



PHARMACOLEARN

It's Important to Know!

BP205T — Computer Applications in Pharmacy

B.Pharm Semester 2 · Unit 5 — Computerised Data Analysis in Preclinical Development

Unit V: Computerised Data Analysis in Preclinical Development

Chromatographic data systems

A chromatographic data system receives detector output, records the signal against time and helps identify peaks. Typical processing includes baseline handling, peak detection, integration, calibration and report generation. The analyst must review integration and document changes rather than accept every automated result.

Laboratory information management systems

A laboratory information management system tracks samples, test requests, methods, results, instruments, users and approvals. A sample identifier links collection, storage, testing and reporting. Role-based access, audit trails, electronic signatures and backups support data integrity.

Text information management systems

A text information management system stores and retrieves documents or text records. Indexing and metadata improve retrieval. Controlled vocabulary, version control and retention rules help distinguish current procedures from obsolete copies.

Data quality and reporting

Reliable analysis requires traceability from raw data to processed result. Record instrument identity, method version, analyst, date, calculations, deviations and review status. Results should be reproducible and protected from unauthorised change.

Unit V: Frequently asked questions

Q: What does a chromatographic data system do?

A: It records detector signals and supports peak detection, integration, calibration and reporting.

Q: Why are audit trails important in a laboratory system?

A: They show who created, changed or approved data and help preserve traceability.

Q: What is the purpose of metadata in a text system?

A: Metadata describes a document, such as its title, version, owner, date and status, making retrieval and control easier.

Unit V: Key takeaways

- Chromatographic analysis converts detector signals into reviewed results.
- LIMS links samples, methods, instruments, results and approvals.
- Text systems depend on indexing, metadata and version control.
- Raw data and processing history must remain traceable.
- Automated output still requires trained review.

Unit V: Practical correlation

Practical correlation: laboratory data integrity. A preclinical result should be traceable from sample identity to raw signal, calculation, review and final report.