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 [   ] of pharmaceutical

[   ] 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

[   ]

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 [   ] would generally not have the means, either

through the senses alone or through any readily available [   ]

measuring devices, by which to detect whether a [   ] product is [   ] or effective.

Good manufacturing practice (GMP) is a set of [   ] addressing not only the quality assurance of [   ] processes and environment in the production of drugs and their active ingredients, but also in those of [   ], foods and animal feed. Quality assurance plays a central role in pharmaceutical production, otherwise quality [   ] will have a direct impact on consumer [   ]. A GMP-compliant quality management system serves to [   ] 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, [   ], 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 [   ].

GMP underlines systems that assure proper design, monitoring and [   ] of manufacturing processes and facilities. Adherence to the

cGMP regulations assures the identity, strength, [_____] and [_____] of the drug product, by requiring that manufacturers of medications adequately oversee manufacturing operations. This includes the following:

1. establishing strong quality management [_____],
2. obtaining appropriate quality raw [_____],
3. establishing robust operating [_____],
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 US 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 [_____], EMA for Europe-wide approvals, and the FDA for approvals on the US market.

Failure of pharmaceutical firms to [_____] with cGMP regulations can result in very serious [_____] 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

[   ], 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/

Aufgabe Lückentext:

Folgende Wörter bitte in den Lückentext einfüllen.
Jedes Wort kommt einmal vor.
Bitte Gross- und Kleinbuchstaben beachten.

compounds, consumer, cosmetics, control, comply, consequences, drug, deviations, guidelines, guarantee, health, hygiene, manufacture, materials, production, products, procedures, purity, quality, regulations, scientific, safe, systems, strict, Switzerland