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STUDY OF QUALITY ASSURENCE IS SPECIAL REFERENCE TO (BMR)

SHIVA SINGH[1*], ADITYA GUPTA[2], JAYANT KUMAR MAURYA[3],

1.Research Scholar, Ashok Singh Pharmacy College Maharoopur Jaunpur U.P. 222180

2.Assistant Professor, Department of Pharmacology Ashok Singh Pharmacy College Maharoopur Jaunpur U.P. 222180

3.Principal, Ashok Singh Pharmacy college Maharoopur Jaunpur U.P.

*Corresponding Author: **SHIVA SINGH**

Abstract:

This article examines the function of documents as a data source in qualitative research and discusses document analysis techniques in the context of actual research projects. The study provides a step-by-step strategy for document analysis and is intended for researchers who are just starting out. It covers the kinds and characteristics of documents, as well as the benefits and technique of document analysis. It also offers specific examples of how documents could be employed during the research process. The application of document analysis is demonstrated through a grounded theory research It is possible to observe significant patterns in information systems that influence their development, such as the documentation. As a result, there have been changes in the ways that systems are approached from the standpoints of IT project management, responsibilities, and resource allocation, as well as the importance of documentation for a development project's success. This research paper outlines the main issues with document management systems as they exist in the construction industry today and makes recommendations for future research.

keyword: Batch Manufacturing Record (BMR)

Introduction:

Because the pharmaceutical industry produces medications that people ultimately use, there must be a high standard of care and compliance at every stage of the production process. In the pharmaceutical industry, documentation is crucial and mandated by several regulations & guidelines, including US-FDA & GMP. The pharmaceutical industry uses many departments for different kinds of documentation, and one of the most crucial documents for the production area is the batch manufacturing record, or BMR. The written instructions that must be followed exactly

while creating a batch are called a batch manufacturing record, or BMR. Every action carried out throughout the manufacturing of a product batch is recorded in a written document known as a batch manufacturing record, or BMR. A written record called a batch manufacturing record, or BMR, details the history of a particular product batch.

Other Names Of BMR

Batch Manufacturing Record is also known as,

- (BPR) Batch Processing Record
- (BPR) Batch Production Record
- (BPCR) Batch Production & Control Record

Explanation

The BMR is issued and filled out in the manufacturing area before any batch of a product is manufactured. All of the information on the manufacturing process and the tools utilised is contained in BMR. BMR instructs operators and qualified individuals on which equipment to use and under what conditions to do a given task. Every task completed is both signed by the operator and cross-signed by the appropriate individual. To put it plainly, BMR captures the data of every activity in real time.

Issue of the Batch Manufacturing Record, or BMR:

The production department creates the manufacturing schedule, develops the request for the issue of the BMR, and forwards it to the QA department based on the planning projection. A master copy or master file of the BMR is kept by the quality assurance department, which prints the BMR after assigning a batch number. After obtaining the initials of the production employee assigned to BMR receiving, the QA department enters the product name and batch number in the BMR issuance register or file and transfers the batch manufacturing record to the production department. After reading over the BMR and Manufacturing, Expiration date, the Production Manager signs it. This Batch Production Record, or BMR, has been cross-signed by the QA manager and is prepared for use in the manufacturing process.

BMR Components

A batch manufacturing record, or BMR, is made up of various parts and falls into one of two primary types.

- Attachable Component
- Fixed Components

BMR's Fixed Components

The sections produced from the Master BMR that make up the Fixed Components of the Batch Manufacturing Record, or BMR, are as follows:

1.Personnel Deployment

2.Batch Information

3.Cleaning & Deployment

4.Sheet Equipment

5.Critical Instructions

6.Sheet Bill Of Material

7.Manufacturing Procedure

8.Batch Reconciliation

9.Yield Portion

10. Batch Information

1**. Batch Information**: The following crucial batch information is included on the first page of the BMR, or Manufacturing Record.

- Batch Number
- Product Name
- Batch Size
- Registration Number
- Expiry Date
- Manufacturing Date
- Brief Product Description Including,
- BMR Revision Number
- Dosage Form
- Dimension
- Shape
- Color
- Shelf Life
- Storage Condition

The Production Manager and QA Manager have signed the designated person signature space at the end of the first page.

1. Employee Deployment Chart

The page containing the names, dates, and signatures of every employee participated in the various tasks is located in the second section of the BMR. As an illustration Using the BMR of the tablet manufacturing batch as an example, we will list all of the persons and qualified staff members who were involved at different phases, such as granulation, compression, and coating, on the persons Deployment sheet. The personnel deployment sheet serves as a means of traceability for the duration of the product's shelf life. In the event that the market files a complaint, we can quickly identify the individuals responsible for that particular batch's manufacturing.

Sheet for Cleaning and Deployment of Equipment

The equipment deployment sheet, which comes next in the BMR, lists every piece of equipment that will be employed in the manufacturing of a batch along with its cleaning process document number.

1. Material Bill

The Bill of Material is the fourth section of the Batch Production Record, or BMR. Another name for bill of material is BOM. Let's talk about what the BOM is now. The BOM is the document that lists all of the excipients and active medicinal components together with their standard quantities. A designated code for a particular material is also indicated on the BOM, along with a space designated for the signature of a certified individual. The chemist confirms the quantity and code of each ingredient before signing the BOM sheet.

2. Essential Guidelines

Any guidelines for managing materials or equipment can be included in the BMR before to the commencement of manufacture.

1. Production Process

The manufacturing technique is the primary part of a batch manufacturing record, or BMR. This section of the BMR contains all the written instructions that must be followed during the manufacturing process. Written instructions, standard values, and parameters are provided in this section, and actual data is entered. Both the chemist and the operator sign each task completed. This section includes time ranges, such as blending and drying times, for which a certain task needs to be completed.

As an illustration

Using BMR as an example, the manufacturing process section of its manufacturing process includes written instructions for,

- Compression
- Granulation
- Coating

Granulation: BMR will provide detailed directions on how to make granules, using wet granulation as an example. Weighing and sieving will be the first phase, followed by dry mixing, kneading, and wet sieving. From wet sieving, there will be drying, dry sieving, and final blending. Additionally included in the granulation process is the following data,

- Mixing Time
- Sieve Number
- Chopper speed
- Kneading time
- Wet Mill Speed
- Impeller blade Speed
- Drying Temperature
- Drying Time
- Final blending Time
- LOD

Compression: All of the methods needed to compress a batch are provided in this section. It comprises the subsequent items:,

- Tablet Weight
- Tablet Dimension
- Tablet Hardness
- Punch Size
- Tablet Friability
- Tablet Thickness
- Weight Variation
- Disintegration Time

Coating: Detailed instructions on how to coat a batch will be included in the tablet coating production process. It consists of the subsequent items: Technique for Preparing Coating Suspensions

- Inlet Air Temperature
- Outlet air temperature
- Tablet Bed Temperature
- Spray rate
- Atomization air pressure
- Pan speed

1. Production and Accounting

Every significant stage, including drying, final blending, compression, and coating, has a yield calculation. When batch manufacturing is finished, the reconciliation is completed, and we compute and record the yield and line loss for each activity on a single page along with weight and numerical values.

Need a BMR

We Need BMR to full fill regulatory requirements & to check Product information like,

- Batch Number
- Batch Size
- Manufacturing Date
- Expiry Date
- Product Presentation
- We need BMR to check which steps are to be used for manufacturing a specific batch.
- BMR is also required to check which equipment is to be used.
- BMR is required to check batch recipes including names & quantities of excipients & APIs.

BMR is used to track the batch history after manufacturing. Following batch production, we receive information such as batch manufacturing records, which are crucial records that provide us the complete history of batch manufacturing. We are able to identify the individuals who worked on a certain batch's manufacture. It is possible to determine which machinery was employed in the production of a certain batch. We are able to locate the skilled

workers engaged in a certain batch's production. We are able to confirm the lot numbers and quantities of excipients that were utilized in a particular batch. We can confirm which batch of APIs was utilized in production. The actual or real-time data at which the batch was coated, filled, granulated, compressed, or filtered is provided by BMR. Additionally, BMR has quality control reports that we can use to track down the batch outcomes. Using the Batch Manufacturing Record as a Research Instrument Unfortunately, BMR & BPR (Batch Packaging Record) are used to follow a batch's history from dispensing to dispatch if it is the subject of an inquiry owing to a market complaint, such as the inclusion of foreign material in a unit of a particular batch. As we previously noted, BMR gathers all of its manufacturing data, making it simple to identify the lots, sources, and excipients or APIs. We can also use the BMR to review and confirm our QC test reports.

In summary

A batch manufacturing record, or BMR, is a crucial document that includes all of the batch's manufacturing history. As such, it is important to always include real-time and accurate data in the BMR at every stage and to avoid manipulating the data, as this could cause problems if an investigation into a batch is ever needed.

REFERENCE

1.Wang, Cynthia & Plume, Jim. (2012). A Review on Document and Information Management in the Construction Industry: from Paper-Based Documents to BIM-Based Approach.

2.Kessel KA, Combs SE. Review of developments in electronic, clinical data collection, and documentation systems over the last decade–are we ready for big data in routine health care?. Frontiers in oncology. 2016 Mar 30; 6:75.

3.Oprea D, Mesnita G. The Information Systems Documentation-Another Problem for Project Management. Inmanaging information in the digital economy: issues & solutions-proceeding of the 6th ibima conference, Khalid S. Soliman, ed 2006 (pp. 332-338).

4.Bowen GA. Document analysis as a qualitative research method. Qualitative research journal. 2009 Aug 3.

5.Goldstein, A. E. & Reiboldt, W. (2004). The multiple roles of low income, minority women in the family and community: A qualitative investigation. The Qualitative Report, 9(2), 241–265. Retrieved 5 January 2009, from http://www.nova.edu/ssss/QR/QR9-2/goldstein.pdf.

6.Hansen, R. E. (1995). Teacher socialization in technological education. Journal of Technology Education, 6(2), 34–45. Hodder, I. (2000).

7.Atkinson, P. A. & Coffey, A. (1997). Analysing documentary realities. In D. Silverman (Ed.), Qualitative research: Theory, method and practice, London: Sage, 45–62.

8.Atkinson, P. A. & Coffey, A. (2004). Analysing documentary realities. In D. Silverman (Ed.), Qualitative research: Theory, method and practice (2nd ed.), London: Sage, 56–75.

9.Yin, R. K. (1994). Case study research: Design and methods (2nd Ed.). Thousand Oaks, CA: Sage.

10. A Textbook of Pharmaceutical Quality assurance by Mr. Sanjay A. Nagdev, Mr. Mayur R. Bhurat, Dr. Md. Rageeb Md. Usman Dr. Krishna R. Gupta, Dr. Upendra B. Gandagule

11. Patel KT, Chotai NP. Documentation and records: harmonized GMP requirements. Journal of young pharmacists. 2011 Apr 1;3(2):138-50.

12. Documentation and Records: Website of GMP Online Consultancy Available from: http://www.gmp-online-consultancy.com/gmp/ Documentation-Records.htm Accessed: [Last cited on 2010 May 8.

13. Bjork, B.-C. (2003). "Electronic document management in construction - research issues and results." ITcon 8: 105-117.

14. Chassiakos, A. P. and S. P. Sakellaropoulos (2008). "A web-based system for managing construction information." Advances in Engineering Software, 39: 865-876.

15. Finch, E. F., Flanagan, R. et al. (1996). "Electronic document management in construction using auto-ID." Automation in Construction 5: 313-321.

16. Hjelt, M. and Bjork, B. C., (2006). "Experiecnes of EDM usage in construction projects." ITcon 11: 113-125.