

STANDARD OPERATING PROCEDURE

created by: matthew martin 05-01-18 approved by: qa department head erik koepke on 05/23/16

New Team Member Training Item #1

WHO OWNS HEALTHY SOLUTIONS?

Healthy Solutions is a partnership consisting of active partners, who work the business and inactive partners, who have invested in the business. Each of the active partners brings a unique set of skills and expertise to the business. As such, each partner is responsible for different departments within the business. Lon Beatty and Matt Martin are the active partners. See the Organizational Chart (later in the training) for details related to the role of each active partner.

IS HEALTHY SOLUTIONS REGULATED BY THE FEDERAL GOVERNMENT?

Healthy Solutions is registered and regulated by the Food & Drug Administration (FDA). The Food & Drug Administration (FDA) is the part of the federal government responsible for protecting the public from products which may cause them harm. One of the ways that the FDA works to accomplish their goal is by establishing and enforcing manufacturing standards designed to ensure the purity and safety of the products produced. Healthy Solutions is required by law to comply with these standards.

WHAT ARE CGMP'S?

The letters cGMP stand for Current Good Manufacturing Practices. The FDA created a list of Current Good Manufacturing Practices to define the regulations, policies and procedures it deems necessary to manufacture safe products. For example: One FDA cGMP requires that manufacturing facilities have a regular pest control program which prevent insects, rodents etc. from entering the manufacturing areas and contaminating products.

WHAT IS A STANDARD OPERATING PROCEDURE (SOP)?

Another example of an FDA cGMP is the requirement that Healthy Solutions create maintain and adhere to written procedures/instructions for all activities that take place within the facility. These written procedures / instructions are called Standard Operating Procedures or SOP's. The purpose of a standard operating procedure is to standardize the performance of a procedure so that all employees perform the procedure in the same way. It is important that you follow all Standard Operating Procedures (SOP's) in order for us to comply with FDA regulations.

FDA CGMP INSPECTIONS:

The Food & Drug Administration (FDA) perform unannounced inspections to determine whether or not we are compliant with the current good manufacturing practices. As an employee of Healthy Solutions, you are expected to act as though every day is inspection day.

WHAT IS CGMP CERTIFICATION?

The FDA has limited resources and is not able to regularly inspect our facility. Healthy Solutions is dedicated to operating in compliance with all FDA cGMP's. One of the ways that we do this is by hiring a company called the NSF to perform regular inspections. NSF inspectors review our standard operating procedures and compare them against the Food & Drug Administrations' list of current good manufacturing practices. Also, the NSF compares our standard operating procedures against what they observe employees doing. Therefore, it is important to always follow the standard operating procedure. Upon finding that we are in compliance, the NSF provides Healthy Solutions with a cGMP certification.

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CARE FOR THE CONSUMER

As an employee of Healthy Solutions, you are expected to put the health and well-being of the consumer above all else. Failure to perform activities as described by a standard operating procedure (SOP) may result in product contamination. Consumption or use of a contaminated product may cause sickness and/or death. Always be asking yourself this question: "Would I give this product to my child, wife, grandmother or other loved ones with confidence that proper procedures were followed?" If at any time the answer is No, you should stop whatever you are doing and alert Quality Control. It is your moral duty to report any event, large or small, which may contaminate and /or otherwise negatively affect the quality of the product we are making.

ORGANIZATIONAL INTEGRITY:

In order to operate efficiently and effectively, each employee must communicate in accordance with the organizational chart. A copy of the organizational chart is provided and will be discussed in detail later in your training. Refer to the organizational chart regularly to be sure you are directing questions, concerns to the appropriate individual or department. You will be held accountable for performing the wrong action because you received information from the wrong individual or department. For example, you notice that the color of the product to be bottled is a bit different from the last time it was made. This is a product quality issue and only quality control can provide you with the ok to proceed with bottling. Receiving authorization to begin bottling from your shift manager or production and packaging department manager is not sufficient. If you have questions about who to address, speak with quality control first or ask a Healthy Solutions Partner.

RECORDATION AND DOCUMENTATION:

As an employee of Healthy Solutions, you are required to document/record your activities whether those activities are right or wrong. Any employee falsifying documentation shall be terminated immediately.

ATTENDANCE, ATTITUDE & WORK ETHIC:

Employees are expected to be on time and ready to work at the start of their shift. Manufacturing is a team effort. As part of our team you must maintain a positive attitude and extraordinary work ethic.

FACILITY TASK MANAGEMENT SYSTEM:

The facility task management system is used by Healthy Solutions ownership and management to centralize, assign & record completion of various tasks. The tasks contained within this system are important to the efficient, safe and cGMP compliant operation of the facility. All employees are expected to participate in completing tasks assigned to their department. Accessing the task list is simple. Using the computer in MFG 6 double click on the "Production" Icon. Select A, enter your badge# and complete the task by following the on screen instructions. Healthy Solutions ownership and management review the task list weekly. We can see who completed tasks and who did not. The number of tasks you complete will be a factor in determining your overall performance and pay.

WHAT DO I DO DURING DOWNTIME?

If there is downtime on the manufacturing line, find something to do. Log in to the task system. Clean, sweep, mop, organize etc... At no time should an employee be seen standing around waiting for something to do. Ask your supervisor for direction.