



Pharmaceutical Personnel Qualification & Competency Checklist 2026

Job Description & Role Definition

Verification of updated job descriptions, clearly defined roles, responsibilities, and required educational/professional qualifications for each position.

Job Title

Write something...

Employee Identification Number

Write something...

Summary of Primary Responsibilities

Write something...

Required Qualification Levels

- ☐ High School Diploma/GED
- ☐ Bachelor's Degree (BSc/BEng)
- ☐ Master's Degree (MSc/MA)
- ☐ Doctorate (PhD/PharmD)

Department/Unit Assignment

- ☐ Quality Assurance
- ☐ Quality Control
- ☐ Production
- ☐ Warehouse/Logistics
- ☐ Regulatory Affairs
- ☐ R&D

Job Description Effective Date

Enter date...

Signed Job Description PDF

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Manager Approval Signature

Initial Onboarding & Orientation

Validation of completion for general company orientation, safety training, GMP (Good Manufacturing Practice) fundamentals, and site-specific SOP overview.

Date of Onboarding Completion

Enter date...

Employee Department

- ☐ Quality Assurance
- ☐ Quality Control
- ☐ Manufacturing
- ☐ Warehouse & Logistics
- ☐ Regulatory Affairs
- ☐ R&D

Completed Orientation Modules

- ☐ GMP Fundamentals
- ☐ Site Safety & EHS Training
- ☐ Data Integrity Principles
- ☐ SOP Overview
- ☐ Contamination Control Training
- ☐ Personal Hygiene & Gowning

Signed Orientation Acknowledgement Form

 Upload File

Training Supervisor Signature

Notes on Specific Training Gaps or Observations

Write something...

Technical Competency Assessment

Documentation of hands-on training, proficiency testing, and competency evaluations for specific laboratory, manufacturing, or analytical tasks.

Assessment Completion Date

Enter date...

Competency Level Achieved

- ☐ Beginner (Supervised)
- ☐ Intermediate (Independent)
- ☐ Advanced (Trainer/Expert)

Methods Evaluated

- ☐ Written Examination
- ☐ Practical Demonstration
- ☐ Oral Examination
- ☐ Direct Observation

Detailed Competency Observations

Write something...

Supporting Evidence (e.g., Test Results/Certificates)

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Assessor Signature

SOP Training & Read/Understand Logs

Audit of training records ensuring all personnel have read, understood, and signed off on all relevant Standard Operating Procedures (SOPs) and Work Instructions.

Date of SOP Review

Enter date...

SOP Version Number

- ☐ v1.0
- ☐ v1.1
- ☐ v2.0

Training Completion Status

- ☐ Read and Understood
- ☐ Practical Assessment Completed
- ☐ Retraining Required

Signed Training Log Scan

 Upload File

Employee Acknowledgement Signature

Notes on Training Gaps or Clarifications

Write something...

Gowning & Aseptic Technique Qualification

Verification of successful gowning qualification, microbial monitoring results (if applicable), and adherence to sterile processing protocols.

Date of Last Gowning Qualification

Enter date...

Gowning Grade/Area Type

- ☐ Grade A/B (Sterile)
- ☐ Grade C
- ☐ Grade D
- ☐ CNC (Controlled Non-Classified)

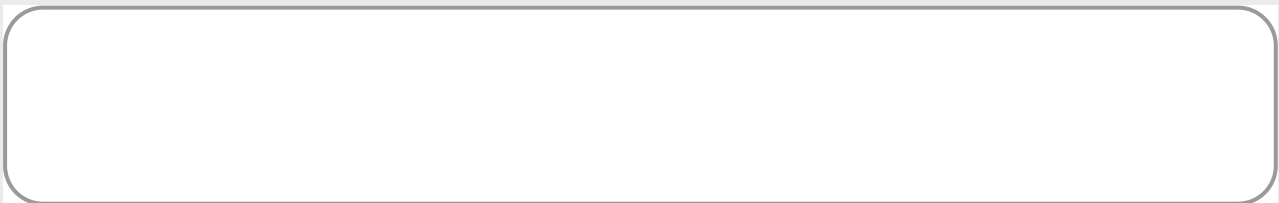
Qualification Passed Criteria

- ☐ Visual Inspection
- ☐ Microbiological Monitoring (Contact Plates)
- ☐ Aseptic Process Simulation (Media Fill)
- ☐ Procedural Adherence Audit

Microbiological Results Report

 Upload File

Supervisor Verification Signature



Observations and Corrective Actions Required

Write something...

Annual Re-Qualification & Refresher Training

Tracking of periodic retraining schedules, updated competency assessments, and completion of annual GMP refresher courses.

Last Refresher Training Date

Enter date...

Training Status

- ☐ Compliant
- ☐ Due for Renewal
- ☐ Overdue

Refresher Modules Completed

- ☐ GMP Fundamentals
- ☐ Safety & Hygiene
- ☐ SOP Updates
- ☐ Data Integrity

Training Certificate/Evidence

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Supervisor Verification

Training Effectiveness Evaluation

Assessment of post-training evaluations, quizzes, or practical demonstrations used to prove that the training resulted in actual skill acquisition.

Evaluation Method Used

- ☐ Written Examination
- ☐ Practical Demonstration
- ☐ Supervisor Observation
- ☐ Case Study Analysis

Assessment Score Achieved

Competency Criteria Met

- ☐ Theoretical Knowledge
- ☐ Procedural Accuracy
- ☐ Safety Compliance
- ☐ Documentation Proficiency

Evaluator Comments

Write something...

Evaluation Completion Date

Enter date...

Evaluator Signature

Personnel Files & Document Control

Review of the integrity, accessibility, and retention of training certificates, diplomas, CVs, and all personnel-related qualification evidence.

Last Audit Date

Enter date...

Audit Outcome

- ☐ Compliant
- ☐ Non-Compliant
- ☐ Observation Identified

Documents Verified

- ☐ Updated CV/Resume
- ☐ Educational Certificates
- ☐ Training Logs
- ☐ Job Description Sign-off
- ☐ Professional Licenses

Upload Audit Evidence

 **Upload File**

Auditor Observations & Findings

Write something...

Auditor Verification Signature

Deviation & CAPA Impact Assessment

Review of training gaps identified during deviations or CAPAs and the subsequent implementation of corrective training actions.

Date of Deviation/CAPA Identification

Enter date...

Impact Severity Level

- ☐ Critical
- ☐ Major
- ☐ Minor

Identified Training Gaps

- ☐ Inadequate SOP Knowledge
- ☐ Lack of Technical Skill
- ☐ Failure to Follow Procedure
- ☐ Incomplete Documentation
- ☐ Other

Root Cause Analysis Summary

Write something...

Proposed Corrective Training Action

Write something...

Supporting CAPA Documentation

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Quality Assurance Approval

Equipment & Instrumentation Training

Verification that personnel are specifically authorized and trained to operate specialized laboratory or manufacturing equipment and instruments.

Equipment Name/ID

Training Status

- ☐ Fully Qualified
- ☐ In Training
- ☐ Retraining Required
- ☐ Not Authorized

Last Training Completion Date

Next Re-qualification Due Date

Competency Areas Covered

- ☐ Standard Operating Procedure (SOP) Review
- ☐ Operational Setup & Startup
- ☐ Calibration & Verification Checks
- ☐ Cleaning & Decontamination Protocols
- ☐ Troubleshooting & Error Handling
- ☐ Data Logging & Report Generation

Training Evidence/Certificate

 Upload File

Trainer/Assessor Verification

< Previous

> Next

✓ Finish

 Generate Sample Report