[Close Approval]
      I --> J[Closed]
      F --> K[Action/s]
      K -.-> G
      I --> L[Effectiveness Check]
      L -.-> I
    
```

New Action
 Start a new Action as a "Child" process. Click on hyperlink.

Create a new [Action](#) form

Related Action/s
 List of initiated Corrective or Preventive Actions.

Action	Action Data Capture	Install an Electronic Document Management System [ACT-000001]
Action	Action Data Capture	Install and validate and Electronic Training System [ACT-000002]

Details of Initial Non Conformance Issue Assessment

Risk Assessment Outcome	<input type="text" value="Major"/>
Issue Assessment Outcome	<input type="text" value="CAPA Required"/>

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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