



## Big pharma plans shift to electronic mode

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Some of the large pharma companies in India are soon likely to move to an electronic training mode from the present manual system to have a higher accuracy while documenting data. This is an after effect of several probes initiated by US FDA and MHRA that eventually banned exports from various domestic drug manufacturers.

Former deputy drug controller Kapil Bhargava pointed out “documentation” deficiencies are the most reported observation by the regulators compared with the total non-compliance reports (NCRs) which are almost 50 per cent. Another major concern according to him is that of data integrity.

Taking note of this compliance and also scalability issue, many Indian companies, alike global multinationals such as Teva Pharmaceutical Industries, Johnson & Johnson, are interested to move from manual system of training and documentation to an electronic system.

Ellen Leinfuss, SVP, UL EduNeering, said, “We are looking at large Indian companies. Large pharma companies wanted to improve on their scalability. We just started this process of educating companies about this mode only a few months back and 6-8 Indian companies have shown interest so far with us. For a small company, it may not be essential to move to this system. But as one scales up, one will have to pay a cost for not doing this since lots of manpower are used to run around with papers and this will only add for more problems.”

“It is definitely expensive but for large companies with a strong global presence, it is not difficult to do it. In fact, not having an electronic mode is an impediment if one grows its base. It is about using the right tool, educating people and educating to use them consistently since there is always a lot of resistance towards using anything electronic initially,” said S M Mudda, executive director, Micro Labs on the sidelines of UL India Pharma Summit, on Thursday.

He also said, “Many Indian companies have started it. Dr Reddy’s is a pioneer, they already started some electronic documentation in modular and phased manner. Around 20-25 Indian companies are moving towards an electronic mode. Even at Micro Labs, we are also moving towards the same process. We have recently gone for an automated warehouse management system.”

Scott Bernard, vice-president — advisory services, UL EduNeering, said, “The paper-based training process poses several risks in audit accuracy as well as in lost or damaged records. It is also an issue of security and validation. Auditors would rather see incomplete records out of a secure and validated source than perfect records from an insecure and non-validated source.”

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