GOOD MANUFACTURING PRACTICES (GMP)

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INTRODUCTION

Good Manufacturing Practices (GMP) are the practices required in order to conform to the guidelines recommended by agencies that control authorization and licensing for manufacture and sale of food, drug products and active pharmaceutical products. These guidelines provide minimum requirements that a pharmaceutical or a food product manufacturer must meet to assure that the products are of high quality and do not pose any risk to the consumer or public. Good manufacturing practices along with good agricultural practices, good laboratory practices and good clinical practices are overseen by regulatory agencies in the United States, Canada, Europe, China, India and other countries. Good Manufacturing Practice guidelines provide guidance for manufacturing, testing and quality assurance in order to ensure that a food or drug product is safe for human consumption. Many countries have legislated that food, pharmaceutical and medical device manufacturers follow GMP procedures and create their own GMP guidelines that correspond with their legislation. All guidelines follow a few basic principles. Manufacturing facilities must maintain a clean and hygienic manufacturing area controlled environmental conditions in order to prevent cross-contamination of food or drug product from adulterants that may render the product unsafe for human consumption.

THE PROCESSES

Manufacturing processes are clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications. Manufacturing processes are controlled and any changes to the process are evaluated. Changes that affect the quality of the drug are validated as necessary instructions and procedures are written in clear and unambiguous language and in good documentation. Practice operators are trained to carry out and document procedures. Cross contamination with unlabeled major allergens is prevented. Records are made manually or by instruments during manufacture. These records demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the food or drug was as expected. Deviations are investigated and documented. Records of manufacture including distribution that enable the complete history of a batch to be traced are retained in a comprehensible and accessible form. The distribution of the food or drugs minimizes any risk to their quality. A system is available for recalling any batch from sale or supply. Complaints about marketed products are examined. The causes of quality defects are investigated and appropriate measures are taken with respect to the defective products. To prevent recurrence, practices are recommended with the goal of safeguarding the health of consumers and patients as well as producing good quality food medicine. Medical devices or active pharmaceutical products in the United States, a food or a drug may be deemed adulterated if it has passed all o

THE PROCESSES

of the specifications tests but is found to be manufactured in a facility or condition which violates or does not comply with current good manufacturing guideline. Therefore, complying with GMP is mandatory in all pharmaceutical manufacturing. And most food processing GMP guidelines are not just prescriptive instructions on how to manufacture products but they are a series of general principles that must be observed during manufacturing where the company is setting up its quality program and manufacturing process. There may be many ways it can fulfil GMP requirements. It is the company's responsibility to determine the most effective and efficient quality process. The quality is built into the product and GMP is the most essential part of ensuring this product quality. GMPs in forests in the United States by the US Food and Drug Administration FDA under title 21 CFR.

WORLDWIDE

The regulations use the phrase 'Current Good Manufacturing Practices (cGMP)'. According to the GMP guidelines, courts may theoretically hold that a product is adulterated even if there is no specific regulatory requirement that was violated, as long as the process was not performed according to industry standards. Since June 2010, a different set of cGMP requirements have applied to all manufacturers of dietary supplements. The World Health Organization (WHO) version of GMP is used by pharmaceutical regulators and the pharmaceutical industry in over

WORLDWIDE

100 countries worldwide. Primarily, in the developing world, the European Union's GMP i.e., EU-GMP enforces similar requirements to WHO-GMP as does the FDA's version in the US. Similar GMP s are used in other countries with Australia, Canada, Japan, Saudi Arabia, Singapore, Philippines, Vietnam and others having highly developed sophisticated GMP requirements.

In the United Kingdom, the medicines act 1968 covers most aspects of GMP. It is commonly referred to as the orange guide and is named so because of the color of its cover. It is officially known as Rules and Guidance for Pharmaceutical Manufacturers and Distributors since the 1999 publication of GMP s for active pharmaceutical ingredients by the International Conference on harmonization itch GMPs now apply in those countries and trade groupings that are signatories to it the EU Japan and the US and applies in other countries for example Australia Canada Singapore which had dropped its guidelines for the manufacture and testing of active raw materials. GMP is a part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards, appropriate to their intended use and as required by marketing authorization or product specification within the European Union.

REGULATORIES

GMP inspections are performed by national regulatory agencies. For example, GMP inspections are performed in the United Kingdom by the Medicines and Healthcare Products Regulatory Agency, whereas in the Republic of Korea i.e., South Korea by The Ministry of Food and Drug Safety, in Australia by the Therapeutic Goods Administration, in India by Central Drugs Standard Control Organization (CDSCO), in Bangladesh by the Director-general of Drug Administration, in South Africa by the medicines Control Council MCC, in Brazil by the National Health surveillance agency and by CDSCO in India .GMP inspections are carried out by state Food and Drugs administration's FDA and these FDA report to the Central Drug Standard Control Organization, in Pakistan by the Drug Regulatory Authority of Pakistan, in Nigeria by NAVTEQ and by similar national organizations worldwide. Each of the inspectors carry out routine GMP inspections to ensure that drug products are produced safely and correctly. Additionally many countries perform pre-approval inspections i.e., for GMP compliance prior to the approval of a new drug for marketing.

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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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