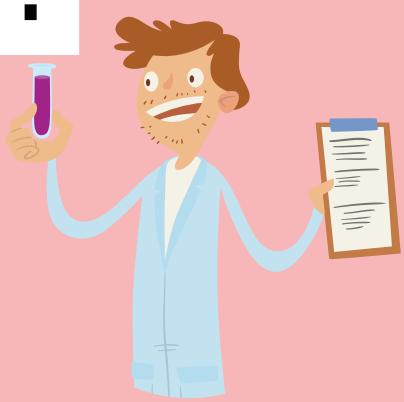
Labtopia SOLUTIONS

What is GMP PHILOSOPHY?

And How Can You Use It to Create The Perfect Lab?



GMP (Good Manufacturing Practice)

GMP regulations provide the standards to ensure efficacy and uniformity in production and quality. In any manufacturing activity, the product cycle resembles linear programming or process. It is comprised of inputs, processes, and outputs.

Ultimately, product manufacturing has to conform to regulatory and customer expectations. GMP supports these processes which are critical to production, laboratory, and the customer.

10 Principles of GMP

WOMEN OWNED

WRITE

Write step-by-step operating procedures and work instructions. It is critical that clear, concise and logical procedures are in place to ensure a controlled and consistent performance.

FOLLOW

Carefully follow written procedures to assure consistent quality. Even though taking shortcuts may save time or make the task easier and ideas for improvement are always encouraged, you should never deviate from a written procedure without the approval of a supervisor of the Quality Department.

DOCUMENT

Promptly and accurately document your work for compliance and traceability. Document work at the time it's being performed by entering complete information to assure record integrity. If it wasn't written down, it didn't happen. Sign or initial all entries to confirm your work.

VALIDATE

Validate the work. By validating your work, you are actively proving that your equipment and processes consistently do what they are supposed to do. Consistent performance is the key to maintaining the safety and effectiveness of every product and enhances a company's reputation for quality and reliability. In addition, new facilities and equipment, as well as significant changes to existing systems, require validation. Thus, all validation activities should be well-planned and clearly defined.

DEVELOP

Develop a good design for the facility and the equipment from the beginning. A logical and well-planned layout will improve productivity. Sometimes you need to step back and reconsider the whole production area rather than applying quick fix solutions. Aim to remove unnecessary traffic in the production area which could result in a hazardous environment, segregate materials, products and their components to minimize confusion and potential for mix-ups and errors.

MAINTAIN

Properly maintaining the facility and equipment. It is important to have a maintenance schedule for facilities and equipment to prevent breakdowns. It also reduces the risk of product contamination and maintains the “validated state” of the facility or equipment, e.g., make sure the calibration due dates are on schedule.

DEFINE

Clearly define, develop and demonstrate job competence. Training will be provided for all employees whose activities could affect the quality of the product. This includes basic training on the theory and practice of GMP as well as specific training relative to their role. Employees must demonstrate their job competence every day by producing quality products in a safe and efficient manner. Companies tend to hire people who know how to do the job right the first time and every time.

PROTECT

Protect our products against contamination by practicing good hygiene. The fight against contamination is a constant battle and is one that requires the attention of every single employee at all time. Always practice good personal hygiene by washing your hands and wearing the required protective garments. Inform your supervisor if you are ill. Minimize contact with product or product contact surfaces and equipment. Never eat, drink, smoke or chew in manufacturing areas. Always follow cleaning and sanitation procedures.

AUDIT

Auditing quality into the product. A basic and substantial philosophy of GMP is "not to test quality into the product but to build it into the product." That is why a pharmaceutical manufacturer has to focus on all items potentially influencing the quality of the final drug products, for example, personnel, buildings and equipment, starting and raw materials, processes, and in-process controls.

CONDUCT

Conduct planned and periodic audits. External bodies such as the Food and Drug Administration (FDA) will conduct these audits. But you should also conduct in-house audits, or self-inspections, to ensure GMP compliance.

Contact Labtopia for your Solutions Selection Process!

Labtopia Solutions provides full consulting support to organizations wishing to seek or maintain ISO-based quality systems, NELAC accredited quality systems, GMP quality systems. Labtopia's consulting services consist of partial or turn-key solutions for every aspect of the quality assurance system. We offer customized solutions based on the client's scope of work.

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