VALIDATION READINESS TOOL

Process Validation Readiness Checklist

Confirm that process knowledge, facilities, methods, materials, people and data systems are ready before PPQ begins.

USE THIS WORKBOOK TO

01	02	03	04
Test PPQ prerequisites	Expose readiness gaps	Define sampling and criteria	Protect the validated lifecycle

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SECTION 1

Process and PPQ scope

Define the commercial process, products, strengths, sites, equipment trains and boundaries included in the validation exercise.

Scope element	Defined?	Reference / rationale
Product, strength, batch size and market		
Manufacturing and packaging stages		
Facilities, utilities and equipment train		
Critical quality attributes		
Critical process parameters / material attributes		
Bracketing, matrixing or family approach		

Validation objective and scope statement

SECTION 2

Process-knowledge readiness

PPQ should confirm a developed control strategy, not discover an inadequately understood process.

Knowledge element	Ready?	Evidence / gap
Development and scale-up history		
Risk assessment and failure modes		
Parameter ranges and proven acceptable ranges		
Material variability and supplier understanding		
Hold times, yields and rework controls		
Prior batches, deviations and trend data		

Knowledge gaps requiring resolution before PPQ

SECTION 3

Facility, utility and equipment readiness

Qualification, calibration, maintenance, cleaning and supporting utilities must be suitable for commercial execution.

Prerequisite	Status	Evidence / open item
Facility and environmental qualification		
HVAC, water, gases and other utilities		
Equipment IQ/OQ and operating ranges		
Calibration and preventive maintenance		
Cleaning validation / verification readiness		
Computerised systems and interfaces		

Open deviations and impact on readiness

SECTION 4

Methods, materials, people and documents

Every supporting element should be approved, available and effective before protocol execution.

Area	Readiness evidence	Status / reference
Analytical methods	Validated / verified and transferred	
Materials	Approved suppliers, specs and representative lots	
Master documents	BMR, SOPs, sampling and cleaning instructions	
Personnel	Training and demonstrated task competence	
Laboratory	Standards, reagents, capacity and turnaround	
Data systems	Validated capture, calculation, review and backup	

Training or document gaps

SECTION 5

Protocol and sampling design

The approved protocol should define responsibilities, challenges, sampling, acceptance criteria and deviation handling before data exist.

Protocol control	Adequate?	Reference / comment
Number of batches scientifically justified		
Worst-case and normal operating conditions represented		
Sampling locations, times and quantities justified		
Acceptance criteria predefined and meaningful		
Statistical methods and handling of variability defined		
Deviation, change and stopping rules defined		

Unresolved protocol issue

SECTION 6

Go / conditional go / no-go review

A multidisciplinary readiness decision should prevent schedule pressure from overriding unresolved quality risk.

Decision	Select	Meaning
GO	[ ]	All critical prerequisites complete; PPQ may begin.
CONDITIONAL GO	[ ]	Only documented non-critical items remain with controls.
NO-GO	[ ]	Critical prerequisite or risk remains unresolved.

Conditions, owners and due dates

Authorisation to start PPQ
Quality, Production, Engineering, Validation and Laboratory

SECTION 7

Review, conclusion and approval

Close only when the evidence supports the decision and all unresolved risks have an accountable route forward.

Closeout confirmation	Yes / No / N/A	Reference
Scope and risk rationale are documented		
Required evidence is complete and traceable		
Exceptions were assessed and escalated appropriately		
Actions, owners and due dates are defined		
Residual risk is understood and accepted by Quality		
Review and approval are independent where required		

Overall conclusion and decision

Follow-up actions / monitoring / effectiveness checks

Final approval - name, role, signature and date
Quality Unit and responsible function