A One-Page Guide to GxP

"Good practices," or "GxP" for short, encompass a wide range of guidelines companies must follow to adhere to the quality and regulatory standards used in quality-sensitive industries.

3 Core Components of GxP

Traceability
Record sufficient information to recreate processes.

Accountability
Maintain records to identify who participated in a process.

Data Integrity
Secure data and follow the ALCOA rule.

ALCOA RULE

Attributable | **L**egible | **C**ontemporaneously recorded | **O**riginal | **A**ccurate

5 P's of GxP

A useful framework to implement traceability and accountability standards is known as the "5 P's" of GxP. These refer to:

People
Training, hygiene, reporting and review systems.

Procedures
SOP's established, accessible and reviewed regularly.

Products & Primary (Raw) Materials
Training, hygiene, reporting and review systems.

Premises & Equipment
Clean facilities, monitoring, safety processes, validation and calibration.

Processes
Overall process documented clearly, validated regularly and followed consistently.

6 Tips for Maintaining GxP Compliance

Record data according to the ALCOA rule.

Store data in a secure, organized way.

Document all processes & procedures using SOPs.

Properly train employees at all levels.

Validate equipment & procedures systematically and continually.

Perform regular internal audits that mimic "official" regulatory audits.

Regardless of industry, the foundation of any successful GxP system is accurate, detailed record-keeping and documentation.