Indian GMP scene; trends & challenges

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The Indian pharmaceutical manufacturer today is in the fore front of the science of manufacturing with a wide range of capabilities in the complex field of drugs, product manufacturing as well as technology.

The Indian pharmaceutical manufacturing is estimated to be worth $ 4.5 billion, growing at about eight to nine per cent annually. It has considerably expanded with more than 20,000 registered pharmaceutical units.

The Indian pharma industry is considered to be one among the biggest producers of the Active Pharmaceutical Ingredients (API) and drug products in the global arena. There are approximately 250 large manufacturing units and about 8000 small scale units which outline the core of the pharmaceutical industry in India. India currently holds a 3.2 per cent share of the global market.

Looking at the growth curve of Indian pharmaceutical industry and the Indian economy as a whole, the future looks very bright for pharma sector. India is fast becoming a lucrative hub for R&D, clinical trials in India, with the cost of a trial US $ 25 million, in comparison with USA where they cost between US$ 300 – 350 million reach, which brings down the final cost of the medicines and making it more accessible to end user. In India, investigational new drug stage costs around US $ 10 – 15 million, which is almost 1/10th of its cost in internationally recognized countries where it costs any where between US$ 100 – 150 million.

To nurture this steady growth curve, we should constantly assess our Good Manufacturing Practices (GMP) current scenario, trends and challenges that the industry and the government should together brace up to ensure that Indian pharmaceutical companies do not succumb

to non-compliance which could be a factor for us to lose out in the global competition.

Currently India has laid down its own GMP requirements in Schedule M of the 'Drugs and Cosmetics Rules'. Indian GMP regulations does not differentiate between GMP for medicinal products and GMP for API. In fact, Part I – F of the Indian Schedule M is for API manufacturing, the complexity of rules are comparatively low. This may create problems for API and drug manufacturers in our country. For instance, auditors for ICH may still find manufacturers non-compliant even if the industry has adhered to their respective national GMP regulation for facing international audits.

The current trend in pharmaceutical companies in India is that they adopt ICH structured guidelines, GMP regulations, audit topics and legal requirements as per target country and gear up for the audit. But necessarily the manufacturer may not follow Schedule M for facing international audits. The difference between the GMP standards of the drug supplying countries and the receiving countries may therefore result in ambiguities and difficulties relating to its compliance.

A major challenge put in front of us is the possibility of interpretation of GMP Schedule M requirements to the auditor. The company specific GMP documents required for the target country may be presented in a way that the auditor is familiar with. Therefore, the company may employ well informed and highly skilled workforce who is adept with regulatory and GMP knowledge so that the risk can be avoided and the auditor is familiarized with the regulatory guidelines laid down in India.

Our country has a large manpower which itself is a major asset. But here in the case of young and fresh candidates coming out of pharmacy colleges are found to lack industrial exposure to take up assignments. Therefore the syllabus should be re-looked and designed in such a way to ensure that there is adequate theoretical know-how about different aspects of pharma regulations which will allow the candidate to comprehend the requirements of the industry he is selected to work.

With the prospects of GMP harmonization coming to play shortly, our industry should take steps to align the requirements of ICH / GMP / QMS(Quality Management Systems) so that during harmonization there will be no room for not adopting quality systems. The problem cannot be solved by tighter regulations alone. Continuous and professional auditing is essential to overcome the challenge of meeting stringent requirements of GMP. GMP is doing the right thing when nobody is watching but it will reflect in the final product being right.

For India, the ground is set for a rapid growth in the world pharmaceutical market. The country has good infrastructure, technology and most importantly skilled and dynamic workforce. Now with the GMP guidelines in place, India can gear up to scale higher peaks in the global pharma market. There are immense opportunities for pharmaceutical players both at the national as well as the global level to prove their strength. But along with opportunities are challenges which need to be overcome in order to achieve sustainable growth in the future.

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