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# Process Validation Protocol

Pharma, Chemicals & Life Sciences

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This guide explains what the tool produces, how to use the output, and what to watch for. The actual output (draft/report) is generated on the tool page.

## Background

Builds a process validation protocol structure — approach (prospective, concurrent), critical process parameters, critical quality attributes, three consecutive batches, sampling and testing, and acceptance criteria, with protocol and report documentation. Use this to demonstrate a consistent, capable process. Validation must follow your VMP and be QA-approved.

## Purpose of this tool & output

Demonstrate a consistent, capable process

## How the output is used

Use the protocol to plan process validation that demonstrates your process is consistent and capable across batches.

## Important cautions

AI-generated structure; validation must follow your VMP and be QA-approved.

## Companion documents

- GMP Implementation Guide
- Manufacturing SOP Writer
- Batch Manufacturing Record (BMR)
- Cleaning Validation Protocol
- Equipment Qualification (IQ/OQ/PQ)
- GMP Self-Audit Checklist