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Qualification Readiness Checklist

A practical pre-execution checklist for DQ / IQ / OQ / PQ readiness

Use this resource to identify missing prerequisites, weak evidence, unresolved risks and documentation gaps before qualification execution begins.

Resource code	VSR-QV-CHK-001
Version	9.0
Issue date	October 2026
Primary basis	EU GMP Annex 15; ICH Q9(R1)
Applicability	Facilities, equipment, utilities and systems; sterile considerations where applicable

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IMPORTANT USE NOTE

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How to use this checklist

Purpose

Use the checklist during project readiness reviews before formal qualification execution. It is designed to surface gaps early, confirm that prerequisite evidence is available, and support a risk-based decision on whether the system is ready to proceed.

Status key

YES	Requirement is complete and objective evidence is available.
NO	Requirement is incomplete, missing, or not adequately evidenced.
N/A	Not applicable to the specific system/project; rationale should be documented.
HOLD	Critical gate unresolved - do not proceed until impact is assessed and dispositioned.

Suggested readiness rating

ValiStera management-aid scoring (not a regulatory acceptance criterion):

- READY: >=90% YES and no unresolved Critical Gate item.
- CONDITIONALLY READY: 75-89% YES, no unresolved Critical Gate item, and all open actions risk-assessed with approved controls.
- NOT READY: <75% YES, or any unresolved Critical Gate item.

Regulatory basis used in this resource

Reference	How it informs this checklist
EU GMP Annex 15 (2015)	Lifecycle planning, approved protocols, URS, DQ, FAT/SAT, IQ, OQ, PQ, requalification, deviations and release.
ICH Q9(R1)	Quality risk management should be science-based and the level of formality/documentation should be commensurate with risk.
EU GMP Annex 1 (2022)	Where the scope involves sterile manufacturing, qualification and control should also support contamination-control and sterile-manufacturing requirements.

Project identification

Project / System		**Asset / Tag No.**	
Site / Area		**Qualification stage**	
Reviewer		**Review date**	
Protocol / Plan No.		**Target execution**	

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A. Governance, scope and planning

Confirm that the project is controlled, risk-based and ready to enter qualification execution.

#	Readiness check	Status	Annex 15 ref.	Evidence / Gap / Action
1	**CRITICAL GATE -** Approved validation/qualification strategy or VMP (or equivalent) defines the lifecycle approach, scope, responsibilities and stage-gates for this project/system.	☐ Y ☐ N ☐ N/A	1.1-1.8	
2	Roles for Engineering, User, QA, Validation, Maintenance, EHS and vendors are defined; appropriate quality oversight is assigned.	☐ Y ☐ N ☐ N/A	1.2-1.3	
3	System boundaries and interfaces are defined, including upstream/downstream utilities, computerized controls and dependent systems.	☐ Y ☐ N ☐ N/A	1.4-1.5	
4	**CRITICAL GATE -** The intended use and GMP impact of the facility/equipment/utility/system are documented.	☐ Y ☐ N ☐ N/A	General; 3.1	
5	**CRITICAL GATE -** A documented quality risk assessment identifies critical functions, parameters, components and data relevant to qualification.	☐ Y ☐ N ☐ N/A	General; 1.7; 2.5	
6	Qualification scope and testing depth are justified based on risk, complexity, novelty and impact on product quality/patient safety.	☐ Y ☐ N ☐ N/A	General	
7	Applicable regulatory, pharmacopoeial, engineering and internal standards have been identified.	☐ Y ☐ N ☐ N/A	1.5; 2.1	
8	Approved document hierarchy is defined (URS/specifications, risk assessment, DQ, FAT/SAT, IQ/OQ/PQ protocols, reports, traceability).	☐ Y ☐ N ☐ N/A	1.5; 2.1-2.3	
9	Protocol templates and report formats are current, controlled and approved for use.	☐ Y ☐ N ☐ N/A	2.1-2.4	
10	Project schedule identifies prerequisite dependencies and formal release points between qualification stages.	☐ Y ☐ N ☐ N/A	1.4-1.5; 2.10	
11	Vendor-supplied qualification documents have been assessed for suitability and planned supplements are identified.	☐ Y ☐ N ☐ N/A	2.6	
12	**CRITICAL GATE -** Open project changes, deviations or design decisions with potential GMP impact are visible in the readiness review.	☐ Y ☐ N ☐ N/A	2.7-2.9	

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B. URS, risk, design and FAT/SAT readiness

Confirm that intended use and GMP requirements have been translated into a traceable, testable design basis.

#	Readiness check	Status	Annex 15 ref.	Evidence / Gap / Action
1	**CRITICAL GATE -** URS and/or functional specification is approved and reflects intended use, product/process needs, quality requirements and key GMP expectations.	☐ Y ☐ N ☐ N/A	3.2	
2	URS requirements are uniquely identifiable and suitable for traceability through design, testing and final release.	☐ Y ☐ N ☐ N/A	3.2	
3	**CRITICAL GATE -** Critical quality and GMP requirements were built into the specification phase rather than deferred to qualification testing.	☐ Y ☐ N ☐ N/A	3.2	
4	**CRITICAL GATE -** Design documentation demonstrates that URS requirements and GMP expectations were addressed.	☐ Y ☐ N ☐ N/A	3.3	
5	Design review/DQ records identify deviations from URS or design standards and document their justification/disposition.	☐ Y ☐ N ☐ N/A	3.3; 2.7	
6	Critical instruments, sensors, alarms, controls, interlocks, utilities and interfaces are identified for qualification.	☐ Y ☐ N ☐ N/A	3.3	
7	Materials of construction and product-contact materials are specified and suitable for intended use.	☐ Y ☐ N ☐ N/A	3.3; 3.9(v)	
8	Cleaning, maintenance, calibration and accessibility requirements have been considered in the design.	☐ Y ☐ N ☐ N/A	3.3; 3.12	
9	Where FAT is applicable, the FAT scope verifies relevant URS/functional requirements before delivery.	☐ Y ☐ N ☐ N/A	3.4-3.6	
10	Any FAT tests proposed for leverage at IQ/OQ have a documented rationale showing transport/installation will not affect the verified function.	☐ Y ☐ N ☐ N/A	3.6	
11	SAT requirements are defined where receipt/installation at site could affect functionality or condition.	☐ Y ☐ N ☐ N/A	3.7	
12	**CRITICAL GATE -** FAT/SAT deviations and punch-list items are assessed for qualification impact and closure timing.	☐ Y ☐ N ☐ N/A	2.7-2.9; 3.4-3.7	
13	**CRITICAL GATE -** Traceability from URS -> design/DQ -> planned qualification verification is available before execution.	☐ Y ☐ N ☐ N/A	3.1-3.3	

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C. Installation Qualification (IQ) readiness

Confirm that installation is stable, documented and supported by current engineering, calibration and vendor evidence.

#	Readiness check	Status	Annex 15 ref.	Evidence / Gap / Action
1	**CRITICAL GATE -** Approved IQ protocol is available, with pre-defined acceptance criteria and required attachments/data sheets.	☐ Y ☐ N ☐ N/A	2.4; 3.8-3.9	
2	**CRITICAL GATE -** Equipment/system installation is complete enough to execute IQ without uncontrolled construction or installation activity.	☐ Y ☐ N ☐ N/A	3.8-3.9	
3	As-built drawings, P&IDs, layouts, wiring diagrams and equipment lists are current and available for verification.	☐ Y ☐ N ☐ N/A	3.9(i)	
4	**CRITICAL GATE -** Installed components, instrumentation, piping, services and interfaces can be verified against approved drawings/specifications.	☐ Y ☐ N ☐ N/A	3.9(i-ii)	
5	Equipment identification, tag numbers and key component identification are complete and legible.	☐ Y ☐ N ☐ N/A	3.9(i-ii)	
6	Required vendor manuals, operating instructions, maintenance requirements and technical data are available.	☐ Y ☐ N ☐ N/A	3.9(iii)	
7	**CRITICAL GATE -** Calibration status is current for instruments required during qualification; certificates are traceable and within due date.	☐ Y ☐ N ☐ N/A	3.9(iv)	
8	Calibration ranges/accuracy are appropriate for the intended operating and test ranges.	☐ Y ☐ N ☐ N/A	3.9(iv)	
9	Materials of construction and product-contact surface evidence is available where applicable.	☐ Y ☐ N ☐ N/A	3.9(v)	
10	**CRITICAL GATE -** Utility connections and required support services are available and meet prerequisite qualification status.	☐ Y ☐ N ☐ N/A	3.9(i-ii)	
11	Software/firmware versions and configuration baselines are documented where the system includes computerized controls.	☐ Y ☐ N ☐ N/A	Principle; Annex 11 link	
12	**CRITICAL GATE -** Safety/EHS prerequisites required for qualification execution are complete and released.	☐ Y ☐ N ☐ N/A	Site procedure	
13	**CRITICAL GATE -** IQ punch-list items/open deviations have documented impact assessment and do not compromise progression to OQ.	☐ Y ☐ N ☐ N/A	2.7-2.10	

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D. Operational Qualification (OQ) readiness

Confirm that the system can be challenged through intended operating ranges, controls, alarms and worst-case conditions.

#	Readiness check	Status	Annex 15 ref.	Evidence / Gap / Action
1	**CRITICAL GATE -** Approved OQ or IOQ protocol is available with pre-defined acceptance criteria linked to intended operating functions and risks.	☐ Y ☐ N ☐ N/A	2.4; 3.10-3.11	
2	**CRITICAL GATE -** IQ completion/release (or approved documented conditional progression) is available before OQ begins.	☐ Y ☐ N ☐ N/A	2.10; 3.10	
3	OQ test cases challenge normal operating functions and critical controls as designed.	☐ Y ☐ N ☐ N/A	3.11(i)	
4	**CRITICAL GATE -** Upper/lower operating limits and justified worst-case conditions are included where relevant.	☐ Y ☐ N ☐ N/A	3.11(ii)	
5	**CRITICAL GATE -** Critical alarms, interlocks, permissives and fail-safe responses are challenged where applicable.	☐ Y ☐ N ☐ N/A	3.11(i)	
6	Operating sequences, recipes, modes and control logic relevant to GMP performance are included in the test scope.	☐ Y ☐ N ☐ N/A	3.11(i)	
7	**CRITICAL GATE -** Required calibrated test instruments and test equipment are available with valid calibration.	☐ Y ☐ N ☐ N/A	3.9(iv); 2.4	
8	Data-recording requirements are defined so raw data, electronic records and observations are attributable and reviewable.	☐ Y ☐ N ☐ N/A	2.1-2.4	
9	Any test prerequisites (utilities, environmental conditions, loads, test media, trained operators) are defined and available.	☐ Y ☐ N ☐ N/A	3.11	
10	Standard operating, cleaning, maintenance and calibration procedures are drafted/approved to support post-OQ operation as applicable.	☐ Y ☐ N ☐ N/A	3.12	
11	Operator/maintainer training requirements are identified and scheduled before operational release.	☐ Y ☐ N ☐ N/A	3.12	
12	**CRITICAL GATE -** OQ deviations, atypical results or acceptance-criterion failures have a defined investigation and disposition process.	☐ Y ☐ N ☐ N/A	2.7-2.9	

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E. Performance Qualification (PQ), release and lifecycle readiness

Confirm that the system is ready to demonstrate effective, reproducible performance and transition into a maintained validated state.

#	Readiness check	Status	Annex 15 ref.	Evidence / Gap / Action
1	**CRITICAL GATE -** Approved PQ protocol is available with pre-defined acceptance criteria based on intended process use and product/process knowledge.	☐ Y ☐ N ☐ N/A	2.4; 3.13-3.14	
2	**CRITICAL GATE -** IQ/OQ completion and formal release (or justified approved conditional progression) are available before PQ.	☐ Y ☐ N ☐ N/A	2.10; 3.13	
3	PQ materials/load or qualified substitutes/simulated product are scientifically justified for the intended challenge.	☐ Y ☐ N ☐ N/A	3.14(i)	
4	**CRITICAL GATE -** PQ includes normal operating conditions and justified worst-case batch/load conditions where relevant.	☐ Y ☐ N ☐ N/A	3.14(i-ii)	
5	Sampling locations, frequency and sample size are justified and adequate to demonstrate process/system performance.	☐ Y ☐ N ☐ N/A	3.14(i)	
6	**CRITICAL GATE -** Required production/support utilities and environmental conditions are qualified and available for PQ execution.	☐ Y ☐ N ☐ N/A	3.13-3.14	
7	Operators executing PQ are trained and qualified for the relevant procedures.	☐ Y ☐ N ☐ N/A	1.2; 3.12	
8	**CRITICAL GATE -** Acceptance criteria are linked to approved process/product requirements and are scientifically justified.	☐ Y ☐ N ☐ N/A	2.4; 2.9	
9	**CRITICAL GATE -** All deviations and failed acceptance criteria are recorded, investigated and assessed for validation impact before closure.	☐ Y ☐ N ☐ N/A	2.7-2.9	
10	**CRITICAL GATE -** Final qualification report summarises results against acceptance criteria, deviations, conclusions and outstanding actions.	☐ Y ☐ N ☐ N/A	2.9	
11	**CRITICAL GATE -** Formal approval/release to routine use is defined and assigned to responsible personnel.	☐ Y ☐ N ☐ N/A	2.10	
12	Requalification triggers/frequency are defined using risk and lifecycle considerations.	☐ Y ☐ N ☐ N/A	4.1-4.2	
13	**CRITICAL GATE -** Change control, preventive maintenance, calibration, periodic review and continued-state-of-control requirements are established for routine lifecycle management.	☐ Y ☐ N ☐ N/A	4.1-4.2; 11.1-11.7	

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Readiness summary and action plan

Use this page to document the final readiness decision and the actions required before execution.

Section	YES	NO	Key unresolved issue(s)
A. Governance / planning			
B. URS / risk / design			
C. IQ readiness			
D. OQ readiness			
E. PQ / lifecycle			
TOTAL / OVERALL			

Final readiness decision

Decision	☐ READY ☐ CONDITIONALLY READY ☐ NOT READY
Critical gates open?	☐ No ☐ Yes - see actions below
Approved by / Date	
Decision rationale	

Priority actions before execution

#	Action / Gap	Owner	Due date	Closure evidence
1				
2				
3				
4				

Reference notes

- EU GMP Annex 15 (Qualification and Validation), revision in operation since 1 October 2015. Particularly relevant: General; Sections 1-4 and 11; and qualification lifecycle clauses 3.1-3.14.
- ICH Q9(R1) Quality Risk Management (Step 4, 18 January 2023): quality-risk decisions should be science-based and the level of effort, formality and documentation should be commensurate with risk.
- EU GMP Annex 1 (Manufacture of Sterile Medicinal Products), fully applicable since 25 August 2024, should be considered where the qualified asset supports sterile manufacturing or contamination control.

Official sources: European Commission EudraLex Volume 4 (Annex 15 and Annex 1) and ICH Q9(R1) Quality Risk Management. Accessed October 2026.

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