7 Common GxP Compliance Pitfalls & How to Avoid Them

1. Missing or Incomplete SOP Library

❏ Ensure you have Standard Operating Procedures for all critical processes (e.g., document control, CAPA, change control).

❏ Verify that each SOP is reviewed, approved, and version-controlled.

2. No Gap Analysis Before Audit

❏ Conduct a formal GAP analysis against your target regulations (GMP, GCP, GLP).

❏ Document findings and assign CAPA (Corrective And Preventive Action) actions before scheduling any inspection.

3. Unclear Roles & Responsibilities

❏ Define and document key quality roles (QA lead, document owner, CAPA manager).

❏ Ensure every team member has a signed responsibility matrix.

4. Inadequate Training Records

❏ Use a training log to record completion of all QMS-related training.

❏ Re-certify critical SOPs periodically or after major updates.

5. Inefficient CAPA & Deviation Management

❏ Implement a clear workflow for logging, investigating, and closing deviations.

❏ Track CAPA progress with defined timelines and verification steps.

6. Poor Document Control Practices

❏ Store all controlled documents in a single repository (electronic or locked folder).

❏ Enforce check-in/check-out, read-receipt, and archive obsolete versions.

7. No Mock Audit or Inspection Drill

❑ Schedule a “mock inspection” every 6–12 months.

❑ Create a checklist of likely questions and processes for your team to rehearse.

Bonus Tips for Fast-Tracking Approval

CRO Alignment Workshop

❑ Host a kickoff meeting to align expectations, deliverables, and quality metrics with your CRO partner.

Tiered Documentation Approach

❑ Start with “must-have” documents for initial filings, then expand into “nice-to-have” content as your program grows.

Regulatory Liaison Plan

❑ Assign a point-person for direct communication with regulators (e.g., TGA, EMA, FDA) to clarify expectations early.