

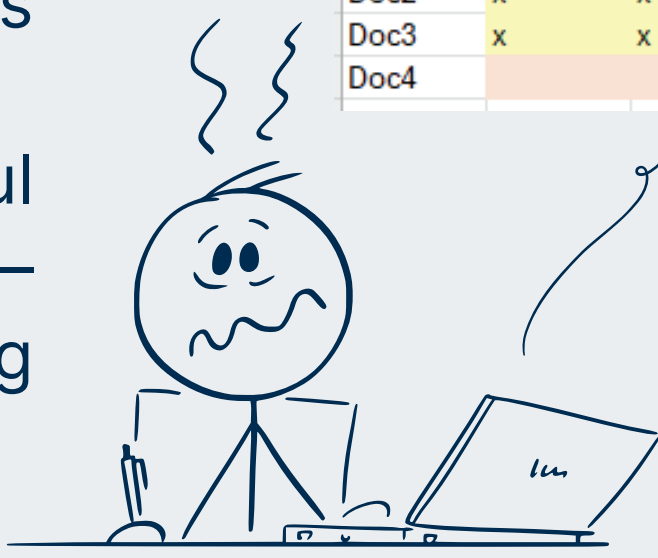
How can agile R Package validation workflows be achieved?

Turning role matrices into transparent, agile validation processes.

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Challenge

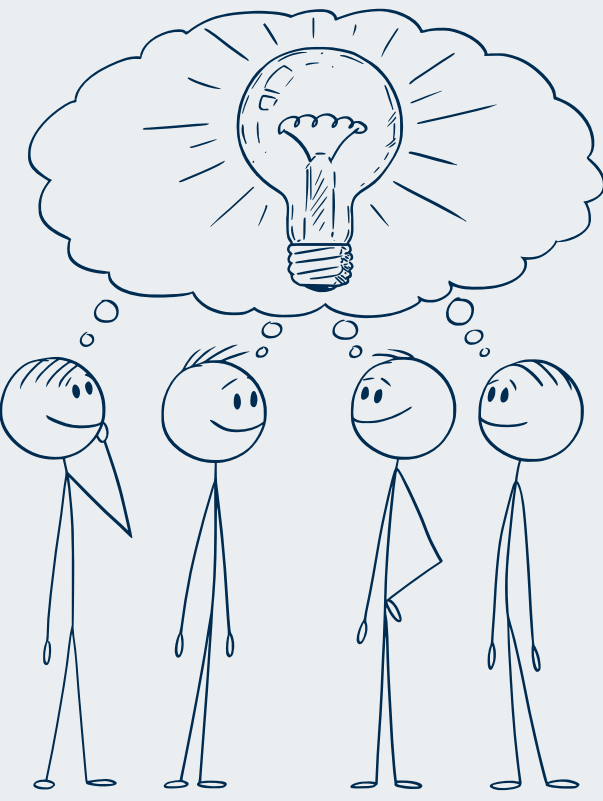
Software validation requires coordination between experts, developers, product owners and validation managers. Many teams still use colorful Excel sheets with “x” marks – often without legends, causing confusion.



Doc	Status	Exp	Dev	PO	VM
Doc1	x	x	x	x	x
Doc2	x	x	x	x	x
Doc3	x	x	x	x	x
Doc4					

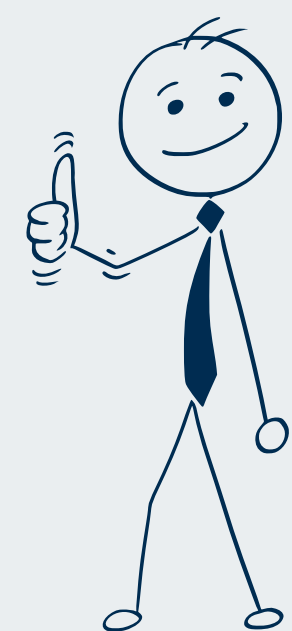
Solution

Responsibilities from validation or change plans are tracked directly in common development platforms. This enables iterative reviews, transparency, and avoids static Excel lists. The approach is illustrated with an R package validation example, but it applies broadly to collaborative validation tasks.



Benefit

Less coordination effort – focus shifts from tracking status to discussing content. Teams gain transparency on progress and stay motivated by using familiar tools. Iterative reviews ensure that specifications and validation artefacts can be continuously refined during development.



Example Use Case: Risk Assessment in R Package Validation

This example demonstrates how an iterative review workflow functions in practice. In a risk assessment for R package validation, experts draft, developers review, the product owner may raise concerns, and approvals can be revoked and repeated. Finally, the validation manager sets the status to Done. The principle applies broadly to other validation artefacts, such as specifications and test case collections.

Iterative Review Workflow

Screenshots from Github illustrate how responsibilities and approvals are tracked step by step.

1 Draft (Expert)

Expert drafts the risk assessment.

Functional_risk_assessment_ID	Functional_risk_assessment_Description	Severity	Occurrence	Detection	Risk_Priority
FAA1	Values are jumbled leading to wrong mapping of IDs to descriptions.	high	medium	medium	high
FAA2	Too long values render the excel table not readable.	medium	medium	high	low

Todo 2 This item hasn't been started HMSEUConnect2025ValidationPosterRepo #3 Tests HMSEUConnect2025ValidationPosterRepo #4 Traceability Matrix	In Progress 1 This is actively being worked on HMSEUConnect2025ValidationPosterRepo #2 Risk Assessment write_by_expert	Done 1 This has been completed HMSEUConnect2025ValidationPosterRepo #1 Specifications approved_by_developer approved_by_expert approved_by_product-owner approved_by_validation-manager
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2 Review (Developer)

Assigned to developer → approve.

Todo 2 This item hasn't been started HMSEUConnect2025ValidationPosterRepo #3 Tests HMSEUConnect2025ValidationPosterRepo #4 Traceability Matrix	In Progress 1 This is actively being worked on HMSEUConnect2025ValidationPosterRepo #2 Risk Assessment approved_by_developer review_by_expert	Done 1 This has been completed HMSEUConnect2025ValidationPosterRepo #1 Specifications approved_by_developer approved_by_expert approved_by_product-owner approved_by_validation-manager
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3 Approve (Expert)

Assigned to expert → approve.

Todo 2 This item hasn't been started HMSEUConnect2025ValidationPosterRepo #3 Tests HMSEUConnect2025ValidationPosterRepo #4 Traceability Matrix	In Progress 1 This is actively being worked on HMSEUConnect2025ValidationPosterRepo #2 Risk Assessment approved_by_developer approved_by_expert review_by_product-owner	Done 1 This has been completed HMSEUConnect2025ValidationPosterRepo #1 Specifications approved_by_developer approved_by_expert approved_by_product-owner approved_by_validation-manager
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4 Concern (Product Owner)

PO raises severity (medium → high) and revokes previous approvals.

Functional_risk_assessment_ID	Functional_risk_assessment_Description	Severity	Occurrence	Detection	Risk_Priority
FAA1	Values are jumbled leading to wrong mapping of IDs to descriptions.	high	medium	medium	high
FAA2	Too long values render the excel table not readable.	high	medium	high	medium

Todo 2 This item hasn't been started HMSEUConnect2025ValidationPosterRepo #3 Tests HMSEUConnect2025ValidationPosterRepo #4 Traceability Matrix	In Progress 1 This is actively being worked on HMSEUConnect2025ValidationPosterRepo #2 Risk Assessment review_by_product-owner	Done 1 This has been completed HMSEUConnect2025ValidationPosterRepo #1 Specifications approved_by_developer approved_by_expert approved_by_product-owner approved_by_validation-manager
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5 Re-approve (Expert, Developer)

Assigned to expert → review and approve.
Assigned developer → approve.

Todo 2 This item hasn't been started HMSEUConnect2025ValidationPosterRepo #3 Tests HMSEUConnect2025ValidationPosterRepo #4 Traceability Matrix	In Progress 1 This is actively being worked on HMSEUConnect2025ValidationPosterRepo #2 Risk Assessment review_by_developer review_by_expert	Done 1 This has been completed HMSEUConnect2025ValidationPosterRepo #1 Specifications approved_by_developer approved_by_expert approved_by_product-owner approved_by_validation-manager
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6 Approve (Product Owner)

Assigned to PO → approve.

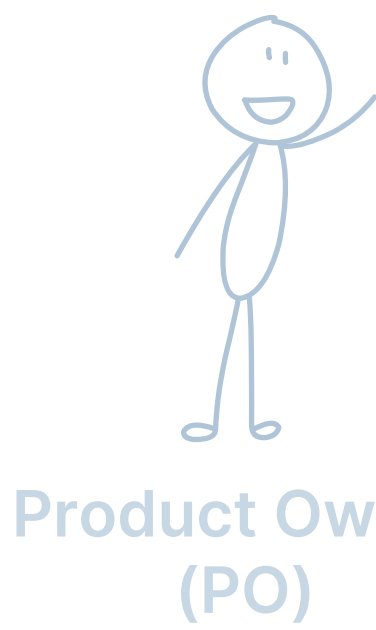
Todo 2 This item hasn't been started HMSEUConnect2025ValidationPosterRepo #3 Tests HMSEUConnect2025ValidationPosterRepo #4 Traceability Matrix	In Progress 1 This is actively being worked on HMSEUConnect2025ValidationPosterRepo #2 Risk Assessment approved_by_developer approved_by_expert approved_by_product-owner review_by_validation-manager	Done 1 This has been completed HMSEUConnect2025ValidationPosterRepo #1 Specifications approved_by_developer approved_by_expert approved_by_product-owner approved_by_validation-manager
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7 Done (Validation Manager)

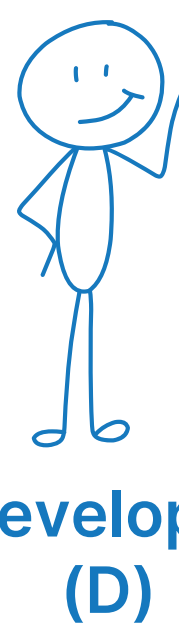
Assigned to VM → approve.
Validation manager sets status to Done.

Todo 2 This item hasn't been started HMSEUConnect2025ValidationPosterRepo #3 Tests HMSEUConnect2025ValidationPosterRepo #4 Traceability Matrix	In Progress 0 This is actively being worked on	Done 2 This has been completed HMSEUConnect2025ValidationPosterRepo #1 Specifications approved_by_developer approved_by_expert approved_by_product-owner approved_by_validation-manager HMSEUConnect2025ValidationPosterRepo #2 Risk Assessment approved_by_developer approved_by_expert approved_by_product-owner approved_by_validation-manager
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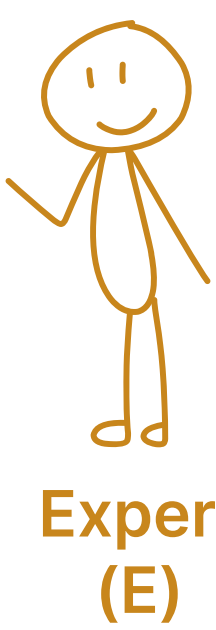
The Team



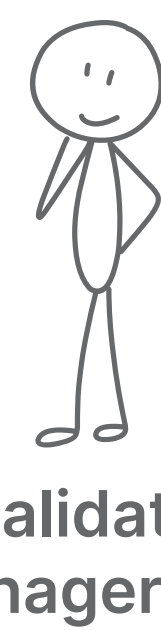
Product Owner (PO)



Developer (D)

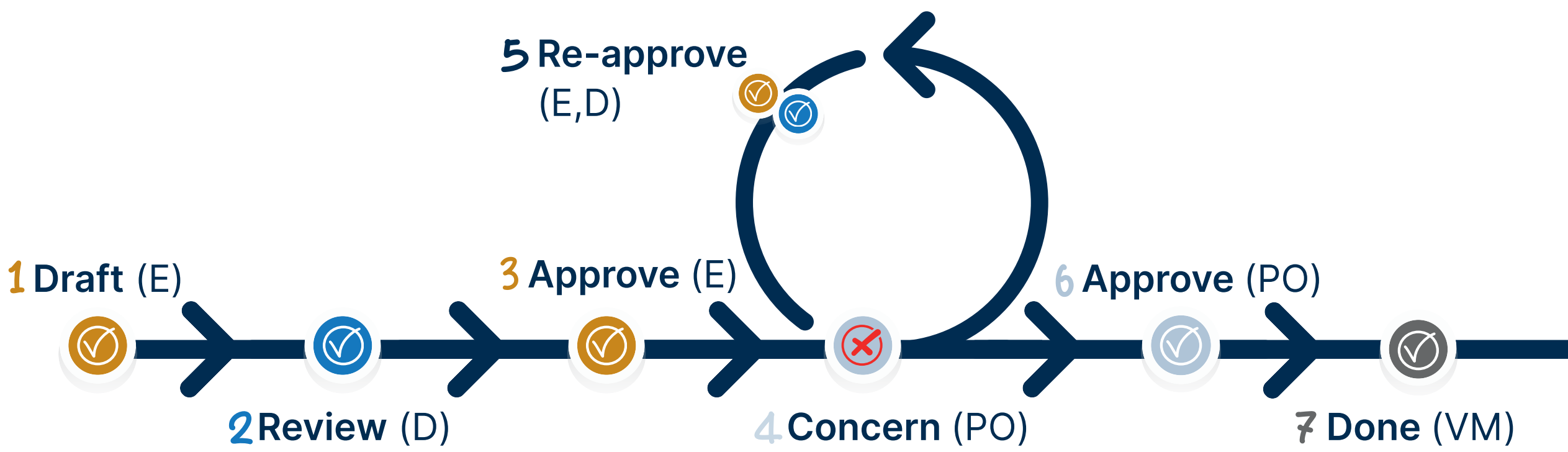


Expert (E)



Validation Manager (VM)

Review Workflow for this Example



Risk assessments are drafted, reviewed, and refined after concerns. Approvals may be revoked and the cycle restarted until all stakeholders agree. Finally, the validation manager sets the status to Done. This ensures transparency and avoids late surprises before formal validation.

Conclusion

This chain of approval mimics the formal signatures that take place in a document management system, but supports the work in progress review process that comes before the formal round of reviews. The cycle in the software development platform could be repeated for small chunks of scope that are released together in a formal validation cycle at a later point in time. Keeping the validation documents in sync close to the development activities allows for the true advantage of agile workflows to enable fast iterations between demos and incorporation of feedback. Don't let the document review process hold you back from building what you truly want - invest in a good process for good products.



More details and background in the full paper – available via the QR code.