

GxP Frame

GMP Training Matrix Architecture Framework

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Representative pages from the framework included in the Training Matrix Architecture package: cover, role-map example, and gap-analysis worksheet. The purchased package also includes the guide, work aid, presentation, and editable matrix.

Preview only. Source mappings and intervals require site review. This PDF is not an approved controlled document and may not be used as evidence of personnel qualification.

GMP TRAINING MATRIX

ARCHITECTURE FRAMEWORK

A Comprehensive Guide to Site-Adaptable Training Architecture
Cell Therapy | Gene Therapy | Biologics Manufacturing

GxP Frame

gxpframe.com
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5. Role-Based Training Maps

This section offers representative role-based training mappings, source citations, proposed intervals, and example assessments. Confirm each item for the site's processes and controls. Progressive operator levels show proposed inheritance, subject to local approval.

5.1 Manufacturing Operator Level I

Core GMP Training (proposed)

Training Topic	Proposed interval	Source / rationale
GMP Fundamentals	Annual	21 CFR 211.25
Documentation Practices	Annual	21 CFR 211.188
Deviation Reporting	Annual	21 CFR 211.192
Personal Hygiene	Semi-Annual	21 CFR 211.28
Safety & Emergency Procedures	Annual	OSHA / Site-Specific

Process-Specific Training (proposed)

Training Topic	Proposed interval	Source / rationale
Cleanroom Entry/Exit Procedures	Semi-Annual	EMA Annex 1
Basic Gowning Qualification	Annual	EMA Annex 1
Material Handling Procedures	Annual	21 CFR 211.142
Equipment Cleaning Procedures	Annual	21 CFR 211.67
Environmental Monitoring Basics	Annual	USP <797>

Quality Systems Training (proposed)

Training Topic	Proposed interval	Source / rationale
CAPA System Overview	Annual	21 CFR 211.100
Batch Record Basics	Annual	21 CFR 211.188
Investigation Support	Annual	21 CFR 211.192

Assessment Requirements

- Written exam (site-approved pass criterion)
- Practical demonstration for gowning
- Annual competency review

5.2 Manufacturing Operator Level II

Inherits all Level I requirements, plus the following:

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8. Templates and Tools

The following templates support implementation and ongoing management of the training matrix architecture. Each template is designed for customization to site-specific requirements.

8.1 Training Matrix Template

The training matrix maps each role against training categories, regulatory citations, and assessment requirements. The example below illustrates the structure for three representative roles:

Role / Function	Core GMP	Process-Specific	Quality Systems	Frequency	Assessment	Level
Mfg. Operator I	GMP Fundamentals	Cleanroom Entry, Gowning	CAPA Overview, Batch Records	Annual / Semi-Annual	Written Exam + Practical Demo	Level 2
QC Analyst	GMP for Labs, Data Integrity	Method Validation, Stability	OOS Investigation	Annual	Written (site set) + Method Demo	Level 3
Mfg. Engineer	Engineering GMP, Process Dev	PAT, DOE, Scale-Up	Risk Assessment, Validation	Annual	Written + Case Study + Presentation	Level 3
Maintenance Tech	GMP for Maintenance	PM Procedures, Calibration	Deviation Reporting	Annual / Semi-Annual	Written + Hands-On Demo	Level 2
QA Specialist	Advanced GMP, Audit Techniques	Document Control, SOP Review	CAPA, Root Cause Analysis	Annual	Written (site set) + Audit Simulation	Level 3

Note: The editable Training Matrix included in this package starts with the 12 roles mapped in Section 5. Review citations, prerequisites, and intervals against current site requirements before use.

8.2 Gap Analysis Worksheet

Current State Assessment:

- Employee Name, Role/Position, Hire Date
- Last Training Date, Current Competency Level

Training Requirements Checklist:

- Core GMP Training (Due Date)
- Process-Specific Training (Due Date)
- Quality Systems Training (Due Date)
- Safety Training (Due Date)
- Regulatory Training (Due Date)

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