PHARMACEUTICAL INDUSTRY

Good Manufacturing Practices

What is GMP?

Good Manufacturing Practices, within the GAMP5 methodology, encompasses the guidelines associated with guidelines and documentation in order to achieve one goal, which is to ensure product quality and consumer safety to the highest standards.

By examining and covering all aspects of the manufacturing process and what revolves around it, is how we avoid risks that could be catastrophic for the products to be consumed. e.g: Adulteration, contamination, disproportionality... It is also important for the correct presentation of the product. e.g: Packaging, labelling, among others.

Therefore, it is important to have **a high-level SCADA system** to ensure optimal quality, because this system improves the efficiency and control of critical process parameters, saves time, sends alerts and corrective notifications in a timely manner, integrates with other monitoring systems, allows predictive and proactive maintenance, creates history reports with a large number of events, etc.

What is GMP?

Good manufacturing practices are divided into the 5P's:

People

Products

Procedures

Processes

Facilities

People

It is important to have clear roles and responsibilities. Compliance with regulations related to personal hygiene, sanitation and other contamination prevention guidelines is essential. This involves training for visitors and more meticulous training for company employees and those in the manufacturing area, also according to the functions of each job.

Products

Ensure the quality of the materials and inputs to be used in the transformation process. Both PM, semi-finished and finished products must undergo multiple quality evaluations with quantitative and qualitative values. This involves visual self-checks, verification of specifications through tests and measurements, verification of supplier sources, laboratory analysis, among others.

Procedures

The company must provide standard operating procedures, work instructions and specific task requirements in such a way that safety regulations are complied with. These should be documented. All critical processes must be covered, non-conformities must be recorded and analysed in order to find the root cause.

Processes

Clear, consistent and well-documented processes are essential for effective good practice, especially in critical parts. These documented processes should be accessible to all employees and regular assessments should be made to ensure compliance and alignment with the organisation's quality standards. Real-time control of process parameters is critical for compliance with the technical specifications of the product, and comprehensive monitoring of the production process is required.

Facilities

It is important to have a master sanitation plan and to carry out preventive maintenance and frequent inspections to guarantee the correct functioning of the equipment (validated and calibrated) and the infrastructure in general (designed to avoid contamination between areas and to facilitate cleaning).

The order and cleanliness of the facilities is a key requirement for success, avoiding contamination and accidents, among others.

If you want to know how we can help you to achieve these good practices, **contact us.**