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INTERNATIONAL CERTIFICATION SERVICES

Good Manufacturing Practices (GMP)

Why do I need GMP?

Is GMP simply "Nice to have", or do manufacturers really need it? Production technology is to remove impurities original present in the product, but the aim of GMP is to ensure that no unnecessary. additional foreign materials are introduced during the process.

The need of good manufacturing practice are to control the changes in the food materials so as to develop the desired qualities in the product, to ensure that the food is safe to eat, and to stop or slow down any deterioration in the food.

Who Need it?

Good manufacturing practice needs throughout the food system, from primary production of the raw materials, through processing of the industrial ingredients, manufacturing of the consumer products, distribution of the final retail products, to the cooking and eating of the final foods.

GMP an overview?

GMP is promulgated by the US Food and Drug Administration under the authority of the "Federal Food, Drug, and Cosmetic Act". These regulations, which have the force of law, require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are safe, pure, and effective.

The GMP regulations

- § 21 CFR Parts 210 and 211 (Drug Industry)
- § 21 CFR Part 820 (Medical Device Industry)
- § 21 CFR Part 110 (Food Industry)

GMP is also sometimes referred to as "cGMP". The "c" stands for "current," reminding manufacturers that they must employ technologies and systems, which are up-to-date in order to comply with the regulation, Systems and equipment used by today's standards.

Good Manufacturing Practices are guidelines that provide a system of processes, procedures, and documentation to assure the product produced has the identity, strength, composition, quality, and purity that it is represented to possess.

The philosophy behind GMP is that there are controls in place that ensure the attainment of the stated quality targets. For a food processing operation the minimum controls required includes:

- § Personnel hygiene
- § Cleaning & sanitation
- § Waste management
- § Pest management
- § Management of foreign objects, chemical and micro-organisms
- § Planned maintenance

How to go about Certification for GMP?



Implementation strategy vary, but essentially there are four steps:

First, set standards of performance.

These include GMP regulations and other standards, which are necessary for your company. Then, train to those standards. All departments in the company should be trained (to varying degrees) on GMP and other standards.

The second step is to reinforce what was learned in training.

This falls on the managers and supervisors in a plant. Therefore, it is important that managers and supervisors be involved in training, so that they can support it through reinforcement.

The third stage is to audit to ensure that your efforts have provided adequate controls by auditing. Audits fall in the following three categories: personal, whereby every individual does a self-check to make sure that he/she is complying with all appropriate standards; internal audit, which should be performed by the quality assurance department as required by GMP, and external audits or you performing a supplier audit.

Finally, the results of audits will help you to know if you need to modify your standards of performance. Of course, no procedures should be changed without appropriate change control and approval from quality assurance.

The glue that sticks the whole process together is commitment. Commitment to GMP and quality is critical at all levels of the organization, starting with top management.

If you foster commitment, use this process, and attend GMP Institute workshops when necessary, we will help you make GMP a Lifestyle, Not Just a Regulation in your company.

You will then improve the overall performance of your workforce,

Benefits of Good manufacturing Systems: Certifying your organization against the requirements of GMP will bring the following benefits to your organization:

1. Commercial Credibility, Trust and Confidence

Increases the creditability and offers a competitive advantage in the marketplace for manufacturers. Increases senior management confidence in the preparedness of manufacturing facilities for any regulatory authorities & other stakeholders

Demonstrates independent third-party verification of continuing conformance to GMPs Increase in consumer confidence in your product.

2. Cost Savings

For budget & financial control purposes it may be beneficial to have a records of major expenditure & extra resources needed as well as the measurable benefits (e.g. reduced number of customer complaints, reduced breakdown time, reduced waste, reduced quantities of product that had to be reworked), improved cost and production control from the implemented GMP programme.

3. Legal Compliance

Decreases the time and cost for companies selecting third-party testing and product certification

4. Commitment

Demonstration of your commitment to producing and trading safe food. Enhancement of your food safety management system & Preparation for HACCP/Food safety certification

5. Operating Level Risk Management

Improved risk management - through greater consistency and traceability of product

6. Employees

Proper implementation of GMP is likely result in a change of culture which promotes a proactive approach to production & quality control. improved staff motivation & performance.

7. Continual Improvement

Understanding how statutory and regulatory requirements impact the organization and its customers and testing compliance through implementing GMP

Good manufacturing practice means understanding, analyzing and controlling the mfg. process. GMP lays the foundation for Quality & Food Safety Management system an improvement GMP is a good business tool which will help to refine both compliance & performance at your company. GMP requirements are largely common sense practices which will help your company better itself as it moves toward a quality approach using continuous improvement.

The question should not be "Do we need GMP?, but rather "Can we afford not to have it? We offer more value than any other certification Body

Are you looking for GMP?

Call for further information at:

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