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Mindsets must change

The way forward would be to learn from the mistakes and mend ways

BY INVITATION

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RECENTLY, various notices and import alerts were issued by the United States Food and Drug Administration (USFDA) to Indian pharmaceutical manufacturing units for violation of current Good Manufacturing Practices (CGMP). These include two Wockhardt facilities in Aurangabad, Agila's Bangalore facility, RPG Lifesciences' facilities in Ankleshwar and Navi Mumbai, Hospira's facility in Chennai, Fresenius Kabi's facility in Nadia, and Ranbaxy's plants at Mohali and Taonsa.

Most of these companies were issued warning letters by the USFDA. However, Ranbaxy's products were subjected to 'import alerts', whereby these products could not be exported to the US unless corrective action was taken. These warning letters and import alerts were based on inspections that pointed out non-compliance with the CGMP.

CGMP specifies the minimum manufacturing practices including methods to be used in the facilities — or controls to be used for — the manufacture, processing, packing or holding of a drug to ensure that the drug meets safety, identity, strength, quality and purity characteristics that it purports or is represented to possess. India has also prescribed good manufacturing practices under 'Schedule M' of the Drugs and Cosmetics Rules, 1945 and all manufacturing licensees in India are required to comply with these standards.

Pharmaceutical companies that choose to export products to the US would have to comply with the CGMP. The fact that good manufacturing practices (GMP) compliance is mandatory by itself should lead to a sense of discipline in the pharmaceutical manufacturing companies. Such discipline needs to come from the top management and companies need to follow a zero tolerance policy for GMP non-compliance. GMP non-compliance could relate to reasons that are unknown to the top management of the companies. However, the non-compliances pointed out in recent audits by USFDA were of a nature that the management could be reasonably expected to know had they exercised diligence. The fact that these non-compliances continue to occur would probably be on account of reasons best known to the management. Probably, one such reason is that GMP compliance involves considerable cost which impact the companies' profitability in the short term. Pharmaceutical companies, however, need to consider that GMP compliance leads to value creation in the long term.

BITTER PILL: If non-compliances continue to occur, it would probably be for reasons best known to the management

Apart from the general change in mindset mentioned above, there are certain other macro and micro steps that may be taken:

Macro steps

- Periodic training for employees: Firms should organise periodic training for their employees, as it is they who implement the GMP. For large corporations, this may be done by in-house compliance teams. For smaller firms, this may be done by engaging external agencies.
- Periodic checks and surprise audits: These would help avoid chances of governmental audits pointing out GMP non-compliances. This need not be done for the entire organisation and could be done for different departments from time to time.
- Learn from the mistakes of others: Most results of investigations are available in the public domain. Therefore, manufacturers should assess whether issues uncovered in audits of other's facilities also exist in their own manufacturing facilities.
- Accept compliance as a process and not a burden: Compliance with GMP should not be seen as a burden, but as a process. firms exporting pharmaceutical products follow basic regulations such as obtaining marketing authorisations etc, GMP compliance should come naturally as a part of the same process.
- Identify the necessary upgrade: In addition to Indian GMP standards, firms engaged in export to developing countries would need to comply with various other GMP standards (including WHO, ICH, etc). Therefore, companies exporting to developed jurisdictions (such as the EU, US, UK, etc) only need to implement additional standards that may exist for these jurisdictions.

Micro steps

These are illustrative in nature in view of issues identified in recent audits and investigations.

- Change control and validation: Equipment and processes should be validated from time to time. The process of validation involves companies establishing documented evidence that processes will yield products with pre-defined characteristics and attributes. More importantly, once validation is completed, it is important that the state of validation is not changed in an uncontrolled manner.
- Establishing and implementing effective procedures: GMP stresses on preparing standard operating procedures (SOP) so that operations can be conducted in a consistent manner without a need to refer to prior experiences. Developing such SOPs could either be done in-house or through external agencies. Where processes are prepared in-house, it is advisable to have these vetted by external agencies. Most importantly, once SOPs are prepared, manufacturers need to ensure that they are followed.
- Invest in facility design: GMP also specifies various aspects of the design and operation of facilities. Accordingly, facility design should be assessed routinely to assess what changes should be made. For new facilities, it is important to plan effectively. Appropriate facility design also aids in maintaining environmental factors.
- Maintain detailed records and documentation: GMP lays importance on maintaining accurate and detailed records. Further, it is important that records are preserved and not altered in the future. This includes keeping records of deviations (whether planned or unplanned). The more detailed and exhaustive the records of deviations, the easier it is to explain these deviations in subsequent audits and investigations.
- Periodic maintenance of facilities: Facilities and equipment are subject to wear and tear and periodic maintenance is an essential part of ensuring quality. This helps retain change control and ensure consistent performance as well.
- Deviation management/plan for corrective and preventive action: Over and above maintaining SOPs for manufacturing activities, it is important to maintain SOP for taking corrective and preventive action when a problem or deviation is discovered. This could include any aspect of manufacturing.

On the whole, businesses need to take these compliances in their stride, invest additional human and financial capital and move forward.

- CGMP specifies the minimum manufacturing practices including methods to be used in the facilities
- India has prescribed good manufacturing practices under 'Schedule M' of the Drugs & Cosmetics Rules, '45
- Pharmaceutical firms that choose to export products to the US would have to comply with the CGMP

Regulatory.