FORGENIC

GMP CONSULTING

GMP Consulting Service Brochure

From facility qualification to continuous compliance

Overview

FORGENIC supports the entire GMP lifecycle for pharmaceutical and biotechnology manufacturing — building compliant systems and reliable production, from equipment qualification and process validation to audit readiness and facility review.

1 Core Services

Qualification

Equipment and facility qualification to ensure systems are installed and function as intended.

- DQ — Design Qualification
- IQ — Installation Qualification
- OQ — Operation Qualification
- PQ — Performance Qualification

Validation

Demonstrating that processes, systems, and cleaning are effective and reproducible.

- Cleaning & Disinfectant Validation
- Sterilization Validation
- Cleanroom / HVAC Validation
- Process & Environmental Validation

Audit Support & Training

Audit readiness and tailored training to strengthen your GMP knowledge and practice.

- Internal Audit
- Supplier Audit
- GMP & Validation Training
- Environmental Monitoring Training

GMP Facility Review

Reviewing facilities and process flows to identify compliance gaps and improvements.

- Facility Layout Review
- GMP Compliance Review
- Operational Flow Review

2 Scope of Work

Cleanroom · HVAC System · Air Handling Unit · BSC · Isolator · RABS · Sterilization & Decontamination · MOCK Inspection

3 Qualification Stages

Stage	Objective
DQ — Design	Verify design meets user requirements and GMP intent.
IQ — Installation	Confirm equipment is installed per specification.
OQ — Operation	Demonstrate operation across the intended range.

PQ — Performance	Prove consistent performance under production conditions.

Our goal is to help you build a robust quality system and maintain compliance with global regulatory standards.

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