

COMPETENCY GAP ANALYSIS TOOLKIT

Systematic Framework for Identifying and Closing Skills Gaps
Across GMP Manufacturing Teams

PREVIEW

Cell Therapy | Gene Therapy | Biologics Manufacturing

GxP Frame

gxpframe.com

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Executive Summary

A one-page briefing for anyone deciding whether to fund and sponsor this program.

Training completion and demonstrated proficiency are different evidence. This toolkit offers a five-phase method for defining role requirements, assessing performance, prioritizing documented gaps, planning remediation, and checking effectiveness. A site must adapt the method to its approved procedures, actual tasks, and quality risk.

The five phases form a repeatable cycle: define competencies, assess current performance, evaluate gaps, remediate, and verify. The illustrative schedule in Section 9 is a planning example, not a required or promised completion time.

- **Regulatory context: 21 CFR 211.25, applicable EU GMP requirements, and ICH Q10 and Q9(R1) are reference points. The site must determine applicability and its own approved controls. This toolkit does not establish regulatory compliance.**
- **What practitioners get:** Written, practical, and supervisor-based assessment instruments; a risk-weighted prioritization matrix; a remediation action plan template; and a CAPA-integration trigger list.
- **Program measures: assessment coverage, gap closure, effectiveness, recurrence, and time to closure. Set targets, denominators, and review frequency in the site program before use; the values in Section 7.3 are examples only.**

Recommended Starting Point: Do not attempt this across an entire site at once. Start with one department, ideally the one with the most recent deviation or audit finding, complete a full 8 to 12 week cycle, and use the results to refine the approach before expanding.

3. Phase 1: Competency Inventory

Define what competency looks like for every critical role before you try to measure it.

The most common mistake in gap analysis is jumping straight to assessment without first defining what you are assessing against. Phase 1 builds the competency framework that serves as your measurement standard.

3.1 Competency Categories

This example groups competencies into four categories. Adjust categories and their importance to actual role requirements:

Category	Description	Examples
Technical Knowledge	Understanding of scientific principles, regulatory requirements, and process theory	GMP regulations, aseptic technique theory, process chemistry, analytical methods
Practical Skills	Ability to physically perform tasks to required standards under normal and abnormal conditions	Gowning, equipment operation, sampling, batch record execution, instrument calibration
Documentation Proficiency	Ability to create, complete, and review GMP documentation accurately and in compliance	Batch record completion, deviation writing, SOP authoring, data integrity practices
Problem-Solving Capability	Ability to identify, investigate, and resolve issues using structured methods	Root cause analysis, OOS investigation, troubleshooting, risk assessment

3.2 Proficiency Levels

Each competency is measured against a 4-level proficiency scale. These levels are deliberately behavioral, describing observable actions rather than subjective impressions:

Level	Name	Definition	Observable Indicators
1	Awareness	Can describe the concept and identify when it applies. Cannot perform independently.	Asks appropriate questions. Recognizes relevant situations. Refers to SOPs correctly. Requires direct supervision.
2	Application	Can perform the task under normal conditions with minimal guidance. May need support for exceptions.	Completes standard tasks independently. Follows SOPs without errors. Escalates exceptions appropriately.
3	Mastery	Can perform under normal and abnormal conditions. Can troubleshoot and train others.	Handles exceptions independently. Trains new employees. Contributes to procedure improvements. Low deviation rate.
4	Expert	Subject matter expert. Can design	Leads investigations. Authors and

5. Phase 3: Gap Identification and Prioritization

Not all gaps are created equal. Prioritize by risk to product quality and patient safety.

5.1 Gap Score Calculation

For each competency, the gap score is the difference between the required proficiency level and the assessed proficiency level:

Gap = Required Level minus Assessed Level, only when both are recorded. Review critical practical tasks separately; do not average away a hands-on deficit.

A score of 0 means the recorded assessed level meets the recorded requirement. A positive value is a gap for review. A negative value can flag proficiency above target, but it does not by itself qualify someone as a trainer or subject matter expert. Missing assessments must remain unscored.

5.2 Risk-Based Prioritization Matrix

For each confirmed positive gap, document patient or product impact, applicable quality or regulatory exposure, and operational impact. The example weights below are adjustable and are not regulatory requirements.

Illustrative dimensions and weights; the site must approve risk criteria before use.	Score 1	Score 2	Score 3	Score 4	Score 5	Weight
Patient Safety Impact	Low assessed impact	Indirect impact	Moderate impact	Significant impact	Direct patient harm possible	40%
Regulatory Exposure	Low assessed exposure	Limited exposure	Material exposure	High exposure	Severe exposure	35%
Operational Impact	No disruption	Minor delays	Schedule impact	Batch failure risk	Production shutdown risk	25%

Illustrative priority score after a confirmed positive gap: (Patient/Product Impact x 0.40) + (Quality/Regulatory Exposure x 0.35) + (Operational Impact x 0.25). Site owner may adjust weights and response.

8. Assessment Instruments

Ready-to-use templates for conducting assessments across all four competency categories.

8.1 Written Assessment Template

Use the following structure for written knowledge assessments. Each assessment should include a mix of question types:

Question Type	When to Use	Example
Scenario-Based Multiple Choice	Measuring knowledge application and decision-making under realistic conditions	During buffer prep, you notice the pH is 0.3 units outside specification. Which action is correct?
Regulatory Identification	Verifying understanding of which regulations apply to specific situations	Identify the approved site requirement for equipment cleaning and explain how the user would verify it.
Short Answer / Reasoning	Assessing depth of understanding and ability to explain rationale	Explain the approved site gowning qualification criterion and the source that establishes it.
True/False with Justification	Testing critical thinking and ability to identify common misconceptions	A result is outside an approved specification. What are the immediate documentation and escalation steps under the site procedure?

8.2 Practical Observation Checklist

Use this checklist structure when observing practical demonstrations. Customize the specific steps for each competency:

Observation Criteria	Level 1	Level 2	Level 3	Level 4
Prepares workspace and materials correctly	☐	☐	☐	☐
Follows SOP step sequence accurately	☐	☐	☐	☐
Demonstrates proper aseptic technique	☐	☐	☐	☐
Completes documentation in real-time	☐	☐	☐	☐
Identifies and reports anomalies	☐	☐	☐	☐
Handles introduced exception correctly	☐	☐	☐	☐
Cleans and restores workspace per SOP	☐	☐	☐	☐