A1 CONSULTANCY & INTEGRATED SERVICES SDN BHD
No. 4-2, Jln Mutiara Melaka 2, Mutiara Melaka, Batu Berendam, 75350 Melaka, Malaysia.
Tel: (6016) 317 8158/8918, Fax: (606) 317 6748, Email: enquiry@acissb.com

GMP from the commercial point of view

GMP is short for Good Manufacturing Practise. It is a part of QA which ensures that the products are consistently produced and controlled to the quality standards appropriate to their intended use. Much has been said about the GMP requirements for the pharmaceutical industry. Although GMP affected the manufacturers to a greater degree, importers and distributors are not spared on the needs to comply with GMP.

GMP aim & objective

GMP was formulated as guidance for manufacturers to comply so as to ensure consumer's safety. Consumers are to be protected that there will be no adverse effects or death resulting from consumption of the manufactured products

Compliance to GMP can also assure consumer of a quality products that is consistently achievable from time to time. Consumers can also be assured that the products are not only safe to consume, but is efficient and meets its intended use.

Previously, GMP was perceived as giving priority only to consumers. However, over time, manufacturers has realised the advantages it has in looking after the manufacturers own interest. GMP was found as a quality system to ensure the smooth operation without any hindrance and 'accidents'. Management are more than happy to adopt GMP fully knowing that this will ensure their products are correctly processed accoridng to the validated procedures and product defects minimised to the lowest.

GMP & Quality management

Most manufacturers make use of a variety of quality tools for the enhancement of their product quality and improvement in their productivity. Each has its own methodology, concept and philosophy. However, all has the ultimate aim of producing the highest quality products with the lowest wastage and highest output. All require the personnel to adopt the spirit of high quality in their product.

TQM or Total Quality Management is one of the commonly used, especially amongst the multinationals and manufacturers of the electronic industries. Others are the japanese originated 5S Practise, Six sigma, and also the various ISO (International Standrd Organisation) standards.

Problem solving tools are oftenly utilised in managing quality. Tools such as the fish bone diagram, pareto analysis and statistical analaysis are commonly used.

Quality concerned individuals and organisations join the quality fray by introducing quality system and relating it to a specific industry or activity. Thus, the acronym GMP for Good Manufacturing Practise is created. Others are GEP (Good Engineering Practise), GLP (Good Laboratory Practise), GCP (Good Clinical Practise), GSP (Good Store Practise), GDP (Good Documentation Practise) and many other G?Ps.

So, it can be seen that GMP is one of the many quality systems available. The main difference of GMP as compared to others is the focus on safety and efficacy issue of the products produced with respect to the users.

Legal requirements of GMP

In Malaysia, GMP is not directly a legal requirement. However, it is indirectly a requirement under the Sales of Drug Act 1952 (revised 1989). Under this act, there is a specific regulation, Control of Drugs & Cosmetics Regulation 1984 (revised 1989) formulated specially for the control of drug and cosmetic products.

Under this act, other than the requirements for products to be registered, manufacturers are also required to obtain a legal Manufacturing license before these registered products can be manufactured. It is an offence if a manufacturer operates or manufactures products without a valid Manufacturing license and this is punishable for a fine or jail sentence, or both, under the said act.

For a manufacturer to be a qualified, the manufacturer must be able to demonstrate the ability to comply to the set of guideline laid down by GMP. Although non-compliance to GMP is not punishable under the said act, non-compliance to GMP may lead to withdrawal or suspension of the Manufacturing License. The effect of this is far substantial as compared to the fine imposed for offence of operating without a valid Manufacturing license.

Due to the great impact and loss suffer from non-compliance to GMP, manufacturers view GMP compliance as a prime factor in the fate of their business operation.

GMP to consumers

Consumers view GMP from a differently, although those related to products may be similar. Consumers expect a high quality product from a GMP approved manufacturer. They will feel that the products are safe to consumed and not detrimental to their health. As some of the consumers are compromised patients due to their bad health or age, they feel their safety and consumer right is look after by GMP.

GMP also provides assurance to consumer that the products are efficient and meets the intended use as claimed by the manufacturers. Consumers are also confident that the claimed shelf-life are genuine and products' quality are intact for the stipulated period.

With GMP, consumers are rest assured that the manufacturers will be responsible and accountable for any defects to the products. Any product complaints submitted by consumers will be given due attention by the authority and corrective actions will be assured.

GMP to Industry

Industries concerned include manufacturers, importers and distributors. As mentioned earlier, the industries viewed GMP as a structured quality system that is able to assure them of their ability to produce quality product consistently.
Industries see GMP as a tool to avoid product complaints due to defects arising from cross contamination, wrong labeling, adulteration, spoilage, etc. This lead to reduce product returns and recall, high productivity, reduce wastages and ultimately, high profit margin.

The big challenge to industries in trying to adopt GMP is the availability of qualified and skilled manpower. These require the service of professionals such as pharmacists, microbiologists, chemists, engineers, etc. even with the recruitment of professionals, training need to be given to provide them the technical as well as GMP knowledge required. Experienced professionals are in high demand due to the small numbers available. Thus, the industries have no choice other than to provide the necessary trainings to new recruits.

GMP imposes another major problem to industries in the form of financial constraints. Most of the manufacturing components, such as facilities, utilities, good finishing and equipment, require compliance to certain GMP standards. Upgrading or installing such GMP compliance components requires high financial investment. This restricts or forms a barrier to new players, especially manufacturers from venturing into the pharmaceutical field. A manufacturer has to justify this high GMP cost with its high output and profitability. Currently, it is the norm for a new manufacturer to break even only after 7 years of business.

End.