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# Introduction to Good Manufacturing Practices (GMP)

## Context

Good Manufacturing Practices (GMP), also called Current Good Manufacturing Practices (cGMP) in the U.S., form the basis of FDA oversight in the life sciences industry. GMP regulations are designed to ensure medical products are consistently manufactured and controlled to meet defined specifications for identity, quality, safety, and performance. By requiring manufacturers to implement strong systems that prevent contamination, errors, and variation, GMP ensures that products perform as intended and are safe for patient use.

The word "current" is crucial. It shows that GMP expectations change along with scientific and technological advances. Companies are expected to use the most recent methods, employ risk-based decision-making, and adopt new technologies that improve product safety and efficacy. Therefore, GMP is not a static checklist but a flexible standard that adapts to the evolving realities of global manufacturing.

## Core Principles of GMP

GMP is founded on several core principles that apply to all FDA-regulated products.

- **Facilities & Equipment:** Manufacturing must occur in well-designed, properly maintained, and controlled facilities, with environmental controls suited to the product's risk. Equipment and utilities must be qualified, calibrated, and validated to ensure consistent and reliable operation.
- **People & Training:** Companies must hire qualified staff and provide ongoing training. Training should cover technical skills, GMP principles, hygiene practices, and accurate documentation. Personnel hygiene and health monitoring are essential in aseptic or sterile operations; management should promote a culture of quality that encourages employees to report any concerns.
- **Governance & Oversight:** A robust quality system features an independent Quality Unit, documented policies and procedures, and regular management reviews. Corrective and Preventive Action (CAPA), change control, and internal audits are crucial for ongoing improvement and ensuring regulatory compliance.
- **Documentation & Records:** Accurate, current, and complete documentation supports all GMP activities. Policies, procedures, and batch records must follow ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, plus Complete, Consistent, Enduring, and Available), whether in paper or electronic systems compliant with 21 CFR Part 11. Prompt review and approval of records ensure traceability and accountability.

- **Materials & Supply Chain:** All raw materials must be sourced from qualified suppliers and tested according to specified standards. Complete traceability from supplier to finished product is required, including supervision of contractors and third-party manufacturers.
- **Production & Process Controls:** Every process must be thoroughly documented and validated, demonstrating a consistent ability to meet established specifications. The FDA requires a lifecycle process validation that includes process design, process qualification, and ongoing process verification, supported by data monitoring and trending.
- **Laboratory Controls:** Analytical methods must be validated or verified, and reference standards established. Stability testing must follow ICH guidelines, such as Q1A and Q1E, to ensure a product's quality throughout its shelf life. Out-of-specification or out-of-trend results require a thorough, evidence-based investigation.
- **Packaging & Labeling:** Written procedures must prevent mix-ups and errors by reconciling issued labels, overseeing label issuance and destruction, and ensuring correct product identification.
- **Distribution & Supply Chain Oversight:** distribution systems must protect product integrity, ensure traceability, and allow quick recalls if necessary. This includes controls over storage, shipping, and handling of returns or complaints.
- **Post-Market Surveillance:** Companies must monitor product performance after release through complaint handling, adverse event reporting, deviation analysis, and recall procedures. These activities support continuous improvement and assist FDA initiatives such as Quality Metrics and Quality Management Maturity programs.

Together, these principles ensure that products are manufactured under conditions that safeguard patient safety, uphold product quality, and comply with regulatory standards.

## Commonalities & Differences in GMP Implementation by Product Type

GMP principles provide a universal foundation to the production of FDA-regulated products, but their practical application varies according to product type. Across all categories, manufacturers must adhere to several core requirements: maintaining validated facilities and equipment, providing comprehensive personnel training, implementing controlled and documented processes, qualifying suppliers, overseeing laboratories with validated methods, enforcing robust data integrity, safeguarding packaging and labeling, and establishing reliable systems for complaint handling and recalls. These shared practices reflect the FDA's expectation that every regulated product is manufactured within a system that prioritizes quality and patient safety.

However, GMP requirements diverge in response to the unique risks and scientific considerations of each product category:

- Biologics and vaccines require stringent sterility controls, validated potency assays, and often FDA lot release, where the agency reviews or tests specific batches before distribution.
- Blood products demand comprehensive donor screening, testing, labeling, storage procedures, and traceability from donor to recipient.

- Cell and gene therapies introduce specialized requirements for donor eligibility, patient-specific chain-of-identity, and comparability protocols to ensure process changes do not affect safety or efficacy.
- Drugs focus on lifecycle process validation, cleaning verification, and stability testing.
- Medical devices are governed by international standards (ISO 13485:2016) and require strict design controls, usability testing, and risk management.

These similarities and differences illustrate how GMP serves both as a universal quality framework and as a set of product-specific standards tailored to the scientific and operational risks of each regulated category.

## Product-Specific GMP Applications

GMP requirements for FDA-regulated products can be understood from two perspectives:

- **Regulatory Scope:** The specific sections of the Code of Federal Regulations (CFR) that establish the legal framework for each product type.
- **Operational Emphasis:** The practical quality controls and procedures manufacturers must implement to comply with these regulations.

While the overarching goal, ensuring product safety, quality, and effectiveness, remains constant, each product category has distinct regulatory and operational requirements:

- **Biologics & Vaccines (21 CFR 600–680)**
  - **Regulatory Scope:** Requirements for manufacturing, sterility, potency, and quality.
  - **Operational Emphasis:** Potency testing, aseptic procedures, and FDA lot release are critical. Manufacturers must ensure consistent product performance and may have batches reviewed or tested by the FDA before distribution.
- **Blood & Blood Components (21 CFR 606)**
  - **Regulatory Scope:** Requirements for collecting, processing, testing, labeling, and storing blood and blood components.
  - **Operational Emphasis:** Establishments must conduct thorough donor screening and testing, apply strict labeling and storage procedures, and ensure complete traceability from donor to recipient to protect transfusion safety.
- **Cell & Gene Therapies (21 CFR 1271)**
  - **Regulatory Scope:** Oversight of human cells, tissues, and cellular/tissue-based products (HCT/Ps), including donor eligibility and product management.
  - **Operational Emphasis:** Strict aseptic processing, environmental monitoring, and rigorous chain-of-identity and chain-of-custody controls are required to match products to patients. Comparability protocols are necessary to confirm that process changes do not compromise safety or efficacy.
- **Drugs (21 CFR Parts 210 & 211)**
  - **Regulatory Scope:** Standards for drug manufacturing, laboratory controls, and facility requirements.

- Operational Emphasis: Manufacturers must validate processes, conduct laboratory controls, implement cleaning validation and stability testing, and perform annual product quality reviews to ensure ongoing compliance.
- Medical Devices (21 CFR 820; transitioning to QMSR in 2026)
  - Regulatory Scope: In January 2024, the FDA issued the final Quality Management System Regulation (QMSR) rule to align 21 CFR 820 with ISO 13485:2016. The rule becomes effective in February 2026 and marks a major step toward global harmonization of medical-device quality systems.
  - Operational Emphasis: Manufacturers must follow design controls, usability testing, and risk management (ISO 14971), maintain effective complaint handling, and comply with FDA adverse event reporting.

GMP provides a consistent framework grounded in validation, documentation, and oversight, while its implementation is tailored to address the specific scientific and operational risks associated with each regulated product category.

## The Critical Role of GMP

GMP compliance is essential in the pharmaceutical, biotechnology, and medical device industries – not only to meet regulatory requirements, but also to protect patient health and maintain public trust. Historical GMP failures have resulted in product recalls, public health crises, and diminished confidence in manufacturers and the healthcare system. Regulatory agencies such as the FDA and EMA respond to violations with warning letters, import bans, recalls, consent decrees, and, in severe cases, civil or criminal prosecution, all of which can have lasting reputational and financial impacts.

Robust GMP frameworks deliver significant benefits: they minimize product variability, reduce costs, improve efficiency, and facilitate successful regulatory inspections and market approvals. GMP compliance also enhances organizational credibility among regulators, healthcare professionals, and patients. Furthermore, GMP principles promote continuous improvement and innovation by embedding scientific rigor and risk-based thinking into daily operations.

GMP regulations have evolved from reactive measures to a proactive, science-driven, and risk-based paradigm, now encompassing comprehensive standards for product development, manufacturing, quality control, and distribution. GMPs are not just legal obligations – they are a professional and ethical commitment to patient safety and product quality, forming the foundation of all other quality management and compliance systems.

In summary, GMP is both a regulatory requirement and a strategic imperative, supporting product quality, patient safety, and organizational success in the life sciences sector.