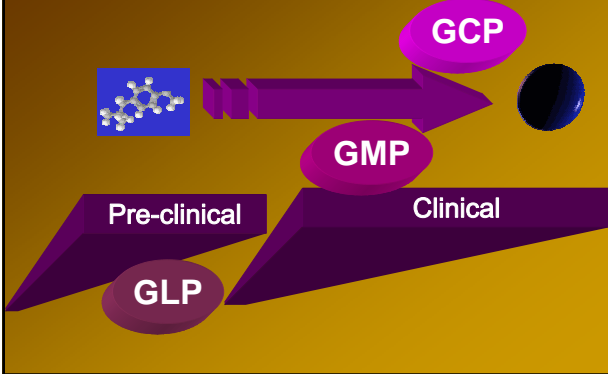


Module II: The Trial Landscape

Contents

- Why clinical trials?
- Main features of clinical trial design
- The history of clinical trials
- The drug development process
- Phases of clinical trials
- Clinical trial players
- Trial guidelines - GCP, GLP and GMP**
- Quality assurance – audits and inspections
- Research ethics
- Risk and benefits of trial participations

Trial guidelines - GCP, GLP and GMP Quality Assurance in Drug Development



Phases of Clinical Trials

GCP, GMP and GLP



Phases of Clinical Trials
GCP, GMP and GLP

Good Laboratory Practice is a quality system concerned with the organisational process and the conditions under which non-clinical laboratory studies are planned, performed, monitored, recorded, archived and reported.

Pre-clinical
GCP
Good Lab Practice
Clinical



Phases of Clinical Trials
GCP, GMP and GLP

Good Manufacturing Practice is the part of quality assurance that ensures that drugs for use in humans are consistently produced and controlled in such a way to meet the quality standards appropriate to their intended use.

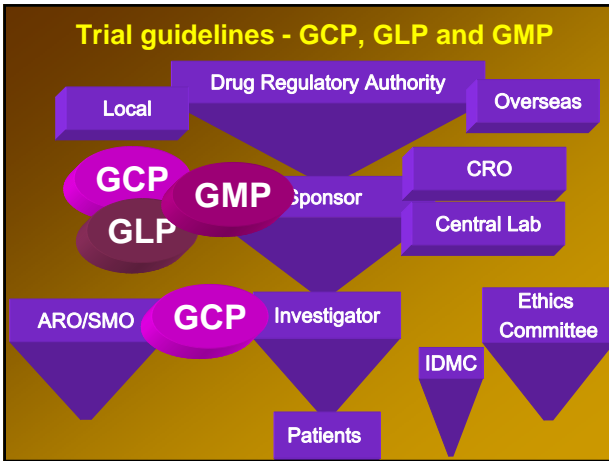
GMP
Good Manufacturing Practice
Clinical

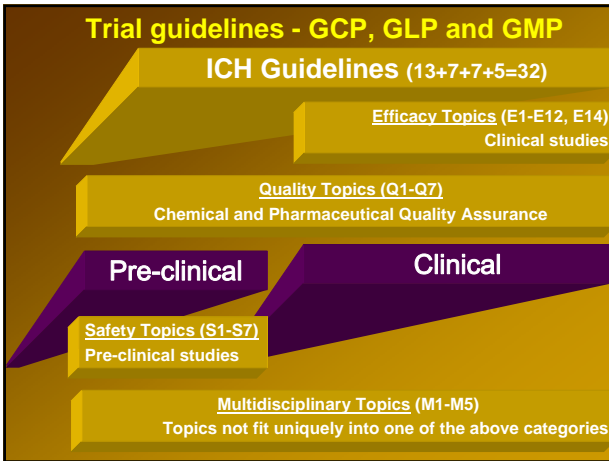


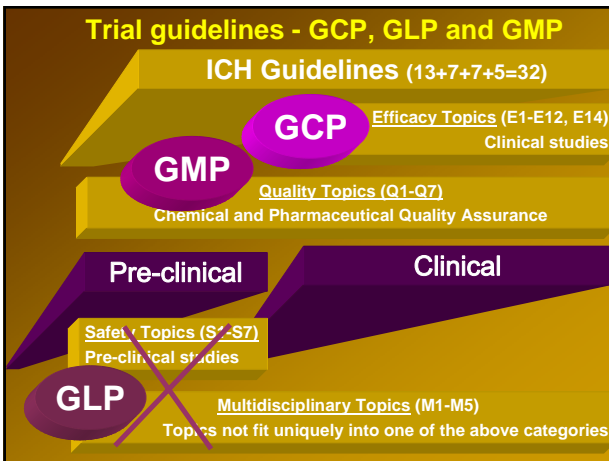
Phases of Clinical Trials
GCP, GMP and GLP

Good Clinical Practice is an ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

GCP
Good Clinical Practice
Clinical







Trial guidelines - GCP, GLP and GMP
ICH Guidelines (13+7+7+5=32)

GLP 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, agrochemicals, cosmetics, food and feed additives and contaminants, novel foods and biocides.

Pre-clinical

GLP is related to a large range of laboratory related issues that can shortly be characterized as follows:

- Laboratory infrastructure and personnel
- Laboratory methodologies and reference values
- Laboratory equipment and maintenance
- Test result records and computerization
- Function of Animal unit and experiments

GLP

Trial guidelines - GCP, GLP and GMP
ICH Guidelines (13+7+7+5=32)

Section 8 of the E6 Guideline "requires copies of current reference ranges, certification, accreditation or established QC and/or external quality assessment or other validation to document competence of the facility to perform required test(s) and support reliability of results".

For the specific case of a clinical laboratory the following should be addressed:

- Analytical methods
- Reference ranges
- Reporting procedures
- The nature of source data
- Access for monitoring, audit and inspection
- Filing and archiving of paper and electronic records in a way which permits rapid retrieval

Clinical

GCP Standards for Clinical Laboratories

Trial guidelines - GCP, GLP and GMP
ICH Guidelines (13+7+7+5=32)

GMP

Quality Topics (Q1-Q7)
 Chemical and Pharmaceutical Quality Assurance

Pre-clinical Clinical

Q7A entitled Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients

Trial guidelines - GCP, GLP and GMP

GMP ICH Guidelines (13+7+7+5=32)

GMP is concerned with both production and quality control. The basic requirements are that the manufacturing processes are clearly defined and controlled and that all critical processes are validated to ensure consistency and compliance with specifications.

The ICH GMP Guideline provides all the necessary key elements for GMP such as:

- qualified and trained personnel
- adequate premises and space
- suitable equipment and services
- correct materials, containers and labels
- approved procedures and instructions
- suitable storage and transport

Clinical

Trial guidelines - GCP, GLP and GMP

ICH Guidelines (13+7+7+5=32)

Efficacy Topics (E1-E12, E14)
Clinical studies

GCP

Pre-clinical Clinical

E6: Good Clinical Practice : Consolidated Guideline

Trial guidelines - GCP, GLP and GMP

ICH GCP – Efficacy Safety Topics N=13



E5 : Ethnic Factors in the Acceptability of Foreign Clinical Data

E6 : Good Clinical Practice : Consolidated Guideline

E9 : Statistical Principles for Clinical Trials

E10: Choice of Control Group

Trial guidelines - GCP, GLP and GMP

ICH Guidelines (13+7+7+5=32)

GCP E6 : Good Clinical Practice : Consolidated Guideline

This Good Clinical Practices document describes the responsibilities and expectations of all participants in the conduct of clinical trials, including: investigators, monitors, sponsors and IRBs.

GCP cover aspects of monitoring, reporting and archiving of clinical trials and incorporating addenda on the Essential Documents.

Trial guidelines - GCP, GLP and GMP

ICH Guidelines (13+7+7+5=32)

1. Accordance to Declaration of Helsinki
2. Risks and inconveniences weighed against anticipated benefits
3. Rights, safety, and well-being of the subjects are the most important considerations
4. Non-clinical and clinical information needed
5. Scientifically sound, and described protocol
6. Compliance with the protocol that has been approved by REC
7. Medical care by qualified physician
8. Staff qualified by education, training, and experience
9. Informed consent
10. Information recorded, handled, and stored in an accurate way
11. Confidentiality of records
12. Investigational products to follow good manufacturing practice
 - Systems with procedures that assure the quality of every aspect of the trial should be implemented.

Conclusion

Trial guidelines - GCP, GLP and GMP

GCP

GMP

GLP

ICH
