



... bridging your enterprise and your plant

Business Reporting in the Manufacturing IT Landscape.

Presented by:
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Europe

Cork . Oss . Istanbul

North America

Boston . Research Triangle . San Francisco . PR

Agenda



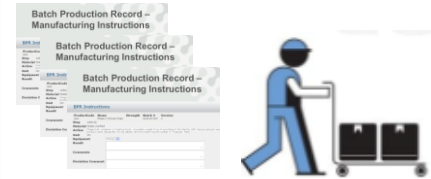
- Objectives.
- Overview of Transition from Paper to MES.
- Defining Business Reporting Requirements.
- Business Reporting Framework.

Objective

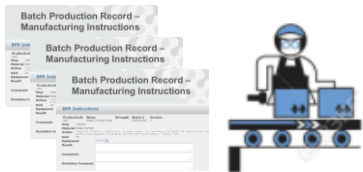


- ❑ To outline a process for **defining business reporting requirements**.
- ❑ Provide context on how the development, design and testing of the **reporting requirements fits within the business strategy** for transitioning from paper based processes to electronic batch records.
- ❑ Outline a sample set of **business logic** which can be used to determine the **benefit for integrating ancillary systems**.

Overview of Transition from Paper to EBR



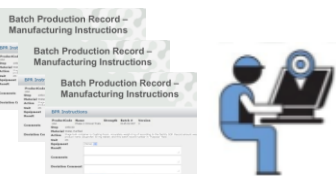
Material Tracking Sheets



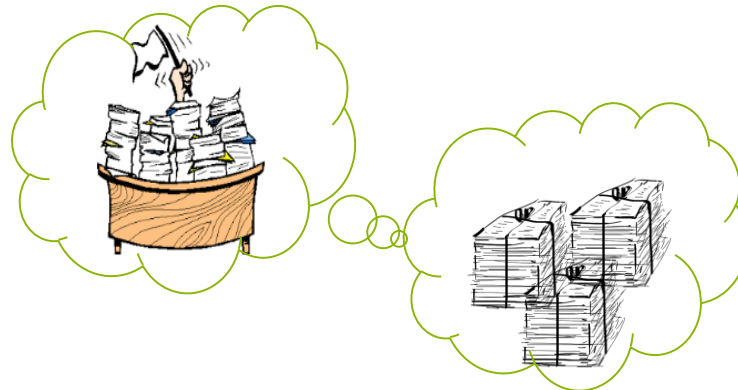
Manual Tasks



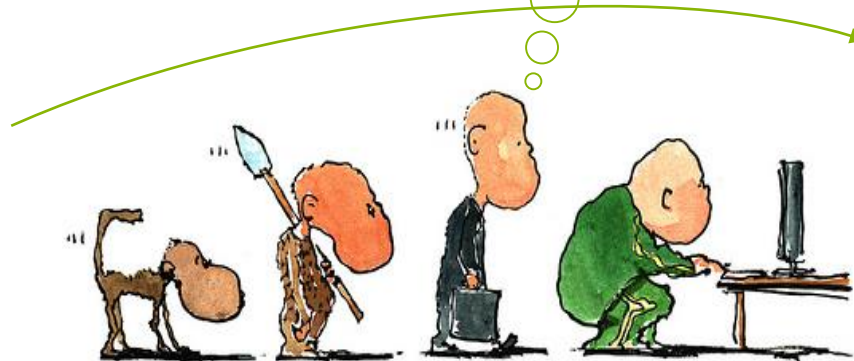
Process Testing



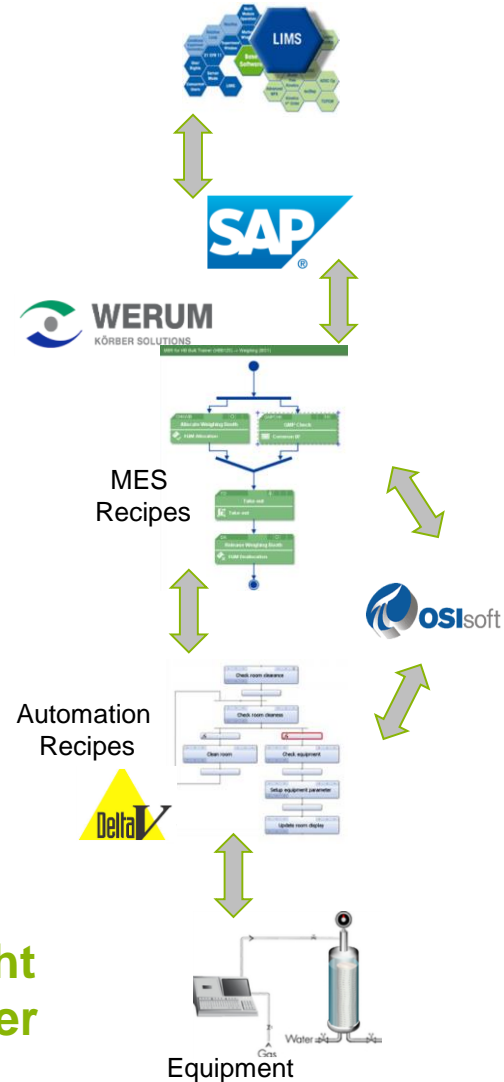
System Reports



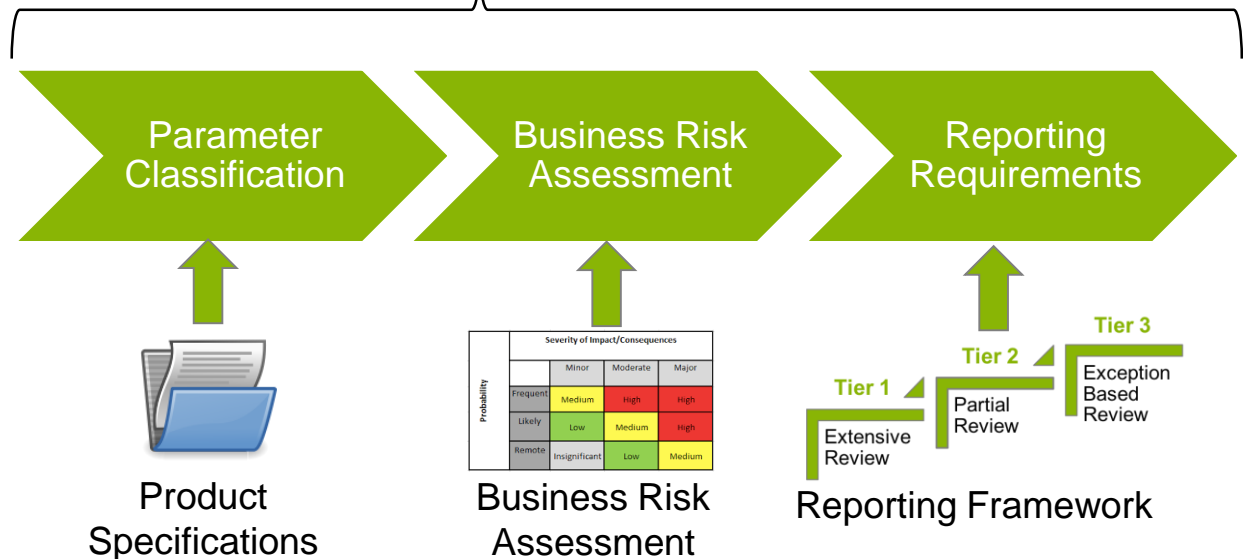
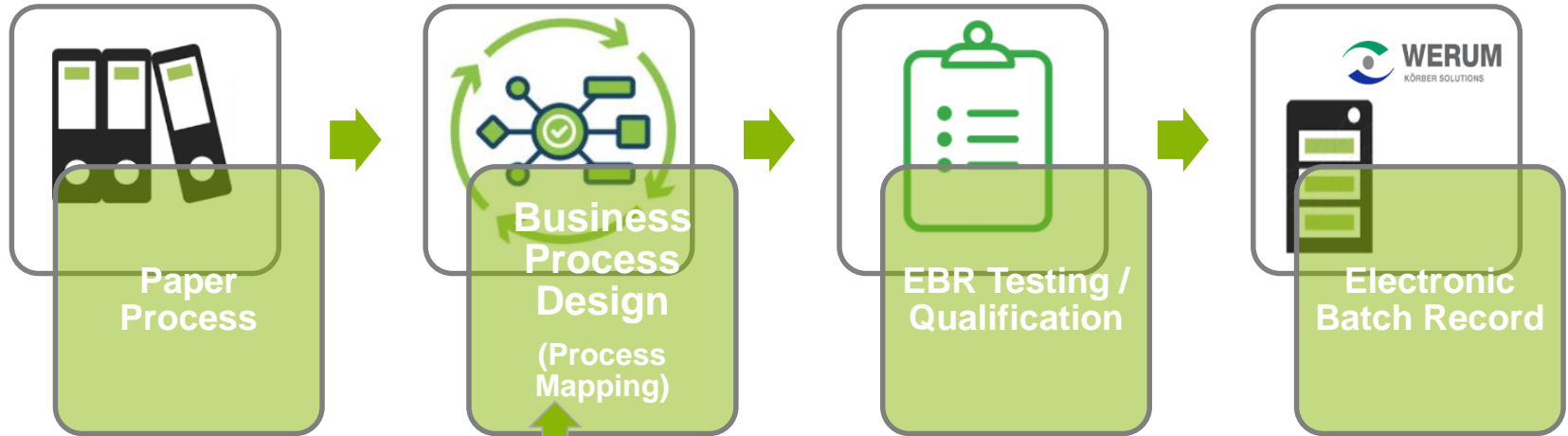
EBR Transformational Curve



It is therefore important to ask the right questions (business & system) in order to be successful.



How to define the business reporting requirements as part of the EBR transition.



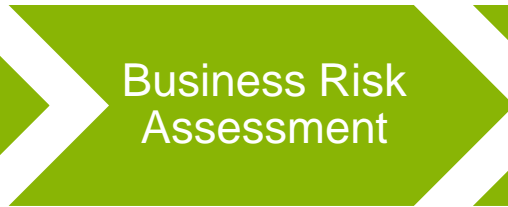
The process to define the business reporting requirements.



Determine the Business Value

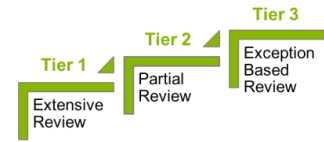


Product Specifications



		Severity of Impact/Consequences		
		Minor	Moderate	Major
Probability	Frequent	Medium	High	High
	Likely	Low	Medium	High
	Remote	Insignificant	Low	Medium

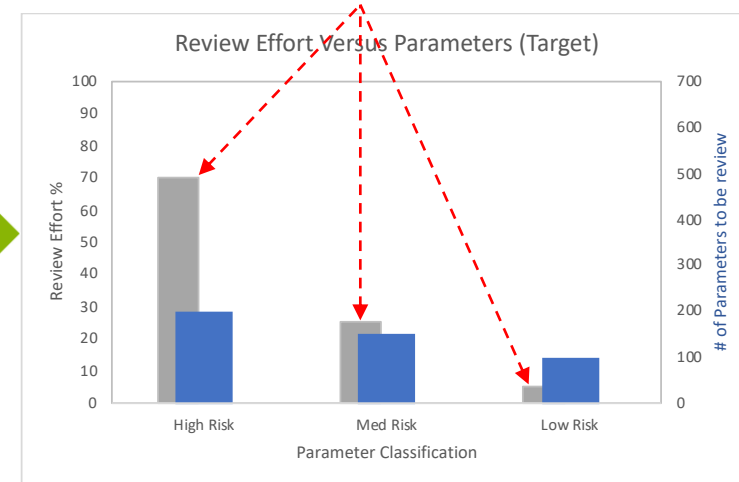
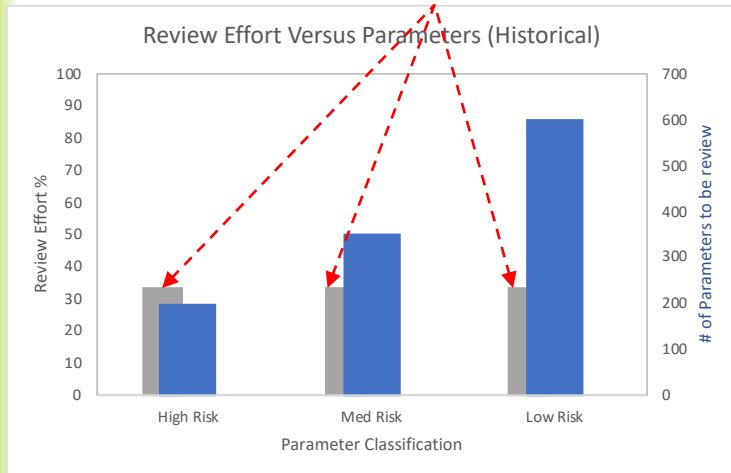
Business Risk Assessment



Reporting Framework

Historically the level of review effort is disproportionate i.e. QA reviewing both value and non value based activities.

Post business justification QA review effort becomes refocused on higher risk items.

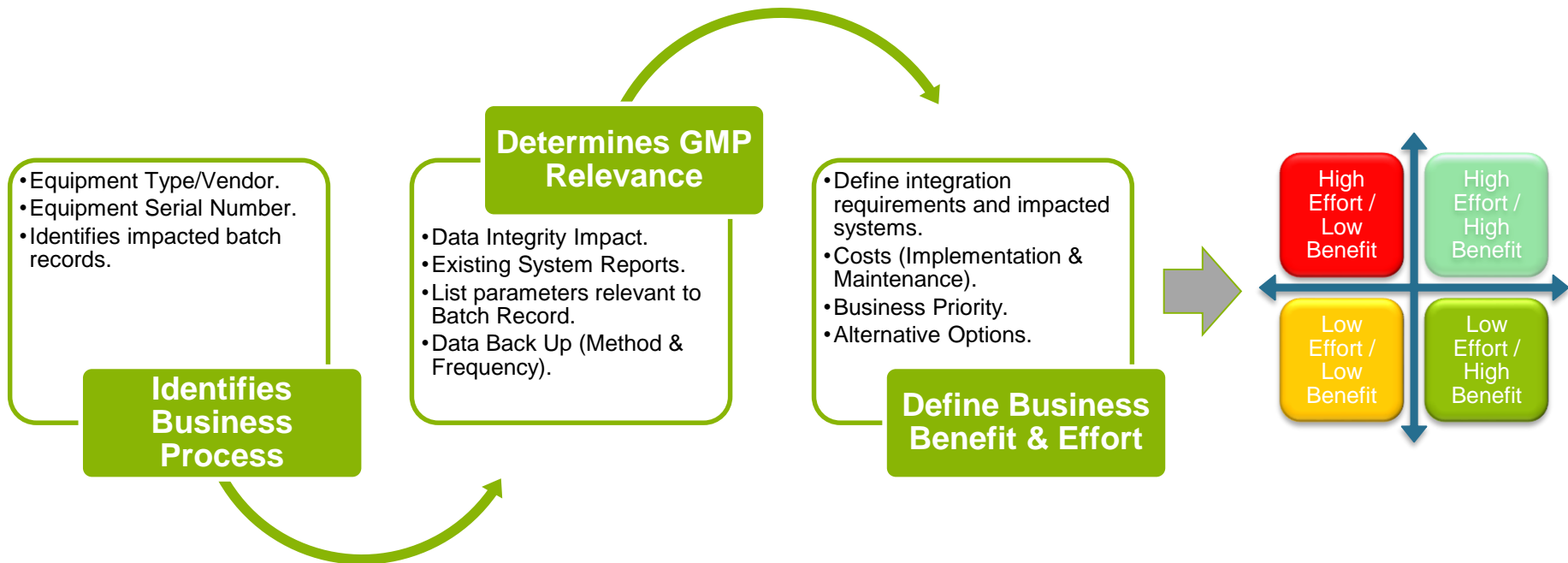


Business Reporting Framework

(Determine the Business Value)



Business Question: Where the existing equipment/system fails to meet the business reporting requirements, does it justify integrating/upgrading the system based on both the GMP impact and the cost versus effort?

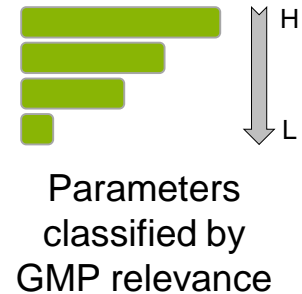
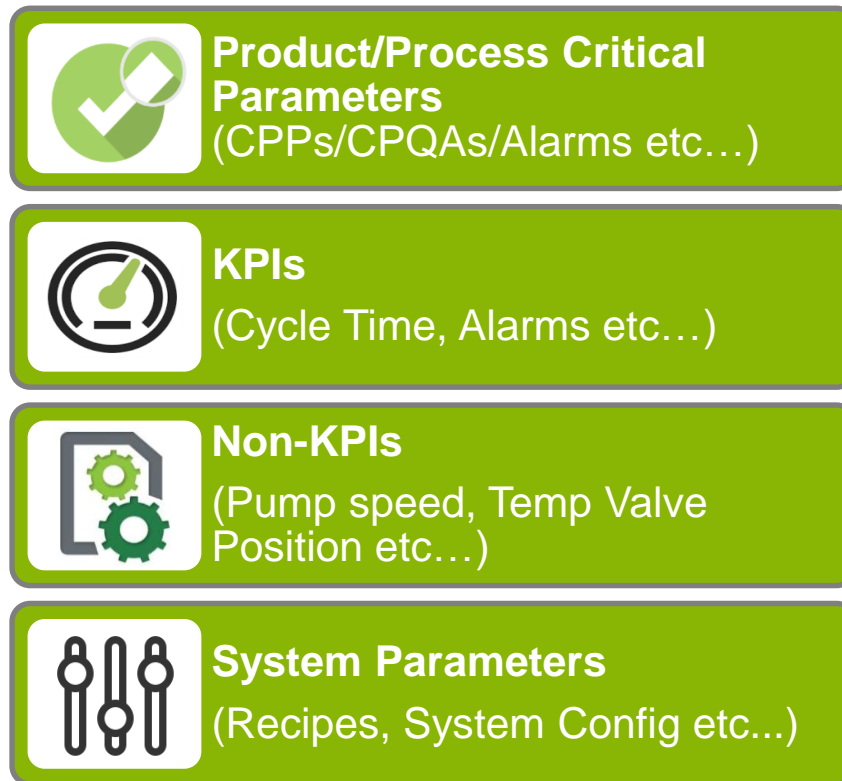


Business Reporting Framework (Parameter Classification)



Parameter
Classification

Provide a basis to classify product parameters. The output will then be used as an input for the business risk assessment.

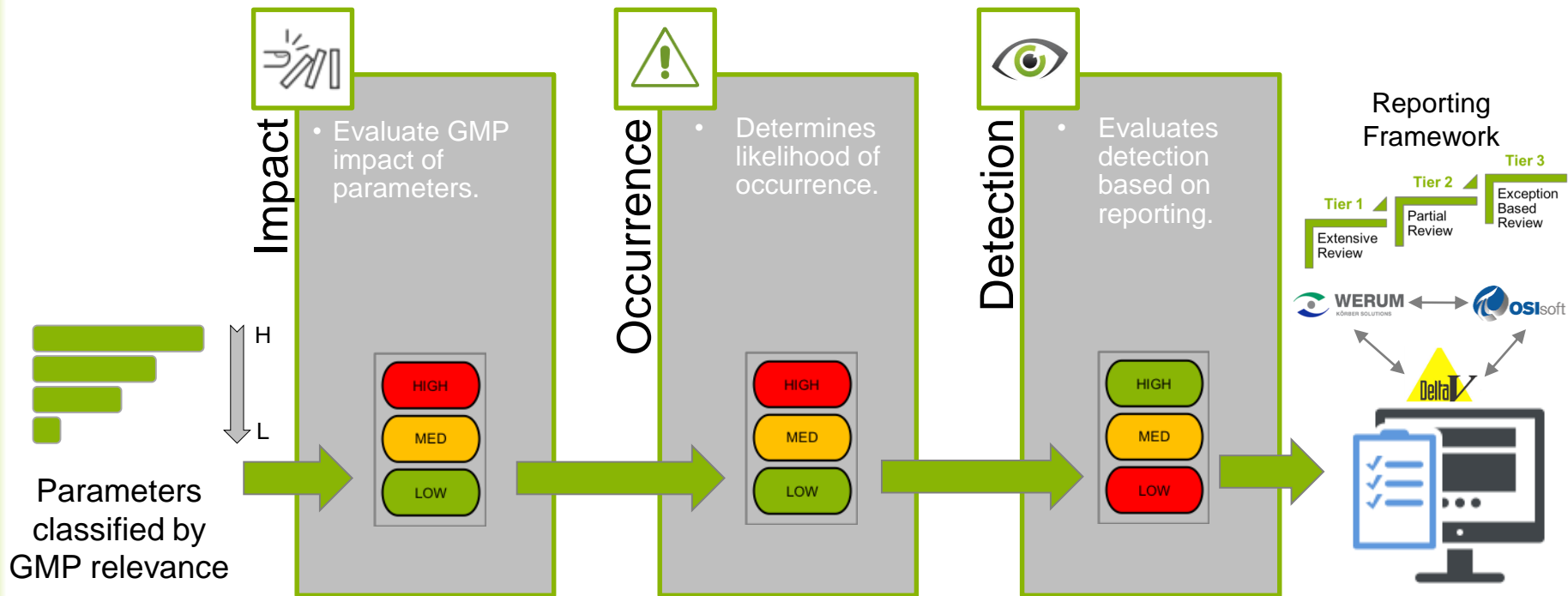


Business Reporting Framework (Business Risk Assessment)



Business Risk Assessment

Once the parameters have been classified the business risk assessment is utilised to determine the reporting requirements and align them with the relevant system i.e. CPP → MES, KPI → OSI PI

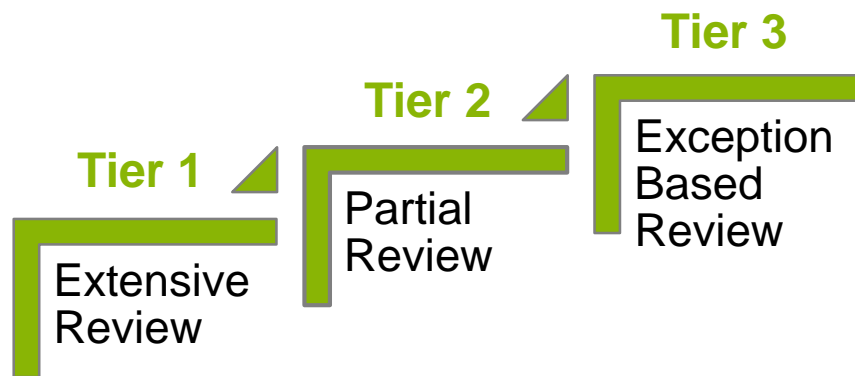





Business Reporting Framework

(Reporting Framework)



Reporting Framework



System	Tier 1	Tier 2	Tier 3
	<ul style="list-style-type: none"> Standard PAS X report (Complete Review). 	<ul style="list-style-type: none"> Reduced PAS X report configured using element markers (Complete Review). 	<ul style="list-style-type: none"> Standard and/or reduced PAS X report generated by system but only reviewed on exception basis.
	<ul style="list-style-type: none"> Exception based reports. KPI reporting (As needed). 	<ul style="list-style-type: none"> Exception based reports. KPI reporting (As needed). 	<ul style="list-style-type: none"> Exception based reports. KPI reporting (As needed).
	<ul style="list-style-type: none"> Process and/or System Reports (As needed). 	<ul style="list-style-type: none"> Process and/or System Reports (As needed). 	<ul style="list-style-type: none"> Process and/or System Reports (As needed). Exception based review.

Key Points



- Just because you can report certain activities, parameter values etc.... doesn't mean you should. By creating the report it means the data inherently becomes subject to review.
- Ensure to challenge the business justification for creating a report.

Questions

