

UNIT-V

COMPUTER AS DATA ANALYSIS IN PRECLINICAL DEVELOPMENT

Points to be covered in this topic

- INTRODUCTION
- CHROMATOGRAPHIC DATA ANALYSIS
- LABORATORY INFORMATION
MANAGEMENT SYSTEM
- TEXT INFORMATION MANAGEMENT
SYSTEM

COMPUTER AS DATA ANALYSIS IN PRECLINICAL DEVELOPMENT

❑ INTRODUCTION

- Computers play a significant role in preclinical development. They help a lot in data analysis.
- Preclinical development refers to **development of adequate data, facts and figures to ensure that a particular drug is safe for human use.**
- Before any drug is tested on humans, a lot of experiments are conducted on animals to ensure that the **treatment goes well as per expectation and outcome is generated.** Only then a drug is declared safe for human testing.
- All the data related to a drug, use, safety, dosage, outcome, interactions, pharmacological effect, preclinical testing methods, FDA approval, over-dosage etc. are considered well before the launch of any product in the market.
- This **crucial information is entered and stored in computers** that can be further analyzed as and when required by scientists, pharmacists, physicians and other healthcare professionals.



➤ Role of computers in preclinical development-

- Act as **storehouse of drug information**
- Aids in study of **toxicology and risk assessment**
- Helps to **develop predictive models** for better decisions
- Makes **pharmaceutical development more efficient**
- **Ensures collection and management** of clinical data
- Aids in **better medical decision making**
- **Improves quality of healthcare management**

❑ CHROMATOGRAPHIC DATA ANALYSIS (CDS)

- CDS refers to software that **simplifies entire workflow process and saves lot of time and energy.**
- It gives better and faster results. This software is used **to collect and analyze chromatographic results** i.e. technique used to separate mixtures in a laboratory.
- Thus, CDS is related to effective workflow within a laboratory.
- CDS can also be referred to as a **workstation that controls all the instruments present in a laboratory.**
- It represents an integrated system with **all the data saved in a central server.**



Chromatography

➤ CDS PRODUCTS –

Some well known CDS products are-

- **Chromeleon 7.2 CDS Software** - It is used to **simplify lab workflow with a unified control** for effective data management.



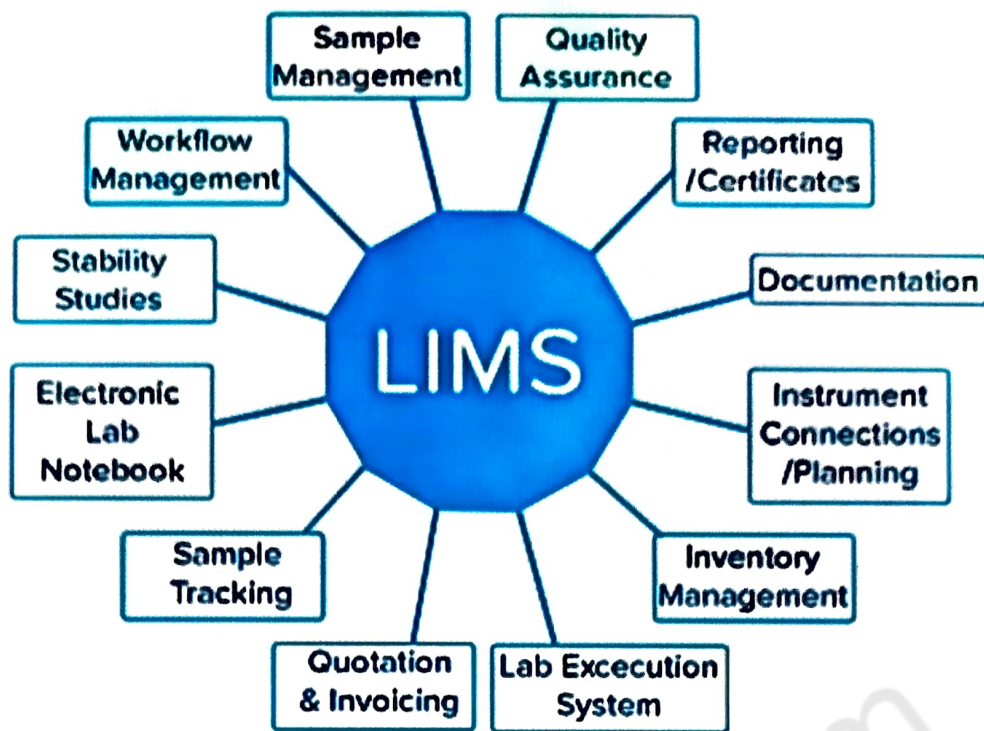
CHROMELEON 7.2
Simply Intelligent

- **Laboratory Information Management Systems** - Manages **all workflow within a - laboratory**. It reduces implementation, training and validation costs of an organization.
- **Scientific Data Management System** - Securely **shares data across multiple users** in an organization.
- **Integrated Solutions** - Provides **most effective lab data** by integrating instruments and software.

The importance of CDS can be judged from the fact that **high-performance liquid chromatography (HPLC) and gas chromatography (GC) play an important role in pharmaceutical analysis**. Research and development in Pharmaceutical companies is almost impossible without these two types of chromatography.

❑ **LABORATORY INFORMATION MANAGEMENT SYSTEM (LIMS)**

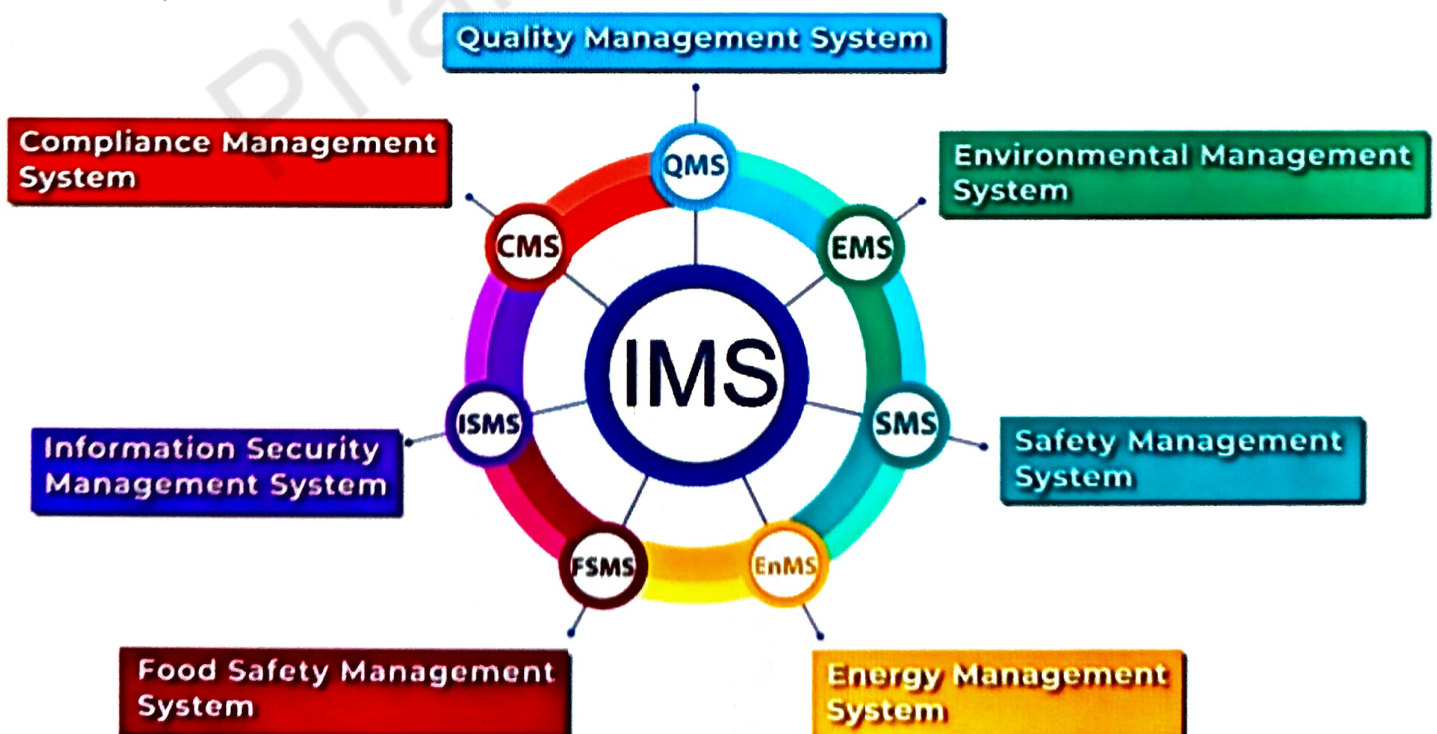
- Laboratory Information Management System refers to **software based data management system that supports all modern laboratory operations**.
- LIMS form an important part of **data management systems used in preclinical development**.
- LIMS were designed to automate major parts of development like **sample tracking, sample distribution, work assignment, result capturing, data processing, data review, report generation, and data sharing**.
- Thus, LIMS has fastened the process of management in preclinical development.



➤ APPLICATIONS OF LIMS-

- **Sample Management** - The primary function of LIMS is management of samples received in the laboratory. **Barcodes are fixed to the sample containers in order to distinguish them from other samples.** A complete record is maintained about the sample and its location in the lab i.e. row, column, box, freezer time, report generation time etc.
- **Instrument and Application Integration** - An effective LIMS requires proper integration of instruments and applications. This **ensures accurate and effective result generation.**
- **Electronic Data Exchange** - Great attention is paid to keep a check on the data entered and output generated in an instrument. **The successful transfer of data from the lab to the appropriate user** (physician, doctor, lab technician etc.) is an important task to be undertaken by LIMS.
- **Report Generation** - LIMS is also responsible for effective **report generation in the specified formats and scheduled time periods.**
- **Inventory Management** -It **measures and records inventory of all vital supplies within a laboratory.**

- It is also an organization's responsibility to **store the data in a secured way and at the same time ensure proper safety** and security of customer's personal information.
- It is an utmost responsibility of an organization to **keep the information confidential and secure** and release it only to the reliable sources.
- TIMS is a type of database management system which **supports an access method based on both select and search queries.**
- TIMS is mainly used by scientists as a report template **to facilitate report writing.**
- Once the **draft is ready, they can send electronic link of the document for review.**
- Necessary changes and amendments are done in the report and then final auditing is done to convert the existing template into final report.
- These reports can be further assessed by different users. Thus, TIMS saves a lot of time and energy.



➤ **BENEFITS OF TIMS**

- ✓ Saves time and energy
- ✓ Faster method of report generation
- ✓ Ensures accuracy
- ✓ Improves efficiency in managing critical data
- ✓ Reduced paper work
- ✓ Strict security
- ✓ Smooth and easy work flow

TIMS is a one step towards encouraging the **process of writing, reviewing, auditing, approving and publishing the pharmaceutical text reports** in one go. However, **changes and up-gradations are still required** to make this process more effective.