

# What are Good Manufacturing Practice (GMP) guidelines?

This acronym GMP stands for Good Manufacturing Practices. These are a series of federal regulations issued by the FDA that require manufacturers, processors, and packagers of drugs, medical devices, some foods, and blood products to be proactive in ensuring that their products are safe, pure, and effective.

The authority for the FDA to issue these regulations comes from the Federal Food, Drug, and Cosmetic Act. Companies failing to comply are subject to serious penalties, including product recall and seizure, monetary penalties, and the possibility of prison.

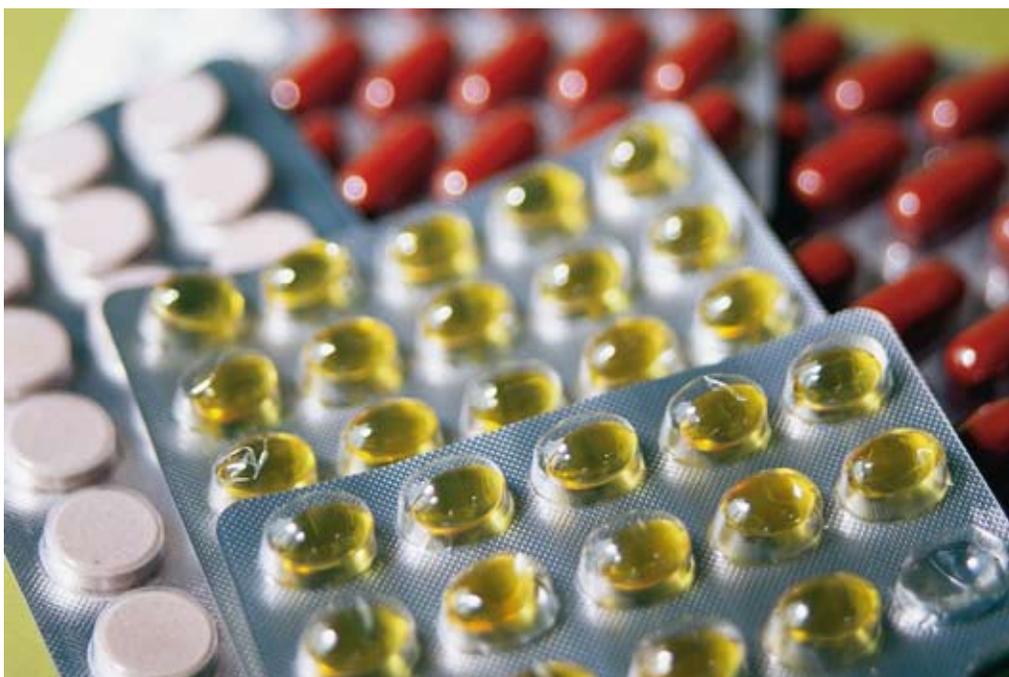
At one time, many medications on the market were untested, promoted for unsubstantiated uses and not labeled with a drug's correct contents. Before the evolution of modern GMP regulations which include the inspection of manufacturing facilities, consumers could not be sure of the content, quality, or purity of the medications they purchased.

## ***What are the consumer advantages?***

The GMP regulations protect consumers from purchasing products that may not be effective – or could be dangerous.

Tragically, there is a recent example of what may happen when GMPs are not followed or enforced. The situation involved the drug heparin, an important injectable anticoagulant (blood thinner) that may be considered a life-saving medication. Heparin is a natural product derived from pig intestines, and the world's largest grower and supplier of pigs is China. Raw heparin produced in China, in some cases from facilities that had not been inspected for GMP compliance, was found to be adulterated and subsequently linked to almost 90 deaths.

The 90 deaths linked to the contaminated heparin may be a small fraction of the true number of deaths. Two factors must be considered to place this number in a meaningful context. First, between only 1 in 10 and 1 in 100 serious adverse drug reactions are ever reported to the FDA, meaning the actual number of deaths may be between 900 and 9,000. Second, all of these deaths may have been prevented if the GMP regulations were enforced.



There are other examples of risks to consumers from products imported without enforced GMP regulations. Contaminations also extend to pet food imported from Asia, and it appears to have been responsible for a number of illnesses and deaths in pets. Toothpaste produced in China was found to contain a type of antifreeze called diethylene glycol, which is highly toxic. It also has been used to formulate medications with devastating results in adults and children in Panama and Bangladesh. Ironically, a sulfa drug used to treat infections was formulated using diethylene glycol in the late 1930s. This product accounted for over 100 deaths (mostly children,) and was one of the trigger events that led to the passage of the Federal Food, Drug and Cosmetic Act in 1938.

Unfortunately, the FDA lacks the trained personnel and resources needed to conduct the GMP inspections and help ensure the public's safety. Recent events, especially the contaminated heparin case, have spurred Congress to address the FDA's resource deficiencies.

***How do I know that my medication is properly manufactured?***

All major U.S. pharmaceutical manufacturers selling prescription and over-the-counter medications are regularly inspected by the FDA to ensure compliance with GMP regulations. This will extend to foreign manufacturing facilities when Congress appropriates the necessary funds to undertake a rigorous inspection regimen overseas.

There are two categories of products sold in this country that fall outside GMP regulations: natural health products or dietary supplements, and so-called pharmacy compounded medications.

The Dietary Supplement Health and Education Act passed in 1994 had the effect of deregulating the dietary supplement industry. This included no requirement for the type of GMP regulations the pharmaceutical industry must follow for prescription and over-the-counter medications. As a result, neither consumers nor health professionals can be sure the label of dietary supplement or a natural health product accurately reflects what is in the bottle. New dietary supplement GMP regulations (see Chapter 52) are due to be fully implemented by 2010. The effect of these regulations in protecting consumers from substandard or dangerous products will depend on the resources provided by Congress.

Pharmacy compounded medication products may be produced in local pharmacies using small-scale manufacturing techniques that do not comply with the regulations. Pharmacy compounded products are best avoided by consumers, except in those very rare instances when there is no FDA-approved product available for treatment.

## Key messages

- ✓ FDA-regulated products must comply with GMP guidelines to ensure product quality and safety.
- ✓ Contaminated products have entered the U.S. due to limited GMP inspections.
- ✓ Dietary supplements or natural health products are not manufactured under conditions that meet strict GMP guidelines.
- ✓ Pharmacy compounded products are not produced in facilities complying with GMP guidelines.

