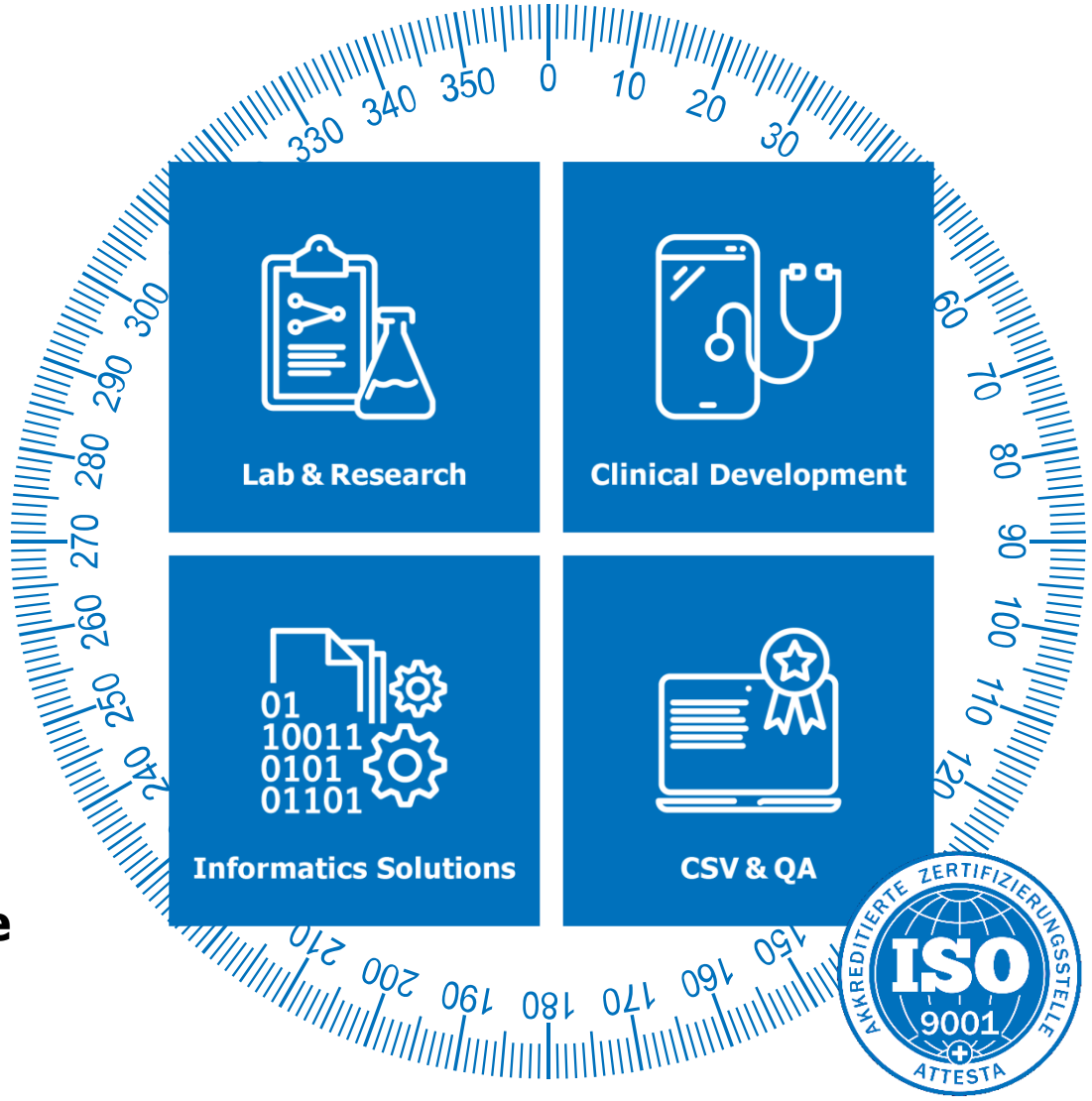
Agile Validation in GxP

About wega
Four Pillars of Excellence



Our four groups are collaborating closely to provide **360° Services in Pharma, Life Science and Healthcare Informatics** ranging from process engineering to software routine maintenance.

Validation Goals

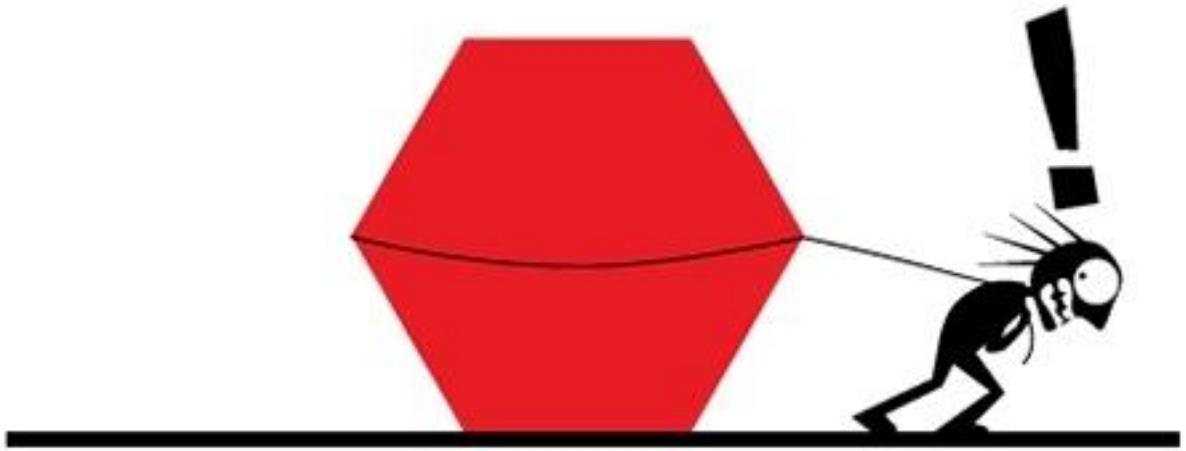
Product Quality

Patient Safety

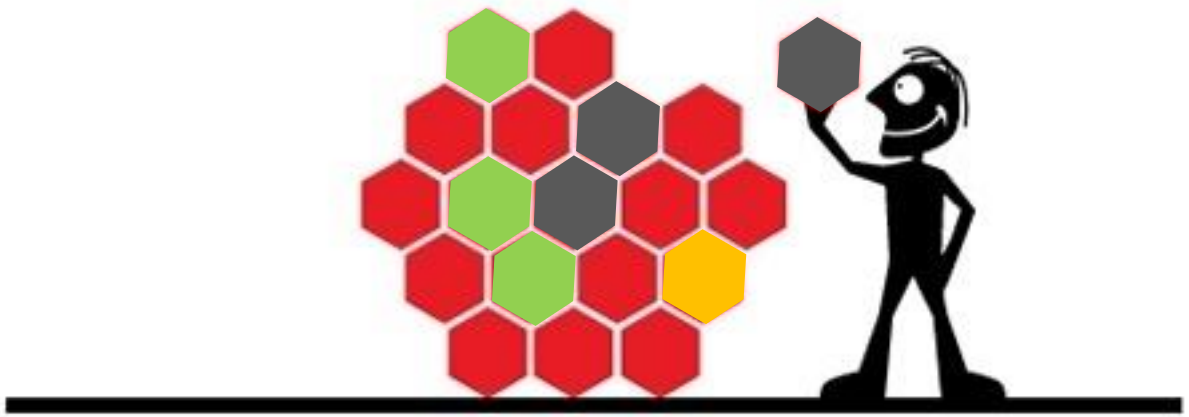
Data Integrity

Agility in a tiny Nutshell

NON-AGILE PROCESS



AGILE PROCESS



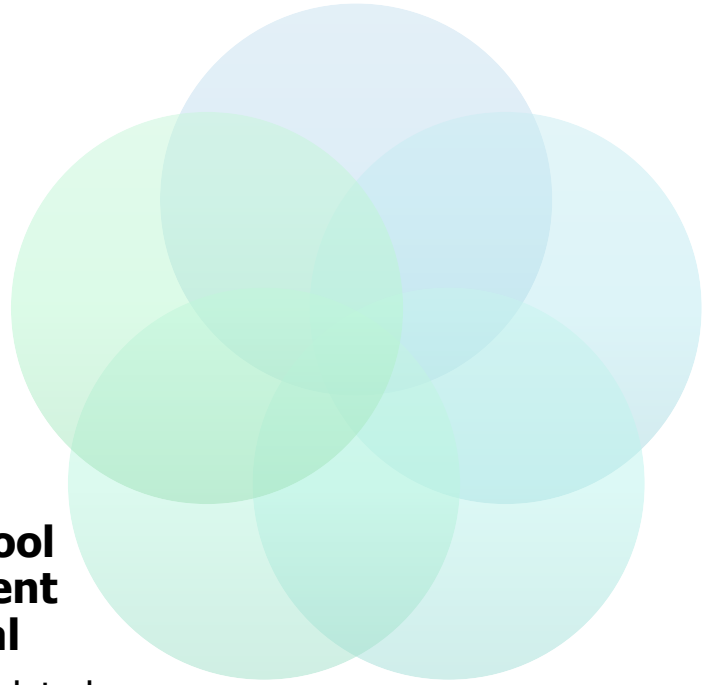
Agile Validation
Main principles

Validation is a mandatory & integral part of the product development

Business, Development & Quality build the product team. Product development team shall be interdisciplinary right from the beginning

There is no one size-fits-all process

Core principles of CSV and agility has to be understood / learned and framework has to be adopted for each environment



Validation activities are consequently risk based.

Business criticality and patient safety are the decision base for testing (e.g. out of the box features with no impact on business or patient safety don't need formal testing)

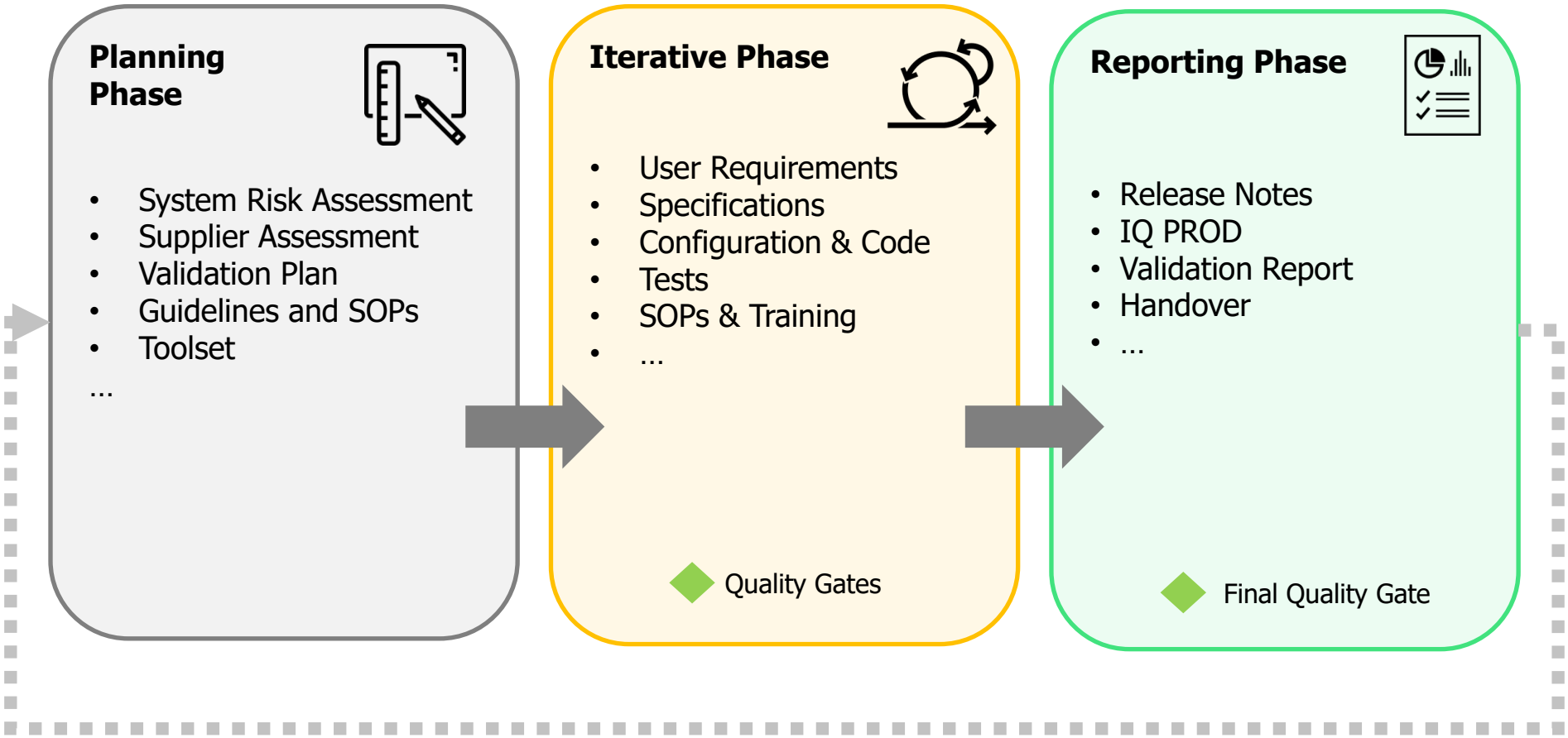
Efficient & effective tool support and transparent reporting is essential

All content is available in a validated web-based system providing the required transparency and traceability

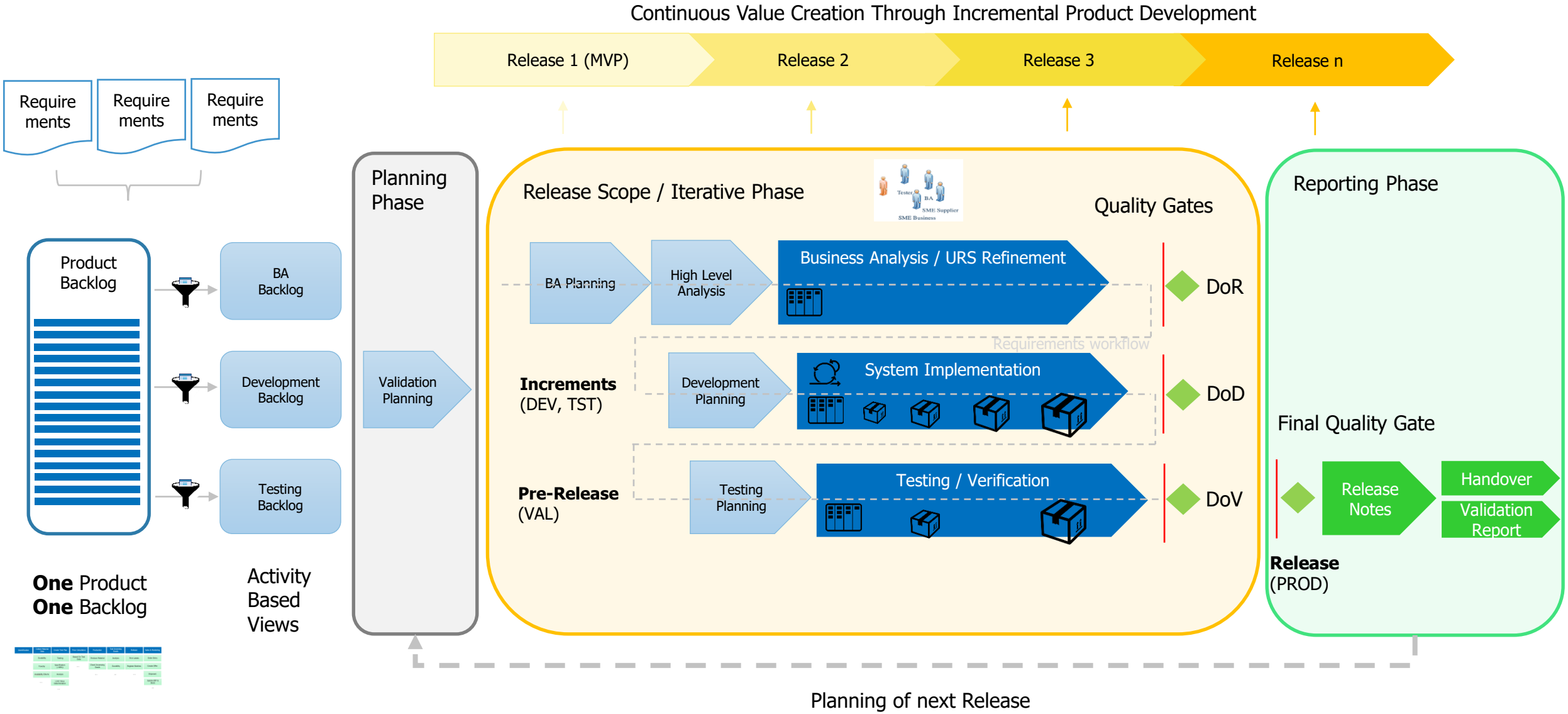
System / Product development is a continuous process

Agile development adds new business value on a regular base and will stop once the system is decommissioned

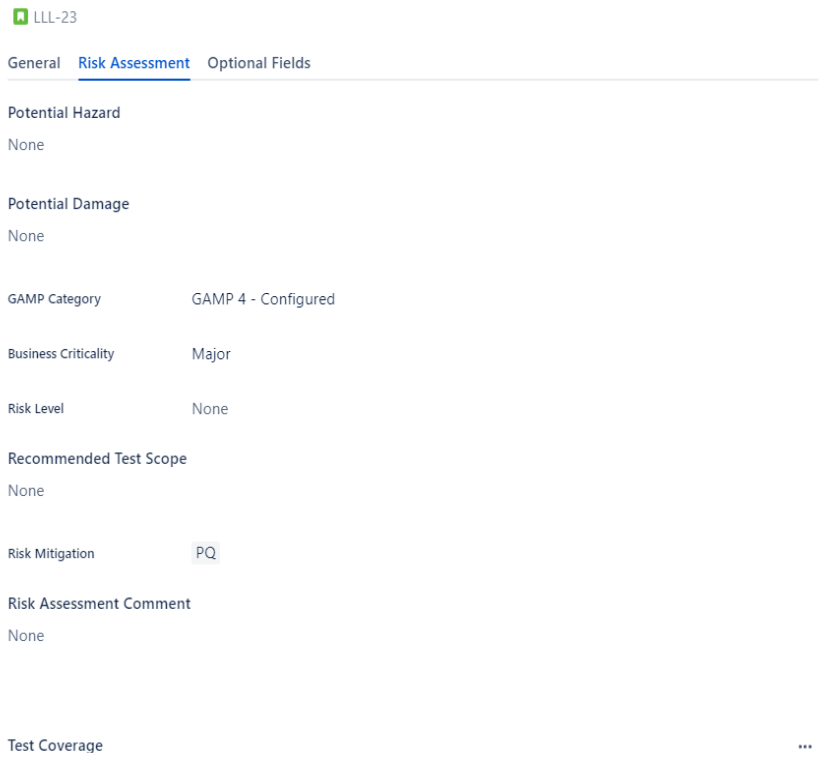
Development Phases



High Level Concept



Risk Management



Risiko-Stufe:
Ist berechnet und sollte für die User nur lesbar sein, nicht editierbar.

Kritikalität * (GAMP Kategorie-2)

-> Maßnahmen notwendig?

GAMP Kategorie:

3 – standard

4 – configured

5 - customized

		Gamp-Cat (-2)			Risiko-Stufe	Maßnahmen
		1	2	3	1,2,3	Optional
Risk	1	1	2	3	4,6	Nur bei Begründung optional
	2	2	4	6	9	Zwingend
	3	3	6	9		

Our Quality Gates during Iterative Phase

Release Scope

Definition of Ready

- ☑ Written according defined template following quality characteristics for requirements
- ☑ Acceptance criteria defined on appropriate level
- ☑ Related documentation or further specification items linked, all links are valid
- ☑ Risk assessment performed
- ☑ Link(s) to corresponding test or verification script(s) available, correct and valid and consistent to the risk mitigation strategy

Definition of Done

- ☑ Feature implemented and technically fully integrated (build successful)
- ☑ In case of coding: Code Review done
- ☑ Code / Configuration under version control
- ☑ Test Cases (IQ/SAT/UAT) created or updated
- ☑ Tests successfully dry run (e.g. on TST)
- ☑ Feature acceptance criteria fulfilled
- ☑ Feature demonstrated and accepted

Definition of Verified

- ☑ IQ VAL executed and passed (or in case of defect, all defects assessed and accepted)
- ☑ All SATs required for verification of "Specification Item" of Target Release executed (on VAL) and passed (or in case of defect, all defects assessed and accepted)
- ☑ All UATs required for verification of "Specification Item" of Target Release executed (on VAL) and passed (or in case of defect, all defects assessed and accepted)
- ☑ Traceability Matrix showing how each "Specification Item" was verified (tested / verified / others e.g. supplier activities)
- ☑ SOPs or other documents defined available, Trainings done.

◆ DoR ◆ DoD ◆ DoV

Success Factors

- Why change?
    1. Burning platform
    2. Leadership (resp. QA) commitment

- Willingness and commitment to challenge and change status quo (SOP's, internal processes & behaviours)
- Consistent risk based approach
- Continuous collaboration of Business, IT & QA
- Tooling

Thank You