



Process Validation IQ/OQ/PQ Kit

Validate special processes the way FDA and ISO 13485 auditors expect.

What's inside

File	What it is / how to use it
01_Master_Validation_Plan.docx	Verify-or-validate decision, register, IQ/OQ/PQ approach, sampling rationale, revalidation.
02-04 IQ / OQ / PQ Protocol and Report	Protocol + report templates with checks, parameter windows, deviations, sign-offs.
05_Sampling_Rationale_Calculator.xlsx	Success-run n for chosen confidence/reliability, binomial n with c failures, Ppk acceptance check.

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Sampling quick reference

Confidence / reliability	n (0 failures)
90 / 90	22
95 / 95	59
95 / 99	299

About the author

Built by Matt Norman, US Navy veteran and former SpaceX Falcon 9 quality inspector and QA supervisor. (Not affiliated with or endorsed by SpaceX.) Norman Quality Tools is Veteran-Owned & Operated. Contains no SpaceX, government, or customer proprietary information; all example data is made up.

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Master Validation Plan (MVP)

Process Validation IQ/OQ/PQ Kit - Document 01 - Rev A (2026-10)

1. Purpose and scope

Defines how [Company] decides which processes need validation and how they are validated, under 21 CFR 820 (QMSR, incorporating ISO 13485 clause 7.5.6) and FDA's process validation principles.

2. Verify or validate?

1. Can the process output be fully verified by later inspection or test (non-destructively, on every unit)? If yes and you choose to verify, document verification and stop.
2. If no (e.g., sealing, welding, molding, sterilization, cleaning, adhesive bonding, software-controlled processes), validate.
3. Even when verifiable, validation may be chosen to reduce inspection cost; document the decision.

3. Validation register

Process	Equipment ID	Verify/Validate	Risk (H/M/L)	IQ	OQ	PQ	Revalidation trigger / interval

4. Approach

Stage	Answers	Typical content
IQ (installation)	Is it installed correctly?	Utilities, calibration, software version, safety, manuals, spare parts, URS check
OQ (operational)	Does it work across the operating window?	Challenge upper/lower settings (DOE or worst case), establish the validated window
PQ (performance)	Does it consistently produce good product under normal production?	Usually 3 runs at nominal, normal operators/materials, statistical acceptance