

(Company Confidential)

## Good Manufacturing Practices (GMPs)

This brochure is provided to you as an employee of (company confidential) so that you are introduced to the quality system requirements the Food and Drug Administration (FDA) prescribes for the medical device industry, called Good Manufacturing Practices (GMPs).

These requirements have the force and effect of law. Please read this material carefully and discuss any questions you have with your manager.

### What are GMPs?

In 1976, the United States Congress added the medical device amendments to the Federal Food, Drug, and Cosmetic Act. Congress also authorized the FDA to establish and enforce GMP regulations.

The requirements are directed toward quality assurance and govern how manufacturers **design, manufacture, package, label, store, install, and service** devices intended for human use.

The GMP regulation is available for anyone to read in the Code of Federal Regulations (Part 820 of Title 21). The information is also posted for the public on the FDA web site (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1>).

### Why are GMPs important?

GMPs are viewed as an essential tool in public safety. They require manufacturers to plan and implement business practices to ensure medical devices meet specifications, and the public is not harmed due to unanticipated events.

Quality assurance requirements, like those in GMPs, are not peculiar to the United States. Many other countries have similar requirements for medical products. In addition, businesses across all industries can choose to adopt voluntary standards that are like GMPs, such as ISO 9000.

### GMPs and the (company confidential) Quality System

GMP requirements are specific in what a manufacturer has to accomplish in business practice. However, the manufacturer decides *how* the requirements are met.

Part of demonstrating how the requirements are met is through the development of written documentation.

**Procedures** are written to reflect *who* does *what*, and *when*. They demonstrate that the manufacturer plans and controls the processes affecting product quality. Additionally, procedures are an important way of communicating job responsibilities to employees.

**Records** are the result of following procedures, and are evidence that important work activities take place. Completed forms, correspondence with customers and vendors, and statements of business transaction are examples of records that must be maintained so that the quality system can be effectively reviewed.

Manufacturers are also required to provide the entire business organization with goals related to quality. These are documented and communicated as the **Quality Policy** and quality objectives.

### Quality Policy

(company confidential) will provide safe and effective medical products to our customers.

### Who is responsible for GMP requirements?

All employees of medical device manufacturers are responsible for ensuring that GMP requirements are met.

FDA regulations are unique in that they apply not only to businesses, but also to individual employees. If you are employed in the medical device industry, you are personally accountable to the FDA.

The good news is that the majority of GMP requirements can be met by simply exercising good work habits. Being aware of your procedures, producing legible records, and keeping an organized and clean work environment are all key elements.

### GMPs and Compliance

People who are internal and external to (company confidential) will perform periodic checks to ensure that requirements are being met.

These checks, called **audits**, may be performed by an Alpha Industries employee, a vendor, a consulting firm, or by FDA.

Audits help to ensure that companies continue to meet requirements and identify areas where they can improve. Deficiencies and improvements are made through a **corrective and preventive action** procedure.

Corrective and preventive action isn't only the result of audits, however. Employees should be diligent in reporting problems or potential problems that may affect product quality.

### The Ultimate Goal: Consumer Safety

In addition to performing regular audits of manufacturers, the FDA monitors public safety through **Medical Device Reporting**.

Reports come to the FDA on a voluntary basis from health care professionals and patients who have first hand knowledge of a device malfunction or adverse patient event.

Manufacturers are required to report device malfunctions that may be associated with patient injury.

(company confidential) has a published Medical Device Reporting procedure. Any employee who becomes aware of a device malfunction should report it to management immediately.