PQS Analytical Method Validation Planning Worksheet

Practical educational planning and review tool aligned to intended-purpose thinking in ICH Q2(R2) / Q14

Product / Material:		Analytical procedure:	
Analyte / Attribute:		Method / SOP No.:	
Protocol No.:		Prepared / reviewed by:	

1. Intended analytical purpose

Reportable result / decision:	
Matrix / dosage form / material:	
Expected analyte level(s):	
Proposed reportable range:	
Specification / decision threshold supported:	
Known interferences / impurities / degradants / matrix risks:	
Prior knowledge / development data available:	

PQS planning rule: Start with the decision the analytical procedure must support. Select studies because they answer risks to that decision, not because every validation template contains the same list.

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2. Validation planning matrix

Characteristic	Needed?	Risk / rationale	Planned evidence / design	Predefined acceptance logic
Specificity / Selectivity	[ ] Y [ ] N			
Accuracy	[ ] Y [ ] N			
Repeatability	[ ] Y [ ] N			
Intermediate precision	[ ] Y [ ] N			
Response / Calibration model	[ ] Y [ ] N			
Reportable range	[ ] Y [ ] N			
Detection limit	[ ] Y [ ] N			
Quantitation limit	[ ] Y [ ] N			
Robustness	[ ] Y [ ] N			
Other method-specific performance	[ ] Y [ ] N			

Acceptance criteria: Document scientifically justified criteria or parameter ranges before executing the study. Do not copy numeric limits from an unrelated method merely because they are common.

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3. Study design details

Study area	Design questions	Planned approach / record
Specificity / selectivity	Which blanks, placebo, impurities, degradants, matrix components or orthogonal evidence are relevant?	
Accuracy	What reference/fortification approach and levels represent the intended range? Are preparations independent?	
Precision	How many independent preparations and which within-lab factors are scientifically relevant?	
Response / model	What calibration/model will be evaluated? How will residuals, slope/intercept or model suitability be assessed?	
Range	How will accuracy, precision and response evidence support the proposed reportable interval?	
DL / QL	Is low-level capability relevant? Which justified approach and confirmatory performance checks will be used?	
Robustness	Which variables were identified during development/risk assessment as potentially critical?	

4. Routine method controls informed by validation

Critical method parameters:	
System-suitability / performance checks:	
Reference standard / sample preparation controls:	
Allowed adjustments / ranges (if applicable):	
Data processing / integration / calculation controls:	

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5. Validation execution evidence checklist

Check	Evidence	Status / comment
[ ]	Approved protocol/current analytical procedure used during validation	[ ] OK [ ] Issue
[ ]	Reference standards, reagents, columns/materials and instrument status traceable	[ ] OK [ ] Issue
[ ]	Independent preparations, raw data, chromatograms/spectra and metadata retained	[ ] OK [ ] Issue
[ ]	Calculations/statistical analysis are controlled and reproducible	[ ] OK [ ] Issue
[ ]	All failed, repeated, aborted or atypical validation data are retained and assessed	[ ] OK [ ] Issue
[ ]	Protocol deviations are documented and their scientific impact evaluated	[ ] OK [ ] Issue
[ ]	Acceptance criteria are evaluated as predefined, or changes are controlled/justified	[ ] OK [ ] Issue
[ ]	Validation conclusions are supported by the complete evidence set	[ ] OK [ ] Issue

6. Deviation / unexpected result record

Observation / deviation:	
Study / dataset affected:	
Immediate action and data preservation:	
Scientific impact assessment:	
Root cause / contributing factor:	
Disposition / repeat rationale (if any):	

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7. Validation report conclusion

Characteristic / study	Conclusion / result reference
Specificity / selectivity	
Accuracy	
Precision	
Response / range	
DL / QL (if applicable)	
Robustness	
Overall fitness for intended purpose	

8. Lifecycle / implementation handover

Question	Decision / evidence
What validation/development knowledge must be reflected in the routine SOP?	
What SST/performance checks protect routine method performance?	
Which parameters or adjustments require change control / re-evaluation?	
What triggers partial or full revalidation / verification?	
If the method moves to another lab, what transfer/verification strategy is needed?	
What trending / continued performance information should be monitored?	

Educational resource: This worksheet does not replace ICH Q2(R2)/Q14, applicable pharmacopoeial requirements, an approved validation protocol, company SOPs, regulatory commitments or Quality Unit decisions.