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CHAPTER

COMPUTERS AS DATA ANALYSIS IN PRECLINICAL DEVELOPMENT

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. The main purpose of preclinical studies is to determine first safe dose of upcoming drug or medicine 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, its existence, use, safety, dosage, outcome, interactions, pharmacological effect, preclinical testing methods, FDA approval, safety measures, adverse effects, 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



Use Of Computers In Clinical Education

- **Multimedia refers to the presentation of information in formats other than text alone. Included in these format types are: sounds, images, graphics, animations and videos.**
- **Computers help a great deal in pharmacy training and education**
- **X.RAYS , Electrocardiograms and other interpretations and values with reference to cases can be shown on multimedia and taught to the students.**
- **E-Books, Websites and Wikipedia are also a great source of help for the Clinical pharmacists and students to gather information and data.**
- **Computer simulations are helpful in teaching techniques i.e Demonstration of complete physiological or pharmacological process.**

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.

CDS Products – Some well known CDS products are as follows -

- **Chromeleon 7.2 CDS Software** – It is used to simplify lab workflow with a unified control for effective data management.
- **Laboratory Information Management Systems** – Manages all workflow within a laboratory. It reduces implementation, training and validation costs of an organization.
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- 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.

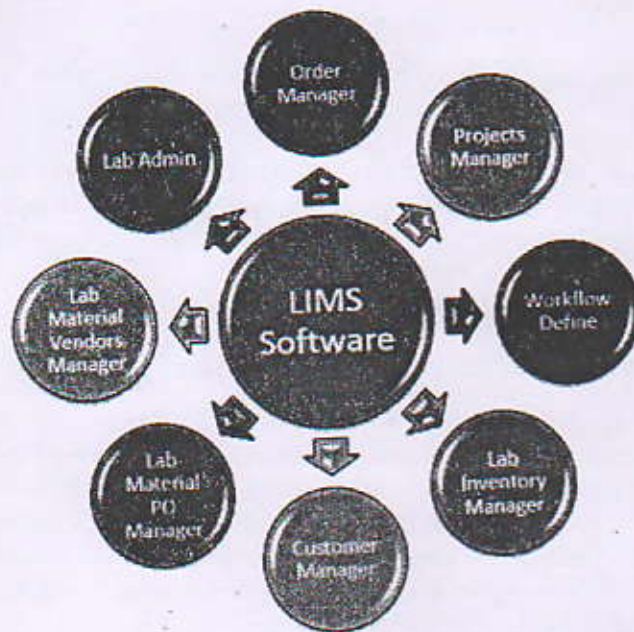
The importance of CDS can be judged from the fact that high-performance liquid chromatography (HPLC) and gas chromatography (GC) play an important role in pharmaceutical analysis. Research and development in Pharmaceutical companies is almost impossible without these two types of chromatography.

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 –

1. 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.
2. Instrument and Application Integration – An effective LIMS requires proper integration of instruments and applications. This ensures accurate and effective result generation.
3. 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. This task should be accomplished with utmost care and accuracy. LIMS provides real-time data exchange with Electronic Health Records used in hospital and clinical operations.
4. Report Generation – LIMS is also responsible for effective report generation. Reports are generated in the specified formats and scheduled time periods.
5. Inventory Management – LIMS ensures management of all laboratory equipment. It measures and records inventory of all vital supplies within a laboratory.



Thus, LIMS provides full application functionality through a web browser. This ensures generation of reliable and accurate results with high speed and low maintenance costs.

BENEFITS OF LIMS

- Fast reports
- Reduction in paper work
- Improved efficiency
- Improved data quality
- Reduced errors
- Avoids duplicacy
- Simple formulas for calculation
- Better integration with other departments

TEXT INFORMATION MANAGEMENT SYSTEM (TIMS)

Text Information Management System refers to collection and management of text information from one or more sources that can be shared with different users at the right time and right place. The information is entered, processed and stored in the computer and later on, can be used as per requirement. The information can be stored in any format like images, video sequences, audio messages, text message, numerical information etc.

For any successful organization, it is mandatory to be structured in a way that it can manage its information through various sources and formats and then deliver the same through varied channels like cell phones and web interfaces. Thus, the capability of an organization to capture, manage, preserve, store and deliver the right information to the right people at the right time is known as Text Information Management System.

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.