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Review Article

A REVIEW ON ELECTRONIC DATA MANAGEMENT IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

The Pharmaceutical industries are in a highly regulated environment, hence it requires effective document management processes. In addition to the strict regulatory environment, the Pharmaceutical companies must find ways of dealing with the increasing amount of information that must be processed. Having timely accurate data is critical for the success of any company. Data has never been easy to manage, and is especially true in pharmaceutical industry. Along with the documentation management, the security of data is also crucial. Note that electronic information includes everything such as emails, adverse event reports, complaints, batch records, quality control records – everything that is stored electronically. A document management system is designed to automate a business process. In its simplest form, this involves capturing of paper documents so that an end user can retrieve the image of paper document from their computer. Several technologies are being used currently in pharmaceutical industry to manage their huge volumes of data generated on daily basis. Some of the latest technologies are discussed in this review article along with their advantages and disadvantages.

Keywords: Document management, electronic records, Technology

INTRODUCTION

Data has never been easy to manage, and is especially true in pharmaceutical industry. Along with the documentation management, the security of data is also crucial. If you think that pharmaceutical companies are not at risk, think again. Assume the worst case when it comes to security and integrity of data. Data integrity is essential to regulatory compliance and the fundamental reason for 21 CFR Part 11. The FDA uses the acronym **ALCOA** to define its expectations of electronic data **[1].**

Attribute, **L**ong – lasting, **C**ontemporaneous, **O**riginal Accurate

According to 21 CFR Part 11(sub part 11.70) the electronic records and electronic signatures must control the electronic data record security, integrity, traceability and the proper use of electronic signatures **[2]**. Refer fig 1 for overview of document management.

A document management system consists of hardware and software that converts paper documents into electronic documents, manages and archives those electronic documents and then indexes and stores them according to company policy. Following are some of the technologies used in electronic data management in pharmaceutical industry.

DISCUSSION

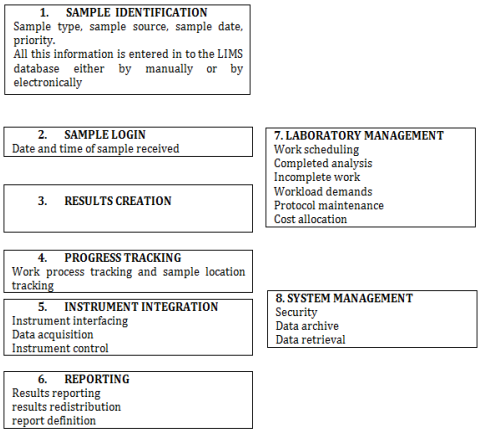
Laboratory information management systems LIMS [3, 4]

It is a software based laboratory and information management system that offers a set of key features that helps supporting modern laboratory's operations. Key features of LIMS include workflow, data tracking, data exchange interface, assay data management, data mining, data analysis, electronic laboratory notebook (ELN) integration etc. Though LIMS is commercially available since 20 years but now many changes have happened according to today's needs.

LIMS holds information about samples in a laboratory, but which information is stored varies a lot between different user organizations. Some laboratories only store information about end results of the analysis. Others utilize the complete LIMS where all instruments are connected to the LIMS, all data is transferred electronically between the instrument and the LIMS. Different industries have different needs for functionality.

- A **QC** laboratory in a production plant will need to include specifications to make sure the sample results are within specifications.
- A pharmaceutical **R&D** laboratory may need to include stability testing data and pharmacokinetic testing.

Refer fig 2 for functional model of IMS



Advantages of LIMS:

1. Makes ergonomical for individuals working in laboratory.
2. Reduction in ambiguity and improvement in consistency of laboratory practices with effective implementation and documenting the same.
3. Increase in productivity occurs when the system is properly integrated in to the daily routine of laboratory operations.
4. All the information can be stored and retrieved from the central database
5. Real time control of data with built in QC specifications

Disadvantages of LIMS:

1. Adequate validation to ensure data integrity
2. Limited interface between lab & field computers
3. Cost of LIMS

Electronic data capture (EDC) [4]:

It is a computer based system designed for collection of clinical data in electronic format. EDC has replaced the traditional paper – based data collection methodology and helps to streamline the data collection and reduction in time to market drugs and medical devises. EDC systems are now being adopted by many pharmaceutical companies and clinical research organizations where it is used for clinical trial data management. Users of EDC are Sites (a place where clinical trial is being conducted), Sponsor (A company/ person who funds the clinical trial), CRO (contract research organization which facilitates planning and conduct of clinicaltrial) etc. It is used in all phases of clinical trials to collect and manage the information. The alternative approach for data collection in clinical trial is Electronic data capture where the information is directly entered in to the software over an internet Connection which is more beneficial over the traditional paper based data collection. Refer fig 3 for EDC in clinical trial.

Figure 1: It shows Document management system

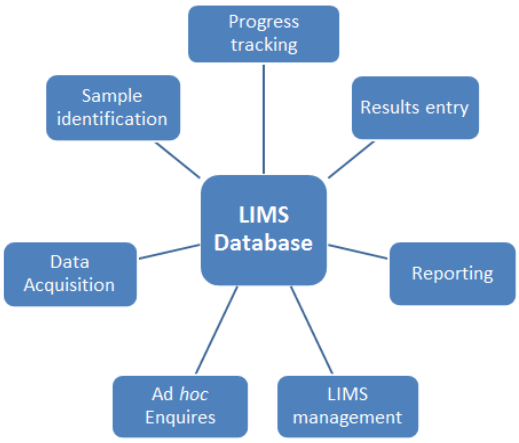


Figure 2: It shows Functional model of LIMS

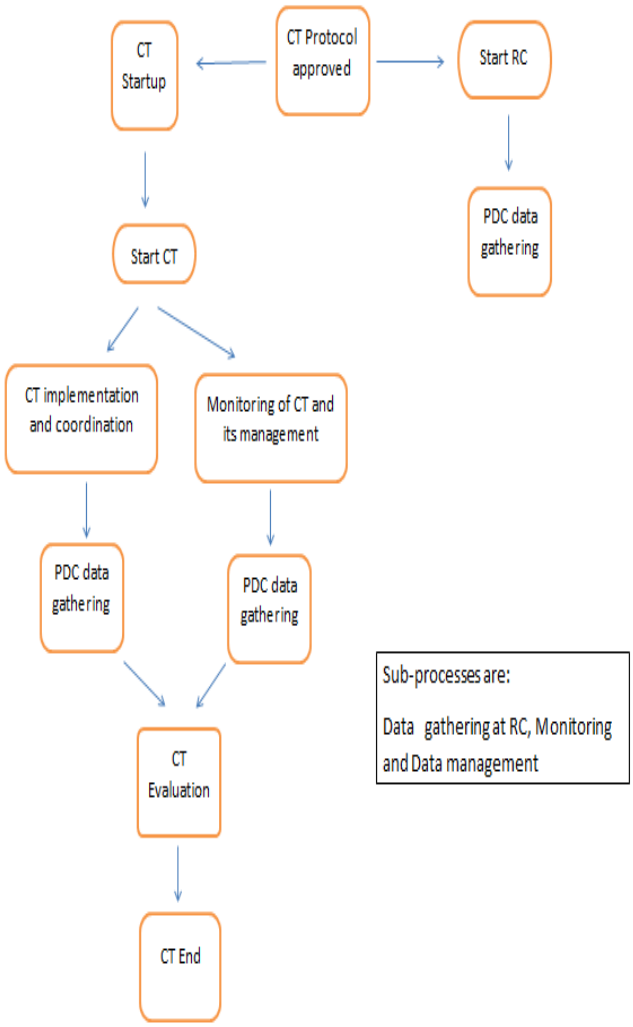


Figure 3: It shows PDC CT Management model. EDC model is the same as the presented PDC model, being different only in sub-processes. (CT — clinical trial, RC — research center)

Table 1: Sub-processes involved in PDC and EDC

Sub-processes involved	PDC	EDC
Data gathering at RC	Using paper case report forms	Using electronic case report forms
Monitoring	Monitoring of CT and review of case report forms is difficult in PDC	Monitoring of CT and review of electronic case report forms is easier in EDC
Data management	Reviewed case report forms are stored in central data base in digital format (digitalization is at the end)	Reviewed case report forms are stored in central data base and digitalization is from the beginning and is easy to store and retrieve the information.

Objectives for implementing an EDC system in clinical trial

1. Real time data access
2. Efficient data transfer and faster impact on marketing a drug
3. Overcoming the shipping of paper CRFs (case report forms) from remote areas
4. Synergy between the serious adverse effect reporting and the data base

Comparison between Paper Data Capture (PDC) and Electronic Data Capture (EDC):

Though EDC tools are available for many years more than two decades, however clinical trials are still conducted using PDC process, the reason being that the technological applications often did not have adequate functionality to improve the data collection

process as a whole and another reason is cost and maintenance of the Electronic systems.PDC CT Management model and EDC model both are same but only difference in sub-processes. As explained in the table 1 and followed by a fig 3 **[5-7].**

Advantages of EDC [8]

1. Faster data transfer
2. Instant data access by the staff
3. Reduced queries
4. Data can be categorized and indexing is possible
5. Decision point can be reached more quickly, this will save both time and money

Disadvantages of EDC

1. Installation of software in each PC which is costlier
2. Availability of Internet connections in remote areas where trial is being conducted
3. Data security is a major problem if public internet is being used
4. Regular validation of electronic devices
5. Regulatory compliance

Share point document management system [9]:

It is a web based application developed by Microsoft in 2001. Share point can be used to provide functions like document and file management, intranet portal, enterprise search, business intelligence and it has unique features like system integration, process integration, and work flow automation capabilities. This application is being used by 78% of fortune 500 companies. Pharma companies invest a lot in documentation and content management, and now they are intrigued by possibilities in share point system.

Using share point document management system one can create document libraries where you can store/ share variety of files. Team members can access these files using their login ID's and approved users can checkout and edit the files.

Applications of share point system

1. Intranet portal: It creates a centralized access to enterprise information within the organization. There by helps the company in employee management, process management. Refer fig 4 share point document system portal service.

Figure 4: It shows Share point document system portal service

2. Enterprise content and document management
   Keeping track of electronic records and images
   - Digital record management
   - Compliance with regulatory requirement in terms of document keeping
   - Centralized location for storing the documents
3. Collaboration system
   It provides a platform for exchange of data with any organization at any place in the world. Refer fig 5 for the share point document system.

Figure 5: It shows Share point document system

Enterprise content management [10]:

The Association for Information and Image Management (AIIM) international, worldwide association for enterprise content management, defined the term Enterprise content management in the year 2000.Enterprise Content Management (ECM) is a software application with collection of different tools like capture, manage, store, preserve, and deliver content and documents related to organizational processes. ECM covers web content management, search, work flow management, capture and scanning, and it primarily aims at managing the life cycle of information from initial publication or creation to archival and eventually disposal. Components of ECM:

a) Capture
b) Manage
c) Preserve and
d) Deliver

a) Capture

It contains the components for processing analogue and electronic information. Capture components are called as "input" components. Refer fig 6 for the components of data "Capture" in ECM.

OCR (Optical Character Recognition), HCR (Handprint Character Recognition), ICR (Intelligent Character Recognition), OMR (Optical Mark Recognition),

As explained in the fig 6, the captured information is recognized, processed, aggregated, indexed and categorized.

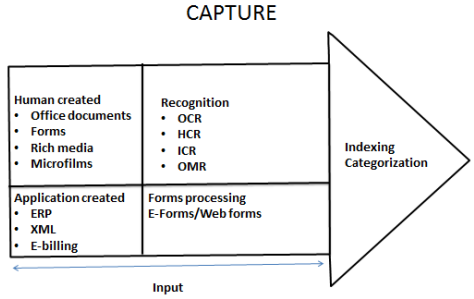


Figure 6: It shows Components of data "Capture" in ECM

Manually generate information includes office documents, emails, forms, videos, electronic office documents, microfilms etc. Automatic or semiautomatic generated data includes e-billing, XML codes, financial applications etc.

To process this information various recognition technologies are being used such as: OCR (Optical Character Recognition), HCR (Hand print character Recognition), ICR (Intelligent Character recognition), OMR (Optical Mark Recognition), and barcodes etc.

b) Manage

It includes Manage components, processing and retrieval of information. It has got Database for data administration and retrieval and access authorization systems to allow only genuine accessing. Refer figure no 07 for the components of "Manage" in ECM.As explained in the fig 7, "manage" has got the following components:

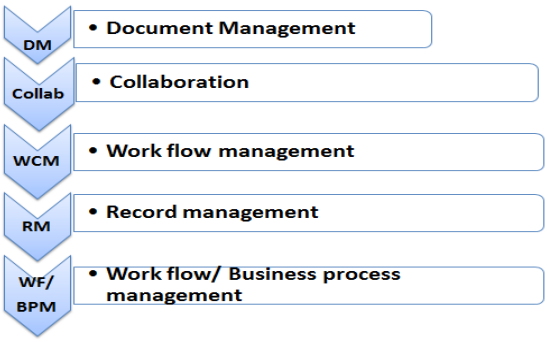


Figure 7: It shows components of "Manage" in ECM

1) Collaboration

Simply called as "working together", Collaboration includes the following functions:

- Database for joint information processing and Integration of information from other application. Communication application such as video conferencing is also possible with collaboration.

2) Web Content Management

- It createsnew content or edits the existing information in a controlled format and automatic conversion for various display formats.
- Secure separation of access to public and non-public information

3) Document management

It includes functions like

- Checking the stored information for consistency, version management, search and navigation and visualizing of different files of different formats.

4) Record management (file and archive management)

- Orderly storage of information, unambiguous indexing of information and management of record retention schedules and deletion schedules.

Business process management (BPM) / work flow:

Production Work flow (work flow is guided by predefined sequence)Work flow

Ad – Hoc Work flow (work flow is determined by the user)

Functions of work flow management include

- Imaging of process and organization structuresand sequential processing of procedures withsimultaneous saving.

Function of BPM includes

- Functionality of work flow
- Process and data monitoring
- EAI or Enterprise Application Integration, to link different applications

c) Store

It acts as temporary / long time storage of information. The components of store include Repositories (storage locations), Library services (administration components for repositories) and storage "Technologies".Refer fig 8 for the components of "Store" in ECM.

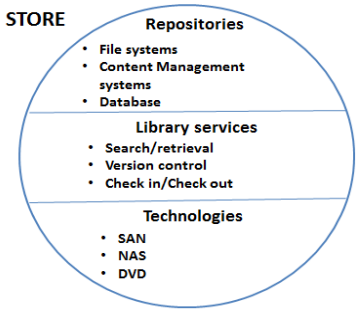


Figure 8: components of "Store" in ECM

Repositories

Different kinds of ECM repositories are used in combination. Some of the repositories are as follows:

- **File system**

File system is primarily used as temporary storage.

- **Content management**

This is the actual storage space for the content which could be a data base or a special storage system.

- **Databases**

This is a storage area for documents, content or media assets etc.

d) Preserve

The preserve components of ECM handle the safe storage and backup of information which is not necessary to archive. Refer fig 9 for the components of "Preserve" in ECM.

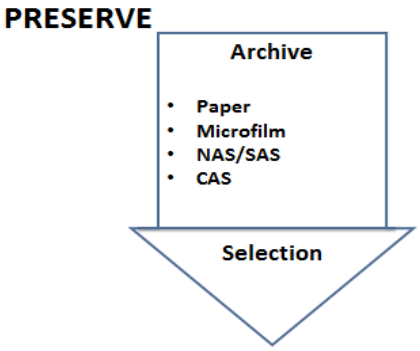


Figure 9: It shows Components of "Preserve" in ECM

e) Deliver

It helps in presenting the information from the other ECM components like "Manage", "Store", and"Preserve"components.

Share point system can be integrated with ECM for a better management system

Limitations of EMC [11,12]

1) Collaboration is not effective when compared to the SharePoint system
2) Managing rules are limitation to the document process it needs integration with better rules engine.

Some other systems like Enterprise Resource Planning (ERP), Ware House Management (WHP), Electronic notebooks, Content Management System (CMS), Library Information Control, and Enterprise Content Management (ECM) are some of the technology solutions available today for the electronic data management in the industry **[13].**

Impact of Electronic documentation on Pharmaceutical industries **[14-17]**:

Pharmaceutical companies come across lot challenges relating to document control from the preclinical stage to post market stage.

- Effective document management software provide an effective document control throughout the product development lifecycle by accelerating time to market and simplifying workflow, promoting efficiency, and makes the compliance easier.
- Collaboration helps in exchange ofviews with any organization or person throughout the world.
- Provide appropriate templates for regulatory submission making it easier for pharmaceutical companies
- Tracking facility of the electronic management system helps in keeping track of all sorts of documents.
- Usage of unapproved and obsolete documents can be prevented with document automation

CONCLUSION

According to a survey most of the companies spend 6% to 15% of its gross revenue in creating and management of documents. So, there is great need for effective document management and the solution is Electronic document management. Though some of the advantages are there for electronic document management like faster information circulation, stream line work flow etc. but it has got some of the limitations as well like ; computer system dependency, bureaucracy development, investment for software, regular validation of systems etc. on comparing all the pros and cons, the advantages overweigh disadvantages. And it is not possible to find another way for information management, without computer technology, without electronic document. But it is also necessary take into consideration all negatives and remembers about them.

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