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# **18BP101** GOOD PRACTICE QUALITY GUIDELINES AND REGULATIONS

## **UNIT – I**

**Good Laboratory Practice:** Fundamentals, WHO guidelines, Role of OECD, Responsibilities of Management, Sponsor, Study director, Principal Investigator, Study and quality assurance personnel.

## **UNIT – II**

**Facilities:** Testing, Building, Materials, Equipments, test systems and study performance.

## **UNIT – III**

**Quality assurance:** Review of Protocol, SOP, Master Schedule, Inspection Plan, Audits, and Inspections, functions and advantages

## **UNIT – IV**

**Quality Assurance:** statements, inspection of material suppliers, reporting of results, Archiving, Indexing, Maintenance of files and records.

## **UNIT – V**

**Quality standards:** Concept of Quality Control, quality of chemicals, drugs, role of Regulatory agencies and good laboratory practices.