Arrelic

Insights

10 PRINCIPLES OF GOOD MANUFACTURING PRACTICE (GMP)

Introduction

The Good Manufacturing Practice (GMP) regulation establishes the minimum standards for the manufacture of our products to assist in preventing adulteration but more importantly, Good Manufacturing Practice needs to be a lifestyle that each company clearly defines and implements through its quality system in order to protect the health and safety of its customers. Let's focus on how the 10 principles of Good Manufacturing Practice will help to make GMP a lifestyle in our plant.

10 Principles of Good Manufacturing Practice (GMP)

Principle No. 1 - Writing step by step operating procedures and work instructions that provide a roadmap for GMP compliance and controlled and consistent performance.
Principle No. 2 - Carefully following our written procedures and instructions to prevent contamination mix-ups and errors.
Principle No. 3 - Promptly and accurately documenting our work for compliance and traceability.
Principle No. 4 - Proving that our systems do what they are designed to do by validating our work.
Principle No. 5 - Integrating productivity product quality and employee safety into the design and construction of our facilities and equipment.
Principle No. 6 - Properly maintaining our facilities and equipment.
Principle No. 7 - Clearly defining developing and demonstrating job competence.
Principle No. 8 - Protecting our products against contamination by making cleanliness and hygiene a daily habit.

Principle No. 9 - Building quality into our products by systematically controlling our components and product related processes such as manufacturing packaging and labeling testing distribution and marketing and finally.
Principle No. 10 - Conducting planned and periodic audits for compliance and performance.

These 10 principles of Good Manufacturing Practice(GMP) provide us with a perfect framework for building and implementing a GMP lifestyle and evaluating how well we are living up to the standards of Good Manufacturing Practice (GMP).

In detail

Principle No. 1 & 2

The first two GMP principles 1 and 2 stress the importance of written procedures. The best way to comply with GMP is to have well-written procedures and to carefully follow them the heart of GMP is the establishment of well-written procedures for each operation. These written procedures give us the controls necessary to minimize the chance of mix ups and errors in manufacturing our products. When we carefully follow our written procedures we not only ensure compliance with the GMP regulation. But more importantly we ensure the consistent quality of our products.

Principle No. 3 & 4

The next two GMP principles 3 and 4 stress the need for us to document and validate our work because documentation and validation are so important to us and to our company. Let's look at

them more closely. We may begin by asking what does documentation really mean in terms of our job performance. Well, documentation requires a specific action on our part i.e., the recording of each significant step we perform as we complete a job task documentation should be made promptly and accurately and in accordance with our written procedures. As important as documentation is, it shows only that we have carefully and exactly followed our written procedures.

Validation is proactive proof that we can produce safe and effective products. Validation requires a series of tests to assure that our systems and processes do what we say they do. We must be sure our production processes consistently meet the specifications our company has established there for. Validation gives meaning to the documented records we keep it is validation which tells us that our written procedures are correct and that our products are truly safe and effective.

Principle No. 5 & 6

GMP principles 5 and 6 focus on the design construction and maintenance of our facilities and equipment. Let's take a look at how GMP relates to the place where we work and the equipment we use. Our key concern is to avoid the possibility of contamination mix-

-ups and errors in our workplace. For example we keep certain areas such as the cafeteria locker room and restrooms separated from the manufacturing area because it is necessary to protect the integrity of our products. We carefully control water air temperature and humidity housekeeping sanitation and maintenance also function to defend against contamination mix-ups and errors.

Principle No. 7

The 7th GMP principle states that good manufacturing practice requires competent people who can do the job right the first time and every time that means it's our personal responsibility to develop demonstrate and continuously improve our job competence. In order to do any job well, we must be properly trained and this is particularly true in the men factoring in quality-control areas. In fact our company must have a formal training program to assure that each employee can competently perform a sign job responsibilities.

Principle No. 8

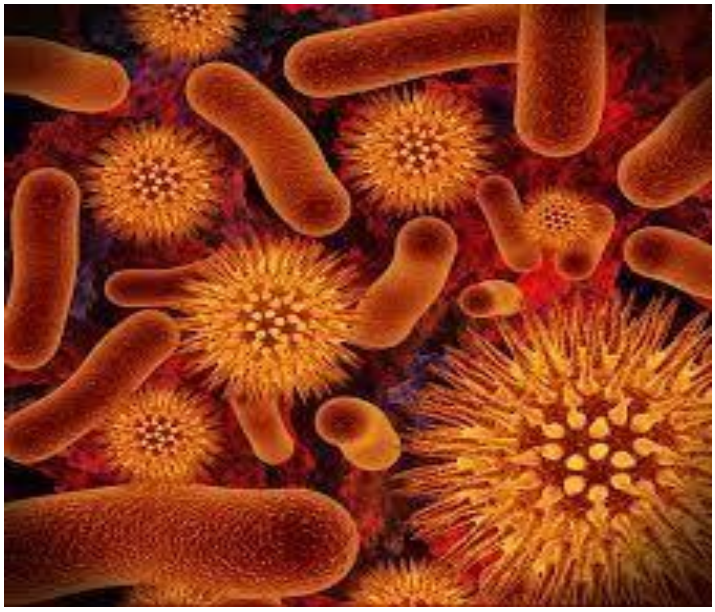
The 8th GMP principle focuses on cleanliness and requires us to be constantly on guard to defend our products against contamination. Contamination can be a powerful and dangerous enemy which takes on many different forms.

i. Particulate Contamination

One of the most common forms is Particulate Contamination. This simply means that a product has been made impure by any particle that doesn't belong in it. For example, dust dirt lint fibers and hair are all potential causes of particulate contamination. That's why, we must be properly dressed to prevent contamination when working with our materials, components and products.

ii. Particulate Contamination

The second form of contamination is Microbial Contamination. This is caused by microscopic organisms known as microbes. Microbes are living organisms that exist on everything in the environment that has not been sterilized and include organisms such as fungus mold bacteria and viruses.



iii. Cross- Contamination

A third form of contamination is Cross-Contamination. Cross-contamination occurs when traces of other materials components and products adulterate or miss-brand the products. we are currently manufacturing, packaging or testing. So, it's critical that we practice good personal hygiene and help keep our workplace clean by reporting any condition or practice in our plant or with our equipment that might be a potential source of particulate microbial or cross contamination.

Principle No. 9

The 9th GMP principle focuses our attention on the importance of building quality into our products by systematically controlling our components and product related processes. To see how GMP helps us build in quality, let's examine the critical areas where we must establish effective controls.

i. Materials and components present the first critical control challenge. We must be sure all of our components and materials satisfy our quality standards upon receipt. They must be carefully examined for damage and contamination. Properly identified and tagged and promptly stored in a quarantined area where required certain components and materials must be sampled and tested to ensure that they meet established standards of identity quality and purity. Only after approval are they released to manufacturing and used on a first in first out basis i.e., the first materials and components approved for release are the first to go to manufacturing.

ii. The second critical area we must control is the manufacturing process itself to assure quality and uniformity of each product. We have master records that outline the specifications and manufacturing procedures individual batch or history records to help us document our conformance to the master record. And written schedules and procedures for cleaning and maintaining our equipment to help us operate in a state of control. We carefully

follow written work instructions accurately collect critical data and promptly document manufacturing results.

iii. Packaging and Labeling is the third critical area where we control for quality. We must inspect the packaging and labeling area before each new lot or batch is processed to help us assure that the packaging equipment is clean and that the area does not contain any packaging or labeling materials from a previous run.

iv. The fourth critical area testing supports all other areas of control- how we handle incoming in process and finish product test samples, how we perform test methods and how we document test results are all significant elements of the testing process and must be performed by qualified individuals.

v. The final critical area of control focuses on how we assure the safety effectiveness and purity of our products as they enter the marketplace. The challenge to control for quality does not end when the finished product is tested and released. We must carefully control the product as we store it in the warehouse and distribute it to our customers. We must closely monitor the sales and marketing strategies we use to interact with our customers. And we must keep accurate records to provide product traceability and promptly respond to any customer problems concerns or complaints.

Principle No. 10

The 10th and final GMP principle entails the need to continually audit our day-to-day job performance and verify that we are in compliance with the Good Manufacturing Practice regulation.

In the pharmaceutical industry in India, CDSCO (Central Drugs Standard Control Organization) has a major responsibility to externally audit our manufacturing operations to see if we are in compliance with the current GMP regulations. But it's our company's responsibility to internally ensure the integrity of our products and most importantly it's our personal responsibility to evaluate how well we are living up to the standards of GMP. By performing a self -audit using the ten principles of Good Manufacturing Practice, you can help make GMP a daily lifestyle at our company and not just a regulation.

In addition to the responsibilities to our customers, the CDSCO also has a responsibility to protect the consumer. In fact, CDSCO can recommend a recall of a product if they find one of our products are contaminated, mislabeled or if our products are not manufactured in compliance with the current Good Manufacturing Practice regulation. So, it is extremely important that we carefully follow the ten principles of Good Manufacturing Practice at our company. We are all concerned about what we do and how we do it. This concern for quality helps us earn the trust of the millions of people who use our product. It's our job to make GMP a lifestyle and live the principles of GMP each and every day.

" We'll help manufacturing industries to improve plant productivity, reliability and minimize total production cost by eliminating machine downtime, lightening management decisions by analyzing the machine data with right mind and expertise; for a worry free operation."

If you have any questions or would like further information on our product and services or if you would like to discuss a potential initiative, you feel we could help with, please don't hesitate to contact us.

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