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REVIEW OF PHARMACEUTICAL DOCUMENATATION SYSTEM

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Abstract: - The purpose of documents as a data source in qualitative research is examined in this article, which also explores document analysis procedures in the context of real-life research experiences. The paper, which is aimed at research beginners, presents a step-by-step method to document analysis. It discusses the nature and types of documents, as well as the Advantages and method of document analysis, and provides concrete instances of how documents might be used in the research process. A grounded theory study is used to demonstrate the use of document analysis. We may notice major trends in information systems that have an impact on their evolution, including the documentation. As a result, the approaches to systems from the perspectives of IT project management, roles, and resource allocation, as well as the relevance of documentation for the success of a development project, have changed. This research study covers the key concerns surrounding the current state of document management systems in the construction sector and suggests a research agenda.

Keywords: Quality Management System (QMS), Standard Operating Procedure (SOP), HIERARCHY, Records, Electronic Document Management System (EDMS), BMR, MFR.

INTODUCTION [1-4]:

The construction industry involves diverse and complex information that flows between the various participants, much of which is conveyed using documents. In common language, the word “document” generally means an information carrier (usually on paper) containing written or drawn information for a particular purpose and a document usually can be easily-transferred, stored and handled as a unit. Construction documents are significant to this industry, because they are the “things” that are actually shared by different project participants and are also gateways to the shared or non-shared project information sources. [1]

Recently, information availability has become more elaborate and widespread, and treatment decisions are based on a multitude of factors, including imaging, molecular or pathological markers, surgical results, and patient's preference. In the past, paper-based documentation was the standard, which has been partially digitalized over the years, often leading to parallel world of documentation in one institution. As disease management steps into the era of modern personalized medicine, including various quantitative data, information becomes a strong focus, thus involving the active contribution of multiple medical specialties. Established structures to gather all significant data are therefore of high importance for reaching the best clinical performance and enhancing interdisciplinary and clinical research. Ultimately, this leads to the improvement, adaptation, and redevelopment of health-care concepts. The documentation of information system is a component of communication, control and monitoring of the development, operation and maintenance project. [2]

Documentation should be regarded as one of the results of the stages of the system life cycle. This is why, the system documentation is important from the viewpoint of the project management and of its development and operation. Unfortunately, one can find that most often in practice the documentation is either incomplete or totally missing**.** [3]

Written mainly for research novices, the article describes the nature and forms of documents, outlines the strengths and weaknesses of document analysis, and offers specific examples of the use of documents in the research process. Suggestions for doing document analysis are included. The fundamental purpose of this article is to increase knowledge and understanding of document analysis as a qualitative research method with a view to promoting its effective use**.** [4]

DEFINING DOCUMENT ANALYSIS [4-9]

Document analysis is a systematic procedure for reviewing or evaluating documents—both printed and electronic (computer-based and Internet-transmitted) material. Like other analytical methods in qualitative research, document analysis requires that data be examined and interpreted in order to elicit meaning, gain understanding, and develop empirical knowledge. Documents contain text (words) and images that have been recorded without a researcher's intervention. For the purposes of this discussion, other mute or trace evidence, such as cultural artifacts, is not include refer to documents as 'social facts', which are produced, shared, and used in socially organized ways.

SPECIFIC USES OF DOCUMENTS

Documents can serve a variety of purposes as part of a research undertaking. Let us consider five specific functions of documentary material. First, as indicated above, document scan provide data on the context within which research participants operate—a case of text providing context, if one might turn a phrase. Bearing witness to past events, documents provide background information as well as historical insight.

Advantages:-

I. **Availability**: - Many documents are in the public domain, especially since the advent of the Internet, and are obtainable without the authors' permission. This makes document analysis an attractive option for qualitative researchers. As argued, locating public records is limited only by one's imagination and industriousness. An important maxim to keep in mind is that if a public event happened, some official record of it most likely exists.

II. **Cost-effectiveness**:- Document analysis is less costly than other research methods and is often the method of choice when the collection of new data is not feasible. The data (contained in documents) have already been gathered; what remains is for the content and quality of the documents to be evaluated.

III. **Lack of obtrusiveness and reactivity**: - Documents are 'unobtrusive' and 'non-reactive'—that is, they are unaffected by the research process. Therefore, document analysis counters the concerns related to reflexivity (or the lack of it) inherent in other qualitative research methods. With regard to observation, for instance, an event may proceed differently because it is being observed.

IV. **Reflexivity**—which requires an awareness of the researcher's contribution to the construction of meanings attached to social interactions and acknowledgment of the possibility of the investigator's influence on the research is usually not an issue in using documents for research purposes.

V. **Stability**: - As a corollary to being non-reactive, documents are stable. The investigator's presence does not alter what is being studied. Documents then are suitable for repeated reviews.

VI. **Exactness**: The inclusion of exact names, references, and details of events makes documents advantageous in the research process.

VII. **Coverage**: - Documents provide broad coverage they cover a long span of time, many events, and many settings.

VIII. **Insufficient detail**: - Documents are produced for some purpose other than research they are created independent of a research agenda. (Again, previous studies located in documents Glenn A. Bowen, 'Document Analysis as a Qualitative Research Method' consequently, they usually do not provide sufficient detail to answer a research question.

IX. **Low irretrievability**: - Documentation is sometimes not retrievable, or irretrievability is difficult. Has noted, access to documents may be deliberately blocked.

X. **Biased selectivity**:- An incomplete collection of documents suggests 'biased selectivity'. In an organizational context, the available documents are likely to be aligned with corporate policies and procedures and with the agenda of the organization's principals. However, they may also reflect the emphasis of the particular organizational unit that handles record-keeping (e.g., Human Resources).

TYPES [10]:-

There are various types of procedures that a GMP facility can follow. Given below is a list of the most common types of documents, along with a brief description of each**.**

1. Quality manual: A global company document that describes, in paragraph form, the regulations and/or parts of the regulations that the company is required to follow**.**

2. Policies: Documents that describe in general terms, and not with step-by-step instructions, how specific GMP aspects (such as security, documentation, health, and responsibilities) will be implemented

3. Standard operating procedures (SOPs): Step-by-step instructions for performing operational tasks or activities.

4. Batch records: These documents are typically used and completed by the manufacturing department. Batch records provide step-by-step instructions for production-related tasks and activities, besides including areas on the batch record itself for documenting such tasks.

5. Test methods: These documents are typically used and completed by the quality control (QC) department. Test methods provide step-by-step instructions for testing supplies, materials, products, and other production-related tasks and activities, e.g., environmental monitoring of the GMP facility. Test methods typically contain forms that have to be filled in at the end of the procedure; this is for documenting the testing and the results of the testing.

6. Specifications: That lists the requirements that a supply, material, or product must meet before being released for use or sale. The QC department will compare their test results to specifications to determine if they pass the test.

7. Logbooks: Bound collection of forms used to document activities. Typically, logbooks are used for documenting the operation, maintenance, and calibration of a piece of equipment. Logbooks are also used to record critical activities, e.g., monitoring of clean rooms, solution preparation, recording of deviation, change controls and its corrective action assignment released for use or sale**.**

QUALITY DOCUMENTATION HIERARCHY [11, 12]

The 4-tiered hierarchy has been established as a best practice for your quality Documentation System.

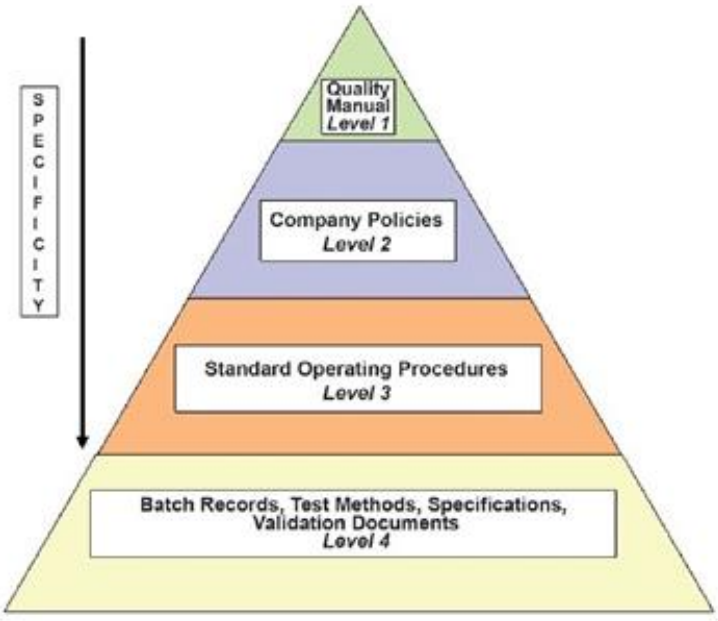

Fig 1:- Quality Documentation Hierarchy.

Quality manual:-

The top tier in the hierarchy is the Quality Manual. This is the guiding document that's authored and approved by upper management and it outlines the company's goals, mission and vision. It should outline what the company stands for and why they exist. It fully describes the scope of QMS that is what should be included in the Quality system. It completely explains each and every requirement of the ISO 9001 standard. It contains complete detail and explanation of exclusions that is what should be eliminated in the Quality system. It contains references for the quality procedures used to describe all the QMS process. The quality policy and the objectives can be part of the manual as well.

The quality manual should include most of the following elements:

- Title and table of content.
- Scope of the QMS.
- Exclusions from ISO 9001.
- Versioning info and approval.
- Quality Polity and objectives.
- QMS description.
- The business process model of the organization.
- Definition of responsibilities of all personnel.
- Reference to relevant documents and relevant appendices.
- It can be used for the following purposes. " To communicate management's expectations for quality to the organization.
- To reveal the organization conformity with ISO 9001 requirements.

- To serve as a measure for compliance to management's expectations for internal audits; ISO registrar audits; Customer audits.

Quality policy:-

A policy represents a declarative statement by an organization to Quality and continuous improvement. Usually, the Policy is used for promotional purposes and should be displayed in the organizations premises and posted on websites, so clear and shot Quality policy is convenient and is the general practice. The Quality policy defines the Quality objectives to which the organization strives. The Quality goals of organizations are defined by quantifying the Quality objectives. It should provide an outline for creating, stating and measuring your performance of the Quality objectives formatting Example: We will consistently provide products and services that meet or exceed the requirements and expectations of our customers. We will actively pursue ever improving quality through programs that enable each employee to do their job right the first time and every time.

• **Quality procedures: -** It can have different formats and structures. They can be narrative that it is described through text; they can be more structured using tables; they can be more illustrative in those flow charts; or they can be any combination of the above.

Quality procedures should include the following elements:-

- Title - for identification of the procedure.
- Purpose - describing the rationale behind the procedure;
- Scope - to explain what aspects will be covered in the procedure and which aspects will not be covered.
- Responsibilities and authorities of all people / functions included in any part of the procedures.
- Records the result from the activities described in the procedure should be defined and listed.
- Document control - identification of changes, date of review, approval and version of the document should be included in accordance with the established practice for document control.
- Description of activities - this is the main section of the procedure, it relates all the other elements of the procedure and describes what should be done, by whom and how, when and where. In some cases, “why” should be clarified as well. Additionally, the input and the outputs of the activities should be explained, including the needed resources.

• **Work instructions:-**It can be part of a procedure. Or they can be required in a Procedure. Generally, work instructions have a similar structure to the procedure; and cover the same elements; however, the work instructions include details of activities that need to be realized, focusing on the sequencing of the steps, tools and methods to be required and accuracy. Training of personal and use of competent personnel decreases the need for highly detailed work instructions.

Work Instructions may cover many of the following details:

- The manner in which the work will be done.
- The equipment and tools that will be used.
- The environment or location associated with the work
- Material handling requirements.
- Safety alerts for the employees.
- Across-reference to any other required processes or work instructions.
- The critical process parameters to be monitored and the instructions on how to monitor.
- Equipment maintenance procedures.
- Methods for verifying that the product meets specification.
- Other non-product related criteria for the final product.

Records: - This Final tier in the Quality Documentation System. All the data, information, records, forms, etc. are archived. Quality records are the objective evidence to prove that the Quality System is being executed per procedure. Quality Records also describe how the quality of the end product was verified to have met the specifications and then meet the customer's needs & expectations.

Records include the following sources:

- Non-Conformance Investigations.
- CAPA's *Audit Results
- Supplier Documentation
- Calibration Results

METHODS [2]

Published data on the subject of clinical documentation and management systems within the last decade were searched for in all NCBI databases with specific inclusion/exclusion criteria. The terms for search were "(data collection system OR electronic data capture OR documentation system OR data management system.

We explicitly did not include the term "Big Data" to characterize the developments solely on clinical documentation of the last decade. The search delivered 895 hits. Subsequently, the following inclusion criteria were applied to the references: English or German language, topic of research, and medical specialty. Based on these criteria, 34 articles not written in English or German language were excluded from the analysis. First, we reviewed the title and abstract of all articles. We looked at the topic of each paper and classified them in use or implementation of data management systems; comparison of new systems with a previous standard; or recommendations about system implementation and discussions about issues after system introduction. Documentation and data management systems are used in many medical and biological specialties. It was not always possible to clearly determine the classification of an article. Particularly, interdisciplinary research activities across multiple disciplines and reveal a clear overlap between multiple topics. We obtained the main discipline of each paper and listed all those containing at least 15 articles. Furthermore, many articles contained insufficient information in the abstract some even had none? In this case, we read the whole paper to determine the topic of research and grouped each paper in a medical or biological specialty. In the final step, we carefully examined all papers containing descriptions about system implementation to find post processing ideas and concepts. A Papers 3 library was used to collect and organize the references.

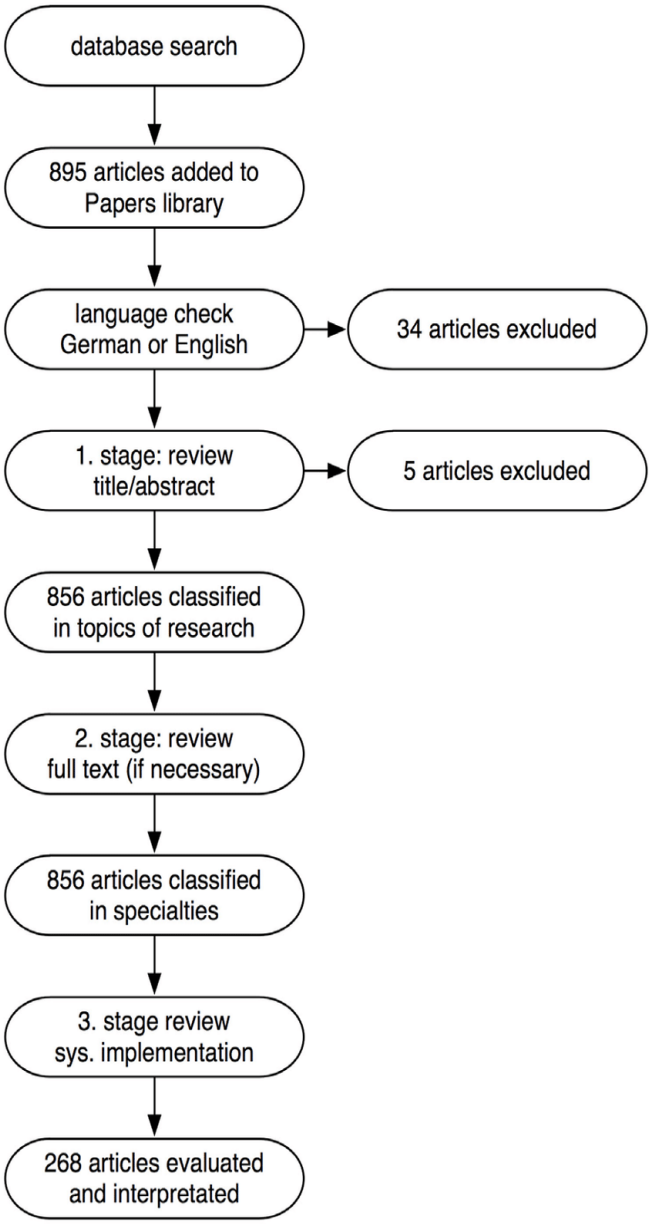

Fig 2:- illustrates the overall review methodology.

Stage 2 - System 469 For clinical trial or analysis 370 • For clinical routine 99 System implementation 268 System comparisons with paper-based standard or other systems 24 System review, recommendations, and issues 95 Not assigned 39 N = 895 |

Specialty No. of articles Biology 96 Chronic disease management 67 Emergency and critical care medicine 63 Epidemiology 24 Health technology and medical informatics 95 Neuroscience 17 Nursing 109 Oncology 41 Palliative medicine 19 Pediatrics 22 Pharmacy 19 Psychiatry and psychotherapy 27 Public health 37 Surgery 31 Teaching 17 Other 172 Not assigned 39 N = 895.

Stage 3 – this article with further process strategies and approaches of collected data. Reference Year Summary. Analysis tools connected to data management system for quantitative image analysis in metastatic lung cancer patients; automatic nodule detection and segmentation for CAD evaluation; communication standards used: DICOM. Analysis tools used on imaging files stored in database in lung cancer patients; manual image analysis; no communication standardization mentioned. Analysis tools connected to EDC system for automatic image and bio signal analysis communication standards used web services, ODM, SOAP, SFTP, HTTP Analysis tools connected to documentation database via SQL interface; semiautomatic CT image registration and segmentation of pancreatic cancer patients, as well as dose calculation of radiation plans; communication standards used: HL7, DICOM, Analysis tools used on local copies of neuro imaging data after query and download from the data management system; results are

transferred back via web services; communication standards used web services, SOAP, DICOM, https CAD, computer-aided diagnosis; DICOM, digital imaging and communications in medicine; EDC, electronic data capture; HL7, health level 7; SQL, structured query language; ODM, object data model; SOAP, simple object access protocol. Developments in Clinical Documentation Systems Frontiers in Oncology | Volume 6 | Article 75 RESULTS Classification of articles into medical specialty and topic of research can be found in Tables 1 and 2, respectively. System Implementation About one-third of all articles (n = 268) specifically discuss the development of a data collection system/database (as opposed to those referring to a system as a tool), and the results of implementing a data management system into the clinical environment. Most of the developed systems provide data utilization through query, analytic, export, and reporting tools. These report and export functionalities are used with regard to statistical analyses, for example, by importing the data into statistic software, such as SPSS, for further calculations. Table 3 summarizes the work of these five research groups.

CYCLE [3]

According to the stages of the system life cycle, we can identify:

1. The documentation of the system microanalysis, which contains a set of documents obtained during the initiation of the project or already existing, the most important ones being: the strategic plan of system development at the level of the organization, the request of system development, the pre-feasibility and the feasibility reports, the detailed plan of the initiated project, the calendar planning of the project, the managerial and communication plan and procedures, the plan of resources, the project preliminary budget;

2. The specifications or the analysis documentation, that formalize the results achieved at this stage. Its purpose is to communicate the results to the interested ones, also serving as a milestone for the following stages, first for the design stage. Therefore, a very precise description, even a mathematical one, is preferred in most cases, but we have to take into account the fact that the specification should be easily understandable by the system users as well, which means that usage to a natural language and to a series of images is more easily grasped and understood;

3. The design documentation, by which the way the system will be developed in order to meet the requirements, introduced in the analysis specifications. In the set of documents of this stage, the description or the model of all system inputs and outputs, of the processing processes, of the user-interfaces should be found. It is recommended to include any time possible examples of screens/forms for collecting data, control procedures or procedures related to the user's interaction with the system. Furthermore, the elements regarding the organization manner of the program and application modules, of the control and security procedures of applications and data, the database structure, the procedures distributed processing etc are presented. Many of the component parts of the design documentation are necessary to the specialists that will participate in the performance of the following stage, having a noticeable technical character, yet they are meant also for users, because they can show many of the system facilities and the way in which one can interact with it;

4. The documentation of implementation, which comprises the elements specific to the implementation planning, the comments on program code generation, the types of tests and the test results, the procedures of system conversion etc;

5. The instruction manual, describes the main elements regarding system operation, the way of interacting with it, the particularities of every application module, the help system, the way of resolving any error, the access levels of various categories of users etc;

6. The operation manual presents the system operation and maintenance conditions that lay at the basis of any intervention to eliminate any bug found during system testing, to add new items or to improve the existing ones.

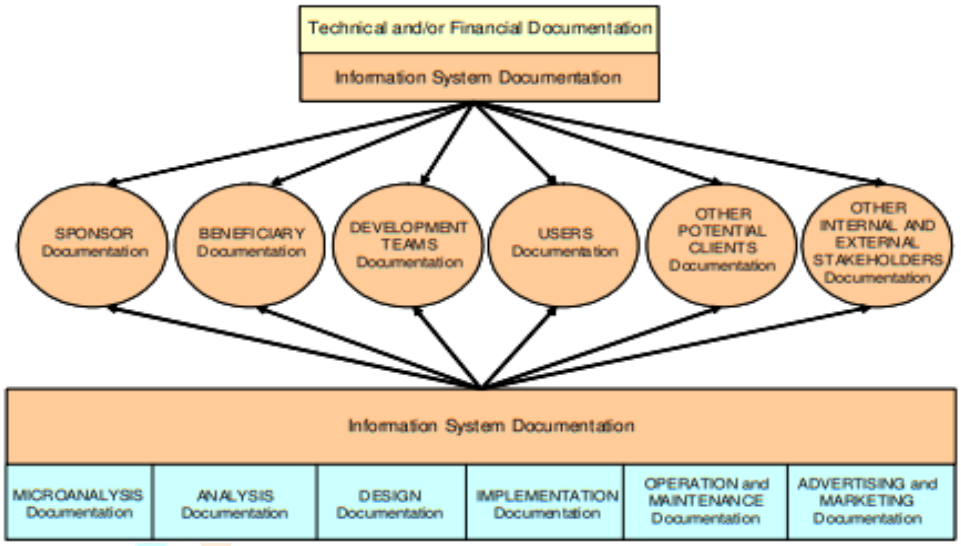

Fig 3:- Information System Documentation.

Records of raw materials, intermediates, labeling, and packaging materials Records should be maintained, including [12]:

- Records should be maintained, including:
- The name of the manufacturer; identity and quantity of each shipment of each batch of raw materials, intermediates, or labeling and packaging materials; the name of the supplier; the supplier's control number(s) if known) or other identification number; the number allocated on receipt; and the date of receipt.
- The results of any test or examination performed and the conclusions derived from this;
- Records tracing the use of materials;
- Documentation of the examination and review of labeling and packaging materials for conformity with established specifications;
- The final decision regarding rejected raw materials, intermediates, or labeling and packaging materials. Starting materials in the storage area should be appropriately labeled. Labels should bear at least the following information:
- The designated name of the product and the internal code reference, where applicable
- The batch number given by the supplier and, on receipt, the control or batch number (If any) given by the manufacturer; these must be documented so as to ensure traceability
- The status of the contents (e.g., on quarantine, on test, released, rejected, returned, recalled, etc.)
- Where appropriate, an expiry date or a date beyond which retesting is necessary Master (approved) labels should be maintained for comparison with issued labels.

Documents/SOPs required [12]

The following documents and procedures should be prepared to fulfill the above mentioned requirements. The data generated through these procedures should be maintained to show compliance with the above mentioned requirements.

- Prepare apex documents like Quality Policy, Quality Manual, Site Master File, Validation Master Plan, etc. to describe the quality commitments of the management.
- Define the roles and responsibilities of all personnel working in the organization.
- Prepare policy for periodic review of documents; Ensure that the current industrial practices and pharmacopoeial requirements are fulfilled by the current versions of documents.
- SOP for document (SOPs, MPCR, BPCR, validation/ qualification protocols, formats) preparation, review, approval, training, distribution, control, and its retention.
- Procedure for maintaining revision history.
- Management, control, and retention of superseded or obsolete documents.
- Document archival and retrieval procedure.
- Handling, archival, retrieval, and retention of electronic records/documents.
- Procedure for control of electronic signatures.
- Equipment cleaning and sanitation procedure.
- Issuance and control of equipment logs.
- Document describing measures taken for avoidance of cross-contamination and its training records.
- Cleaning validation master plan.
- Procedure for batch-to-batch and product-to-product cleaning and its verification to ensure removal of residue of previous batch/product.
- Records for incoming raw materials and packaging materials.
- SOP for preparation of process validation protocol and reports.
- SOP for preparation of master production control records.
- SOP for preparation of batch manufacturing and control records.
- SOP for allocation of batch number.
- Calibration master plan and calibration reports.
- Batch release procedure.
- SOP for preparation and control of QC data sheet.
- SOP for allocation of analytical control number.
- Procedure for review of analytical data.
- SOP for investigation of OOS results.
- SOP for change control, revision of any process or documents, or up gradation of facility or equipment should be routed through impact assessment and change control procedure.
- SOP for deviation handling system.
- SOP for corrective and preventive action (CAPA)
- SOP for stability testing.

THE DEVELOPMENT OF ELECTRONIC DOCUMENT MANAGEMENT SYSTEMS [13, 15, 16]

The Rise of Electronic Documents

Over the last decades, due to the development of information technology, the term “document” has undergone a radical change. This is due to the paradigm shift from paper based documents to electronic documents which has significant impact on the creation and the management of construction document. However, argued that construction documents have not undergone major changes since the middle of the 20th century with plan drawings, sections and elevations, bills of quantities, specifications and others look

much the same as decades earlier, although agreed that the technology for producing, managing, duplicating and distributing such documents has, nonetheless, undergone a number of fundamental changes. The development of construction document management methods can be dated from the past few decades, and is well summarized by Hjelt and Bjork.

1) The introduction of photocopying in the 1960s. This development spawned a great number of dedicated copying firms to handle large size documents typically needed in the construction industry. The cost for duplicating documents was significantly lowered.

2) The proliferation of personal computing and fax in the 1980's. The production of documents was greatly facilitated by word-processing and spreadsheet software and the fax became a popular data transfer method in a very short time during the 80's. The affordable applications like AUTOCAD started to raise the share of CAD-produced drawing documents towards the late 1980's. Fax was used very efficiently for handling small-scale graphics and quick changes, but it is not good for large drawings and useless for reusing the data at the receiving end.

(3) The development of computer networking (such as local area networks, modem dial-up) in the late 1980's and early 1990's. The network technique has made possible the use of document management systems for project documentation. From late 1990's, the widespread use of the Internet has radically enhanced the possibility of electronic document transfer. The maturity of CAD and other disciplinary-based software have made the production of electronic documents a daily practice for the construction industry.

Electronic Document Management Systems [1, 13, 14]

Electronic Document management systems (EDMS) focus on facilitating the management of documents pertinent to particular enterprises, projects and work groups in computer networks. EDMSs offer a level of control over information flow within the construction process, whether documents are in hard copy or in electronic format. In addition to the basic file management capabilities of operating systems, EDMS contains enhanced features related to the life-cycle and versioning of particular classes of documents divided the documentation managed by the various EDMSs into three main categories based on the different actors that produced the documents:

(1) Common general information, produced for the industry by material vendors;

(2) Company specific general information; and

(3) Project specific information. An EDMS makes it easier for users to complete their work and provides the company with security, reliability of data and work process management. Nevertheless, Bjork (2003) criticized early EDM systems as being often limited to usage within dedicated networks with user interfaces of their own and it was often very difficult to get the technical infrastructure in place. With the expansion of the Internet, almost all EDM systems are migrating to using the general Internet as their physical network, web servers as the storage medium and web browsers as the main platform for building user interfaces. Inevitably, the proliferation of Internet access has driven a number of professional information technology companies to develop commercial web-based systems for document management in the construction industry. This truly reflects a clear trend away from in-house solutions, typically provided by one of the main project participants such as the architect or the main contractor, towards outsourcing of document management to third parties known as Application Service Providers (ASP). So, at present not only the document management systems can be leased as ASP, the systems can also be sold as web-enabled software that is maintained then by the construction company itself.

BATCH MANUFACTURING RECORD (BMR)[12]

Definition:-

Batch manufacturing record is a written document of the batch, prepared during pharmaceutical manufacturing process. It contains actual data and step by step process for manufacturing each batch. Batch manufacturing record is like a proof that batches were properly made and checked by quality control personnel. Batch production records should be prepared for each intermediate and API/formulation and should include complete information relating to the production and control of each batch. The batch production record should be checked before issuance to assure that it is the correct version and a legible accurate reproduction of the appropriate master production instruction. If the batch production record is produced from a separate part of the master document, that document should include a reference to the current master production instruction being used. Before any processing begins, a check should be performed and recorded to ensure that the equipment and workstation are clear of previous products, documents, or materials not required for the planned process and that the equipment is clean and suitable for use. These records should be numbered with unique batch or identification number and dated and signed when issued. In continuous production, the product code together with the date and time can serve as the unique identifier until the final number is allocated. The batch number should be immediately recorded in a logbook or by electronic data processing system. The record should include date of allocation, product identity, and size of batch. Documentation of completion of each significant step in the batch production records (batch production and control records) should include:-

- Dates and, when appropriate, times.
- Identity of major equipment used (e. g, reactors, driers, mills, etc.)
- Specific identification of each batch, including weights, measures, and batch numbers
- Raw materials, intermediates, or by reprocessed materials used during manufacturing. Actual results recorded for critical process parameters.
- Any sampling performed.
- Signatures of the persons performing and directly supervising or checking each critical step in the operation.
- In-process and laboratory test results.
- Actual yield at appropriate phases or times.
- Description Of packaging and label
- Representative label (commercial supply).

- Any deviation noted, its evaluation, and investigation conducted (if appropriate) or reference to that investigation (if stored separately).

- Results of release testing

.• All analytical records relate to the batch that will permit their retrieval.

- A decision for the release or rejection of the batch, with the date and signature of the

- They are responsible for the decision.

- The production record review.

Production and quality control records should be reviewed as part of the approval process of batch release. Any divergence or failure of a batch to meet its specifications should be thoroughly investigated. The investigation should, if necessary, extend to other batches of the same product and other products that may have been associated with the specific failure or discrepancy. A written record of the investigation should be made and should include the conclusion and follow-up action;

The following information should be recorded at the time each action is taken (the date must be noted and the person responsible should be clearly identified by signature or electronic password):-

- The name of the product, the batch number and the quantity of product to be packed, as well as the quantity actually obtained and its reconciliation.
- The date(s) and time(s) of the packaging operations.

- The name of individual person is responsible for the packing operation.

- The checks made for identity and conformity with the packaging instructions, including the results of in-process control; whenever possible, the regular check for correctness of printing (e.g. batch number)

- Expiry date and other additional overprinting) and specimen samples collected. Detail information about any special person, including any deviation from the packing instruction, with written authorization by appropriate person.

- The quantities and reference number or identification of all printed packaging materials and bulk product issued, used, destroyed, or returned to stock and the quantities of product obtained; this is necessary to permit an adequate reconciliation
- Details of the packaging operations carried out, including references to equipment and the packaging lines used and, when necessary, instructions for keeping the product unpacked or a record of returning product that has not been packaged to the storage area.

- **MASTER FORMULA RECORD[12]**

Definition:

A document or set of documents specifying the starting material with their quantities and the packaging materials, together With a description of the procedure and precautions required to produce a specified quantity of a finished product as well as the processing instructions, including the in-process controls." Master production instructions should include:

Master production instructions should include:

The name of the intermediate/AP/ formulation being manufactured and an identifying document reference code, if applicable

A complete list of raw materials and intermediates (designated by names or code497sufficiently specific to identify any special quality characteristic)

Where the quantity is not fixed, the calculation for each batch size or rate of production should be included. Variations to quantities should be included wherever justified.

The production location and major production equipment to be used

- Detailed production instructions, including the:

- i. Sequences to be followed

ii. Ranges of process parameters to be used

iii. The methods, or reference to the methods, to be used for preparing the critical equipment (e.g., cleaning, assembling)

iv. Sampling instructions and in-process controls, with their acceptance criteria where appropriate

v. Time limits for completion of individual processing steps and/or the total process, Where appropriate.

vi. Expected yield ranges at appropriate phases of processing or time Where appropriate, special notations and precautions to be followed, or Cross.

Master Formula Record is also called MFR, Master Production Record. MFR is used as reference standard for preparing batch manufacturing record (BMR) by manufacturing units. It is prepared by the research and development team of the company. It contains all Information about the manufacturing process for the product. Master Formula Record (MFN) is a master document for any pharmaceutical product. MFR plays an important. There shall be Master Formula records relating to all manufacturing procedures for each product and batch size to be manufactured. These shall be prepared and endorsed by the competent technical staff i.e., head of production and quality control. A Master Formula Record is ether prepared based upon experience of impotent qualified staff like manufacturing chemist or analytical chemist or prepared based upon batch manufacturing record of a batch size.

MFR includes-

Product Details: - Name, logo and address of the manufacturing company

- Dosage form name. Brand name, Generic name
- Product code and Label claim of all ingredients
- Product description: Batch size, Pack size and packing style
- Shelf life and Storage conditions
- MFR number and date: Supersede MFR number and date
- Effective batch number
- Authorization by the production and quality assurance head
- Equipment: A list of all required equipment and machines required in the Manufacturing process with their capacity.

Steps in preparation of MFR:

Production Department in association with PD prepares MFR. It is divided into two sections

1) Manufacturing
2) Packaging

The first page of both the sections shall have following details: Name, address and logo of the company, Dosage form, Brand name Generic name Product code Label claim include all ingredients and text included in product permission. The secondary page of manufacturing section shall include-Processes to monitor. Subsequent pages shall include the processes to be monitored. The list of equipment machines, utensils to be used, shall be described. The subsequent page shall include any Special precautions to be taken for the product during manufacturing and packing. The same should also include Batch Manufacturing formula At the end of every important stage, include a statement of the yield with the acceptable Limits. In-process quality checks during and at the end of important steps and stages with their limits are included. The process shall include the equipment to be used. The methods or the reference of the methods/procedures to employed for preparing, cleaning assembling, operating the various equipments are given. Detailed stepwise processing instructions (example: checks on materials, pretreatments, sequence for adding materials, mixing times, temperatures, humidity etc.) is included. The requirements for storage conditions of the products are also present. The secondary page of packaging section of MFR should include complete list of all then

packaging materials required for a standard batch size including quantities sizes and types Include line clearance checking during batch cording and batch packaging operations.

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