

## Good Manufacturing Practice Regulations

### Your objectives:

At the end of the lesson, you should be able to (1) identify, and appropriately apply, good manufacturing practice and (2) list the different authorities, identifying the key regulatory mechanisms in the manufacture of pharmaceutical compounds and devices.

### Overcoming challenges



The term “Good Manufacturing Practice” was introduced in 1962 by the Food and Drug Administration through the “current good manufacturing practice” (cGMP\*) initiative, or regulations are enforced by the US Food and Drug Administration (FDA, aka. USFDA).

Why have GMP regulatory mechanisms been put in place? Just imagine what would happen were there no existing rules and regulations; the consumer would generally not have the means,

either through the senses alone or through any readily available scientific measuring devices, by which to detect whether a drug product is safe or effective.

Good manufacturing practice (GMP) is a set of guidelines addressing not only the quality assurance of production processes and environment in the production of drugs and their active ingredients, but also in those of cosmetics, foods and animal feed. Quality assurance plays a central role in pharmaceutical production, otherwise quality deviations will have a direct impact on consumer health. A GMP-compliant quality management system serves to guarantee product quality and to meet the requirements of the health authorities that are binding for the sales and marketing division.

The regulations within GMP delineate issues such as record-keeping, personnel qualifications, hygiene, cleanliness of rooms and equipment, equipment verification, process validation and compliancy with managing processes.

Most GMP requirements are mostly general and open-ended, allowing each manufacturer to individually decide how best to implement and administrate the given controls. Though these guidelines allow for flexibility, GMP also that the manufacturer interpret the requirements in a manner that makes most sense within its own products.

GMP underlines systems that assure proper design, monitoring and control of manufacturing processes and facilities. Adherence to the cGMP regulations assures the identity, strength, quality and purity of the drug product, by requiring that manufacturers of medications adequately oversee manufacturing operations. This includes the following:

1. establishing strong quality management systems,
2. obtaining appropriate quality raw materials,
3. establishing robust operating procedures,
4. detecting and investigating product quality deviations, and
5. maintaining reliable testing laboratories.

Common rules and guidelines are outlined on a global level by the following bodies:

1. the European Commission,
2. the Pharmaceutical Inspection Co-Operation Scheme (PIC/S),
3. the U.S. Food and Drug Administration (FDA), and
4. the International Council for Harmonization of Technical Requirements (ICH)

Depending on which market a product is to be supplied, the respective state authority has to give its approval: *Swissmedic*, as the Swiss authority, is responsible for nationwide approvals for Switzerland, EMA for Europe-wide approvals, and the FDA for approvals on the US market.

Failure of pharmaceutical firms to comply with cGMP regulations can result in very serious consequences including recalls, fines and jail time. It goes without saying, not doing so would greatly affect health of patients in need of proper medication, which is why it is crucial that drugs be manufactured under strict, stringent, established conditions and practices so as to ensure quality is built into the design and manufacturing process at every step.

\* “[The terms GMP and cGMP] are largely interchangeable”:  
<https://www.pharmout.net/gmp-vs-cgmp-whats-difference/>