



GMP – Standard to Meet or Barrier to Overcome?

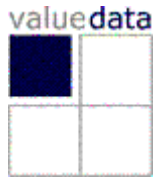
GMP stands for Good Manufacturing Practices.

Has anyone ever wonder why it is only "good" manufacturing practices and not "best" manufacturing practices? The reason is simple - the regulators set the minimum requirements for manufacturers to meet. It is as good as saying there are only 2 types of practices in this world - the good ones and the bad ones. Good practices of all kinds (and that's why we have GxP nowadays) are codified and are easily available from the web. Manufacturers, depending on the countries where they want to market their products, have to stick to these rules. These are the rules in the pharmaceutical manufacturing. It is a **standard** to meet if you are a manufacturer.

The good news is that these rules form a **barrier** to overcome - for the new entrants. New manufacturers trying to compete in this multi-billion-dollar market have to break this barrier before the first sale can be made. In other words, new entrants first have to have a GMP-ready facility before they can compete for the pie.

Knowing that, are existing manufacturers protected from competition? Obviously the answer is NO. Otherwise, there would not be warning letters, product recalls, quality problems, and patients' adverse effects. Existing manufacturers must **continuously** meet this level of standard. There is no scaling back just because the facility has passed the inspection. GMP-certified manufacturers not meeting GMP requirements are actually cheaters having free rides on the system. They reduce the barrier of entry jointly created by all other existing manufacturers.

We must push the scenario to the extreme to illustrate this case. Suppose every pharmaceutical manufacturer is maintaining a high level of GMP compliance with their quality system running on full integrity. Any new entrant will find itself very hard to participate in this high barrier market if it does not have the same level of compliance. Now, imagine a black sheep tries to ride on the effort of others, in an environment of ethical manufacturers, accepting poorly designed and constructed facility, adopting ineffective quality system, cutting down on employee training, etc. This black sheep will be identified very quickly (and easily) by the regulators and be punished. The black



sheep can then choose to improve itself or exit the market. The end result will be that the overall GMP climate is maintained.

On other hand, if this climate started out with dark clouds and heavy storms, where the general level of compliance for existing manufacturers is low, new entrants will have no difficulties clearing inspections. We have pharmaceuticals that are manufactured in the backyard. How is this possible? Because of the **feedback mechanism** that is inherent of the regulatory system. If all pharmaceutical companies cannot meet GMP, then GMP is irrelevant. Irrelevant GMP will be revised to be relevant - with respect to prevailing climate. One can draw example from the exponential growth of computerized system usage and the revision of corresponding guidelines. Drugs are needed by mankind and manufacturers must supply them to meet this demand. The benefits of an availability of a life saving drug is balanced delicately against the risk of its manufacturing processes not meeting GMP.

Getting back to the dark cloud climate. If new entrants can clear the barrier easily, the net result will be that all manufacturers are worse off. In addition, the patients are worse off. Just imagine your competitors undercut you because they managed to reduce cost by reducing GMP. They sold more substandard products to more patients. They snatched away your customers. Ethical manufacturers cannot stay afloat this way and unethical ones thrive up to the point when enough suffering patients mentally blacklist and boycott products from these companies. This kind of consequences is deleterious to everyone.

Today, if your company is already in the industry, set that barrier to overcome for new entrants. Meet the standards of GMP.

*The pharmaceutical, biologics and medical device industries are collectively referred to here as the Pharmaceutical Industry.