

Audit Readiness: Achieving EU-GMP and GACP Compliance

Audit readiness is not a temporary project. It is a continuous state of operational excellence. For facilities navigating European Union Good Manufacturing Practice (EU-GMP) and Good Agricultural and Collection Practice (GACP), an inspection can happen at any time. True compliance means your facility, processes, and team are always prepared.

The Compliance Landscape: GACP vs. EU-GMP

Understanding where boundaries sit prevents critical compliance gaps.

[Cultivation & Harvest: GACP] → [Primary Processing] → [Extraction & Packaging: EU-GMP]

- **GACP Focus:** Governs the cultivation, harvest, and initial drying of medicinal plants. It ensures botanical identity, prevents contamination, and guarantees batch consistency.
- **EU-GMP Focus:** Governs the transformation of plant material into finished medicinal products. It enforces strict validation, sterile environments, and rigorous quality control.

4 Pillars of Continuous Audit Readiness

1. Data Integrity and Documentation

Your documentation is the primary evidence of your compliance. If a process is not documented, an auditor assumes it never happened.

- **ALCOA+ Principles:** Ensure all data is Attributable, Legible, Contemporaneous, Original, and Accurate.
- **Logbooks:** Maintain real-time, tamper-evident records for all equipment and cleanrooms.
- **Traceability:** Link every finished batch directly back to its seed or starting material source.

2. Robust Facility Design and Sanitation

Physical environments must actively prevent contamination and mix-ups.

- **Zoning:** Separate GACP agricultural zones cleanly from EU-GMP manufacturing suites.
- **HVAC Systems:** Validate pressure differentials to keep airborne contaminants out of clean spaces.
- **Sanitation:** Execute and document strict, validated cleaning validation protocols between batches.

3. Comprehensive Training Programs

Auditors routinely interview floor staff to test the depth of your quality culture.

- **Role-Specific SOPs:** Train employees thoroughly on the exact procedures they execute.
- **Gown Validation:** Mandate and document formal cleanroom gowning certifications for EU-GMP zones.
- **Behavior:** Cultivate an environment where operators confidently report deviations immediately.

4. Lifecycle Deviation Management

A robust quality management system (QMS) embraces errors as opportunities for systemic improvement.

- **Root Cause Analysis:** Utilize structured tools like the 5 Whys or Fishbone diagrams.
- **CAPA Systems:** Implement Corrective and Preventive Actions that address the root cause, not just the symptom.
- **Trending:** Review recurring deviations monthly to identify failing equipment or blind spots.

Survival Guide: During the Inspection

When inspectors arrive at your facility, manage the interaction systematically.

- **The War Room:** Establish a back-room team to review requested documents before they reach the inspector.
- **Scribe Assignment:** Designate a staff member to record every question asked and document reviewed.
- **Direct Answers:** Answer questions concisely. Do not volunteer unrequested information.
- **Evidence Gathering:** Copy or photograph the exact files and locations the auditor examines.

Partner with LYRA QMS Compliance

Achieving zero-deficiency audits requires deep technical expertise. At LYRA QMS Compliance, we design and implement custom, audit-ready quality systems tailored to your unique facility footprint.

Contact us today to schedule a comprehensive gap analysis and secure your compliance roadmap.