С.Ж.АСФЕНДИЯРОВ АТЫНДАҒЫ
ҚАЗАҚ ҰЛТТЫҚ МЕДИЦИНА УНИВЕРСИТЕТІ

КАЗАХСКИЙ НАЦИОНАЛЬНЫЙ МЕДИЦИНСКИЙ
УНИВЕРСИТЕТ ИМЕНИ С.Д.АСФЕНДИЯРОВА

ИНСТИТУТ ФАРМАЦИИ

GOOD MANUFACTURING PRACTICE

Executed :Қайыржанова
Б
Checked:

Plan

- Good manufacturing practice
- High-level details
- High-level details

- **Good manufacturing practices** (**GMP**) are the practices required in order to conform to the guidelines recommended by agencies that control authorization and licensing for manufacture and sale of food, drug products, and active pharmaceutical products. These guidelines provide minimum requirements that a pharmaceutical or a food product manufacturer must meet to assure that the products are of high quality and do not pose any risk to the consumer or public.

High-level details

- Good manufacturing practice guidelines provide guidance for manufacturing, testing, and quality assurance in order to ensure that a food or drug product is safe for human consumption. Many countries have legislated that food and pharmaceutical and medical device manufacturers follow GMP procedures and create their own GMP guidelines that correspond with their legislation.

- All guidelines follow a few basic principles:
- Manufacturing facilities must maintain a clean and hygienic manufacturing area.
- Controlled environmental conditions in order to prevent cross contamination of food or drug product from adulterants that may render the product unsafe for human consumption.

- Manufacturing processes are clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications.
- Manufacturing processes are controlled, and any changes to the process are evaluated. Changes that affect the quality of the drug are validated as necessary.

- Instructions and procedures are written in clear and unambiguous language. (Good Documentation Practices)
- Operators are trained to carry out and document procedures.
- Cross contamination with unlabelled major allergens is prevented.
- Records are made, manually or by instruments, during manufacture that demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the food or drug was as expected. Deviations are investigated and documented.

- Records of manufacture (including distribution) that enable the complete history of a batch to be traced are retained in a comprehensible and accessible form.
- The distribution of the food or drugs minimizes any risk to their quality.

- A system is available for recalling any batch from sale or supply.
- Complaints about marketed products are examined, the causes of quality defects are investigated, and appropriate measures are taken with respect to the defective products and to prevent recurrence.

Guideline versions

- GMPs are enforced in the United States by the U.S. Food and Drug Administration (FDA), under Title 21 CFR. The regulations use the phrase "current good manufacturing practices" (cGMP) to describe these guidelines. Courts may theoretically hold that a product is adulterated even if there is no specific regulatory requirement that was violated as long as the process was not performed according to industry standards.[*citation needed*] Since June 2010, a different set of cGMP requirements have applied to all manufacturers of dietary supplements.[


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