World Journal of Pharmaceutical and Life Sciences
WJPLS
www.wjpls.org
SJIF Impact Factor: 6.129

A REVIEW ON CGMP

Dr. Osman Ahmed*[1], Ashraf Unnisa[1], Meher Afrin[1] and Mohammed Akthar Sulthana[1]

Department of Pharmaceutical Analysis, Deccan School of Pharmacy, Hyderabad, Telangana State, India.

***Corresponding Author: Dr. Osman Ahmed**
Department of Pharmaceutical Analysis, Deccan School of Pharmacy, Hyderabad, Telangana State, India.

Article Received on 13/09/2021 **Article Revised on 03/10/2021** **Article Accepted on 23/10/2021**

ABSTRACT

Good Production Practices (GMP) was coined to describe pharmaceutical manufacturing and packaging standards. The guide to GMP, often known as the Orange Guide, was published in 1971. US GMP rules were established in 1963 and have had a significant impact on how we understand GMP today. Good Manufacturing Practices (GMP) are based on the principles of protecting patient health while also manufacturing high-quality medicines, medical devices, or pharmaceutical actives. Over 100 nations, from Afghanistan to Zimbabwe, have adopted GMP since it was first formalised in the 1960s. For pharmaceutical goods, the Indian schedule M specifies GMP standards and the location, facility,and equipment needed to meet them. It is important to keep track of the following:. the Master Formula Records; the Packing Records; Batch Packaging Records; Standard Operating Procedures (SOPs) and records. The spaces, surfaces, and equipment used to make the goods must all be maintained clean at all times throughout the manufacturing process. Products must not be contaminated by dirt or the germs it harbours. Specific hygiene programmes tailored to the requirements of each industrial location should be developed.

KEYWORDS: Schedule M, Standard Operating Procedures (SOPs) and Good Production Practices (GMP).

INTRODUCTION

The phrase Good Production Practices (GMP) was coined to describe pharmaceutical manufacturing and packaging standards. The guide to GMP, often known as the Orange Guide, was developed by the Medicine Inspector of the Department of Health and Social Security of England in collaboration with other relevant organisations. Medicines Act-regulated drug production was originally documented in this handbook in 1971 when it was released in its first version. As a result of the inclusion of a 2-page addendum on sterile medical goods to the 1972 reissue third impression, the book was downsized to 20 pages. The Orange Guide got its name from the colour of its cover. In 1977, a revised and expanded version (with an additional five appendices) was released. Published in 19831, the third version has 110 pages and five appendices.

2007 saw a new version of the Orange Guide from the Medicines and Healthcare Products Regulatory Agency (MHRA). US GMP rules were established in 1963 and detailed the GMP procedures to be followed throughout completed pharmaceutical product manufacturing, packaging and storage in the US. The US FDA established GMP rules, which were published in 1978 as part of CFR Chapter 21 in the United States. The regulation's idea was similar to that of the Orange Guide, but unlike the UK guide, it was enforceable by law. The Federal Ani-tempering Act of 1983 was enacted by the US Congress and makes tampering with packaged consumer goods a criminal.

The US Food and Drug Administration (FDA) started issuing guidance papers in the 1980s, and they have had a significant impact on how we understand contemporary Good Manufacturing Practices (GMP) (cGMP). To help with the inspection of computerised systems in the drug manufacturing process, guidelines on general principles of process validation were issued in 1983 and 1987, respectively. 21 CFR Part 11 of the FDA's Food and Drug Administration Regulations was published in March 1997 and addressed the use of electronic records and signatures. Risk management was incorporated into device development by the US FDA in 2000, according to a guideline paper published at the time3.

Guidelines for Good Manufacturing Practices (GMPs)- Pharmaceutical and medical device firms in many countries are required by law to establish their own GMP standards that adhere to the country's specific laws. GMP standards are based on the basic principles of protecting patient health while also manufacturing high-quality medicines, medical devices, or pharmaceutical actives. 4. Over 100 nations, from Afghanistan to

Zimbabwe, have adopted GMP since it was first formalised in the 1960s. Here are a few instances of this.

Pharmaceutical Inspection Convention (PIC): Guide to GMP for pharmaceutical products - Australia, Austria, Belgium, Canada, Italy, Latvia, Liechtenstein, Denmark, Finland, France, Hungary, Ireland, Malaysia, The Netherlands, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Spain, Sweden, Switzerland and the United Kingdom. a. Pharmaceutical Inspection Convention (PIC):
General rules for Brunei Darussalam, Indonesia, Lao People's Democratic Republic, Malaysia, Cambodia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam are outlined in the Association of South-East Asian Nations (ASEAN).

Guide on Good Manufacturing Practices for Medicinal Products (GMP) for the European EconomicCommunity (EEC) All of these nations (and more) are represented in the European Union as well as the Commonwealth of Independent States (COI). Individual variances and interpretation are acceptable under GMP guidelines for achieving consistent product quality. As part of the 1938 Food, Drug, and Cosmetic Act (Section 501), the United States FDA enforces GMP. Guidelines are referred to as "current good manufacturing practises" in the rules (c GMP). There are five components to Good Manufacturing Practices (GMP).

As a result of GMP, the manufacturing process must be thoroughly specified before it can begin, as well as all of the required infrastructure. Staff must be properly educated in practise, appropriate facilities and equipment must be utilised, correct materials must be used, authorised processes must be followed, acceptable storage facilities must be provided, and appropriate transportation must be made available.

For pharmaceutical goods, the Indian schedule M specifies GMP standards and the location, facility, and equipment needed to meet them. Part I covers the fundamentals. Storage space, production space, and quality assurance space are all examples of this. Personnel, Support Areas, and so on Raw materials, equipment, documentation and records, labels and other printed materials, worker health, clothing and sanitation, manufacturing processes and controls, sanitation in the production premises ensuring high standards of performance, an audit of one's own performance and thequality of the work a method for ensuring product quality, Specification, It is important to keep track of the following: the Master Formula Records; the Packing Records; the Batch Packaging Records; the Batch Processing Records; the Standard Operating Procedures (SOPs) and records; the Reference samples; Reprocessing; and recoveries; the Distribution records; Validation and process validation; product recalls; complaints; and the Site-master file. Part I-A through Part I-E discusses the particular requirements for the production of various products, whereas Part I-F discusses the specific requirements for manufacturing facilities, equipment, and materials for active pharmaceutical ingredients (bulk drugs). Part II discusses the different dose forms and the corresponding plant and equipment requirements. WELL-MANAGED COMPANY

Patients are not put at risk by poor safety, quality or effectiveness when a manufacturer has a manufacturing licence. The holder of such authorization must make sure that medical goods are suitable for their intended use and conform with the marketing authorization criteria.

The achievement of this quality goal is the responsibility of top management and requires the involvement and dedication of employees from a wide range of departments and levels throughout the organisation, as well as from business partners and distributors.

7 To a large extent, quality management in the pharmaceutical industry is defined as the aspect of management function that determines and implements the "quality policy," i.e., the overall intention and direction of an organisation with regard to quality, as formally expressed and authorised by top management. 8.

QUALITY ASSURANCE

Critical steps of the manufacturing processes and significant changes to the process are validated;
• All necessary facilities for GMP are provided including appropriately qualified and trained personnel; b adequate premises and space; and •all necessary facilities for GMP are provided with a. appropriately qualified and trained personnel; c adequate premises and space

In addition, instructions and procedures are prepared in a clear and unambiguous instructional manner that is unique to the facilities offered; v- Operators are taught to follow processes properly; It is documented, manually or by recording devices, that all actions needed by the specified processes and instructions were in fact performed, as well as demonstrating that the product quantity and quality met expectations throughout manufacturing

9. There are systems in place to ensure that any significant deviations are fully recorded and investigated; vii. Records of manufacturing, including distribution, allow the complete history of a batch to be traced; viii. The distribution (wholesaling) of the products minimises any risk to their quality; ix. A system is available to recall any batch of product from sale or supply; x. Complaints about marketed products are examined, the causes of quality degradation are investigated.

Hygiene and sanitation
There should be a high standard of cleanliness and

hygiene maintained throughout the whole pharmaceutical product production process. Equipment and apparatus, manufacturing materials and containers and everything that may become a source of contamination for the product are all included in the scope of sanitation and hygiene. A thorough sanitation and hygiene programme should be implemented to remove potential contamination sources. 12

Those who enter industrial facilities must do so with safety gear tailored to their work.

It should be mandatory to follow personal hygiene procedures such as wearing protective clothing for anyone entering production areas, whether they are temporary or full-time employees or visitors to the company's property such as contractors' employees, visitors, and senior management and inspectors who are on company property.

Wearing clean body-coverings suitable to their tasks, including proper hair covering, will help safeguard the product from contamination while also ensuring the safety of the employees. Clothes that have been used should be kept in airtight containers until they can be thoroughly washed.

Specific hygiene programmes tailored to the requirements of each industrial location should be developed. Included in these processes should be health, hygiene, and uniform policies. Every individual whose responsibilities take him into the production or control areas should understand and strictly adhere to these processes. Management should encourage hygiene programmes and explain them extensively in training sessions.

Upon recruiting, all new employees should undergo a medical checkup. Instructions that ensure that the manufacturer is aware of health problems that may have an impact on product quality must be the manufacturer's responsibility. After the first medical checkup, routine medical and work-related health checks should be performed on a regular basis. Periodic eye exams should be required for visual inspectors as well.

The spaces, surfaces, and equipment used to make the goods must all be maintained clean at all times throughout the manufacturing process. Products must not be contaminated by dirt or the germs it harbours. Dirt has the ability to render disinfectants ineffective. Microorganisms may also be protected from disinfectants by dirt (especially oily or greasy coatings and protein-like substances). As a result, cleaning surfaces thoroughly is critical before disinfection. If there is a lot of dirt on the surface, it may be essential to scrape it all off first. After that, surfaces can be cleaned by scrubbing them with a cleaning agent and then letting them dry naturally.

Validation

As a result, validation is described as the act of gathering recorded proof that a planned procedure will provide the desired results on a regular basis. It is critical that validation studies support GMP and follow well specified processes. It's important to document your findings and conclusions. The first stage in implementing a new manufacturing recipe or preparation technique is to make sure it can be used in regular production. 14.

As a result, validation includes the qualification of systems and equipment. It's a requirement of the FDA's recommendations and other food-and-drug regulators. Since a broad range of methods, processes, and activities need to be verified, the area of validation is split into a number ofsubsections including the following:
Validation of Equipment, Buildings, HVAC Systems, Cleaning, and Process Validation Validation of analytical procedures, computer systems, and packaging

CONCLUSION

GMP is a quality-control and manufacturing process that helps in the production of a high-quality final product. Many countries have enacted laws mandating pharmaceutical companies to adhere to GMP standards, and these guidelines have been created in compliance with those regulations. The basic concepts behind all of these suggestions are similar in that they seek to safeguard the patient's health while also guaranteeing the production of high-quality medicines.

Quality goals can only be met by carefully developing and executing a QA system, as well as actually applying GMP. Adherence to Good Production Practices (GMP) necessitates a significant lot of attention and information about each component that must be incorporated at each step, from product conception through manufacturing.

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