[Why GMP? An explanation of Good Manufacturing Practice](http://blog.fisherbioservices.com/why-gmp-an-explanation-of-good-manufacturing-practice)

Posted by [Johannes Gross](http://blog.fisherbioservices.com/author/johannes-gross) on Oct 27, 2015 10:00:00 AM

GMP refers to the Good Manufacturing Practice Regulations published by the FDA under the Federal Food, Drug, and Cosmetic Act. As a response to concerns about substandard drug manufacturing practices occurring at the time, Congress enacted the [1962 Drug Amendments](http://uscode.house.gov/statutes/pl/87/781.pdf). These amendments instructed the FDA to require all drugs to be made according to [Good Manufacturing Practice](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm090016.htm) (GMP) as defined under FDA 21 CFR Part 210-211.



The first set of [Good Manufacturing Practices (GMP) regulations](http://www.fisherbioservices.com/quality/regulatory-compliance) were published in 1963. These regulations are meant to guide companies in the production of safe and effective drugs. The regulations outlined in the GMPs are the minimum requirementsnecessary to ensure safe and effective products.

In this blog we'll discuss the definition of GMP, various regulatory components, and why it's important for companies in the life sciences space.

Trained inspectors for the FDA examine facilities around the world, including those facilities that produce the active ingredients and final products. The FDA also reviews consumer and industry complaints filed about the drug, using these reports to identify sites that could benefit from inspection.

**About GMP**GMP is a set of regulations that ensures the [quality of drugs](http://connect.fisherbioservices.com/download/fisher_bioservices_qualification_validation_services_brochure), medical devices, blood, and some types of food. The regulations cover manufacturing, facilities and controls for the manufacturing, processing, packaging or holding of a drug product.

When discussing current good manufacturing practices, many agencies use the acronym cGMP, with the letter ‘c’ standing for ‘current.’ This nomenclature reminds companies to use the most up-to-date technologies and systems in order to comply with current regulations. Many older GMP practices, specifically those designed to prevent errors, mix-ups and contamination, are now outdated and inadequate.

**About Part 210 and 211**21 CFR Part [210](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=210) and [211](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=211) outline the manufacture, processing, packing, or holding of a drug specifically, although supporting companies and services can benefit by compliance with these standards as well.

Part 210.2 applies to drug products intended for human use and lays out definitions for terms used within the document. Part 211 describes important issues.

Its 11 subparts discuss all sections of drug manufacturing operations:

A. General Provision
B. Organization and Personnel
C. Building and Facilities
D. Equipment
E. Control of Components and Drug Product Containers and Closures
F. Production and Process Controls
G. Packaging and Labeling Controls
H. Holding and Distribution
I. Laboratory Controls
J. Records and Reports
K. Returned and Salvaged Drug Product

Each section of code outlines a different GMP activity. 211.22 details the responsibilities of a quality control unit, for example, while 211.25 discusses personnel qualifications, 211.28 deals with sanitation, clothing, protective apparel, hygiene and health habits and 211.34 offers guidelines on working with consultants. Part 1271 subparts C and D describes donor-eligibility and applicable current good tissue practice procedures for owners and operators of establishments engaged in the recovery, donor screening, donor testing and other types of testing, processing, storage, labeling, packaging, or distribution of human cells, tissue samples, and cellular and tissue-based products (HCT/Ps).

**What GMP Means for Companies in the Life Sciences Space**GMP regulations address a wide range of production activities, including starting materials, sanitation and cleanliness of the premises, equipment verification, and process validation. GMP regulations even extend into human resources and general offices, offering practice guidelines for record keeping, personnel qualifications, complaints, training, and personal hygiene of staff working in regulated areas. GMP requires documented proof of consistent adherence to established procedures at every step in the production process.

While stringent in their requirement for quality, most GMP regulations are open-ended and flexible in that they allow individual companies the latitude to decide on the best way to implement the controls necessary to achieve the highest quality within each organization. Failure to comply with these regulations may result in regulatory action for the drug and for the company responsible for the failure.

Virtually every person in the United States is affected by the quality of pharmaceuticals. Nearly 70 percent of Americans take a prescription drug, according to [Mayo Clinic](http://newsnetwork.mayoclinic.org/discussion/nearly-7-in-10-americans-take-prescription-drugs-mayo-clinic-olmsted-medical-center-find/), and almost half take two. The use of non-prescription or over-the-counter (OTC) drugs and supplements is also widespread. cGMPs are important because consumers cannot easily detect an unsafe or ineffective product[simply by looking, smelling or touching it](http://blog.fisherbioservices.com/implementing-pre-qualified-shippers-into-ambient-and-controlled-room-temperature-operations). GMP testing, typically performed on small samples from a batch, ensures that the rest of the batch provides the high quality medication or supplementation desired by these consumers.

While this blog focuses on GMP in the United States, in Europe, Qualified Persons (QP) serve as the eyes and ears of the UK Medicines and Healthcare product Regulatory Agency (MHRA) and ensure that products have been manufactured according to GMP and European Union regulations.