С.Ж.АСФЕНДИЯРОВ АТЫНДАҒЫ
ҚАЗАҚ ҰЛТТЫҚ МЕДИЦИНА УНИВЕРСИТЕТІ

КАЗАХСКИЙ НАЦИОНАЛЬНЫЙ МЕДИЦИНСКИЙ
УНИВЕРСИТЕТ ИМЕНИ С.Д.АСФЕНДИЯРОВА

ИНСТИТУТ ФАРМАЦИИ

GOOD LABORATORY PRACTICE

Executed :
Checked:

Plan

- Good laboratory practice
- History
- GLP principles include

- In the experimental (non-clinical) research arena, the phrase **good laboratory practice** or **GLP** specifically refers to a quality system of management controls for research laboratories and organizations to try to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical (including pharmaceuticals) non-clinical safety tests; from physio-chemical properties through acute to chronic toxicity tests.

- GLP was first introduced in New Zealand and Denmark in 1972, and later in the US in 1978 in response to the Industrial BioTest Labs scandal. It was followed a few years later by the Organization for Economic Co-operation and Development (OECD) Principles of GLP in 1992; the OECD has since helped promulgate GLP to many countries.

- Good Laboratory Practice (GLP) embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed for pharmaceuticals (only preclinical studies), agrochemicals, cosmetics, food additives, feed additives and contaminants, novel foods, biocides, detergents etc.... GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments.

- GLP was first introduced in New Zealand and Denmark in 1972. GLP was instituted in US following cases of fraud generated by toxicology labs in data submitted to the FDA by pharmaceutical companies. Industrial BioTest Labs (IBT) was the most notable case, where thousands of safety tests for chemical manufacturers were falsely claimed to have been performed or were so poor that police investigators could not piece together what work had been done...even though IBT superficially delivered the test results their contracts with the manufacturers specified.

GLP principles include

- Organization and PersonnelManagement-Responsibilities
- Sponsor-Responsibilities
- Study Director-Responsibilities
- Principal Investigator-Responsibilities
- Study Personnel-Responsibilities

- Quality assurance program
  - Quality Assurance Personnel
- Facilities
  - Test System Facilities
  - Facilities for Test and Reference Items
- Equipment, reagents and Materials
- Test systems
  - Physical/Chemical
  - Biological