



Is Business Ready to Introduce GMP Standards?

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Introduction of GMP standards is getting a more crucial issue for Ukrainian manufacturers. Obtaining a licence on production that complies with requirements of good manufacturing practices (GMP) is a key stage in development of the pharmaceutical industry that transfers it on tracks of international requirements. Ukrainian pharmaceutical sector, except for small number of leaders, is lagging behind the world pharmaceutical industry. Possibility of closing factories after introduction of strict licensing requirements is getting more realistic. Besides, impact of world financial crisis makes questionable the introduction of GMP standards in required deadline. Only powerful regulatory policy and necessary government support can help a pharmaceutical manufacturer to remain competitive in modern business environments.

It is obvious that as long as non-compliance to GMP standards is not considered as a threat of losing a pharmaceutical business, companies will not be interested in its implementation. Unavailability of GMP must force owners to undertake quick and adequate actions. The most difficult is understanding how quality is related to business operations, profit and costs and how this components may be utilized for improvement of quality system. Management of companies must address the most important issues: whether a business is ready to introduce GMP standards and what priorities must be selected at this stage.

While discussing the topic of transfer of pharmaceutical companies to GMP standards, one can sense paradox of the situation. Today Western pharmaceutical journals contain comprehensive discussion of new quality philosophy of culture of manufacturing. In 2002, US Food and Drug Administration (FDA) acknowledged the need in modification of its current CGMP in order to move into the 21st century (1). In September 2006, the FDA issued final version of quality system that was described in the Quality Systems Approaches to Pharmaceutical Current Good Manufacturing Practice Guide (2).

By having created new documents, the FDA hopes that manufacturers will be constantly supporting high-quality products and improving production efficiency. The Administration believes that this would help to decrease costs and prevent shortage of critical medications due to losses as a result of product recalls. One of the directions of regulatory policy of the FDA is to decrease manufacturer's expenses. In this case a business will gain real advantages such as reduction of wastes, additional cost related to re-processing, costs associated with product recalls and so on.

The real ways of transfer to GMP standards can be divided into organizational ones that allow developing, introducing and maintaining a reliable quality system within a company, and executive ones that determine and implement measures related to change of engineering systems, purchase of equipment, and construction of facilities and so on. The first part deals with development of required systems and documentation, personnel training, setting up control methods for determining regulatory compliance and for determining long-term quality policy. This part is not costs absorbing; however, it is very important in view of building up the quality

system. The second part of measures determines the most critical aspects that require financing and resources to be applied.

Regulatory authorities will be responsible for preparation necessary documentation, training of inspectors who will determine compliance of a pharmaceutical production facility to GMP requirements. Inspection authority will analyze all components of the quality system and render a decision about the level of its maintaining in order to ensure standards for production management, quality rating and control systems. The role of inspectors is hard to overestimate since they play a key role in either sanctioning a licence or in closing a company. Regulatory authorities and business community are both responsible for maintaining strategy of utmost trust between each other and understanding each party's interests.

The model of current pharmaceutical business is based on fast change of economic situation under conditions of actively developing market and unstable regulatory policy. In most cases a business is planned for a short term and this does not allow implementing a target-oriented quality policy. In this situation responsibility of management for making a decision is very crucial. This is within ability of top-managers to find balance and approach with necessary impact on the right implementation. Business must see the advantages in regulatory compliance and should be interested in reaching such compliance. At the same time profitability of company should not be neglected and it should be based on costs saving as a result of production efficiency but at the expense of low quality of products.

Most of obtained successful results in pharmaceutical business are associated with the fact that development of a medication, its adequate manufacturing, quality control policy and management are combined and interrelate as a whole. Is business able to make necessary decisions to introduce advanced pharmaceutical quality system? No doubt the answer is affirmative. More than anybody else a business is interested in production efficiency and new markets and it depends on introduction of an adequate quality system. A properly built-up system makes business more competitive, enables effective development and attracts investments.

Source references:

1. FDA, CGMP for the 21st Century, provided at:
http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport2004.htm
2. FDA, Quality Systems Approaches to Pharmaceutical Current Good Manufacturing Practice (CGMP) Regulations (Sept. 2006), provided at:
<http://www.fda.gov/cder/guidance/7260fnl.htm>