Indian pharma companies to soon get GMP compliant as mandated by US FDA

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In the wake of a spate of warning letters on Indian pharma companies by US FDA, US-based online compliance and regulatory learning solutions company Underwriters Laboratories (UL) Eduneering, which trains drug regulators to ensure safety of FDA related pharma products is planning to equip leading Indian pharma companies on maximising compliances related to consent decree, Form 483, data integrity and quality management systems. This would entail maintenance of electronic records for inspection readiness of Indian companies.

This comes as a welcome change as US FDA commissioner Margaret Hamburg plans to hold multi year capacity building workshops for domestic regulators to understand US FDA standardised processes of GMPs and cGMPs in drugs and medical devices segment. The workshops are planned to be held in Ahmedabad, Gujarat, Hyderabad, Chandigarh and Goa.

Informs Kavita Mehrotra, Global Head, UL, "Considering the fact that certain Indian companies have got critical global attention due to certain evasions, violations and avoidances during US FDA inspections, compliance is required for development of closed systems which captures electronic signatures, audit trails and any changes made in the system or content and also simultaneously offer, track, record and report at the same time. This is in accordance to 21 CFR Chapter 11 compliance of US FDA guidelines."

To serve compliance and regulatory needs of the fast growing life science community in India, UL and US FDA have also extended their Cooperative Research and Development Agreement (CRADA) for five additional years, extending the agreement till 2019. US FDA's CRADA with UL is the only learning technology agreement of its kind between US FDA and a private sector company.

The extended CRADA agreement between US FDA and UL is designed to address training needs that include topics related to international inspections, import and export of products that fall under US FDA purview and intra agency and intra government cooperative agreements. It also involves access to the FDA's Office of Regulatory Affairs online curriculum via ComplianceWire, which is UL EduNeering's cloud based learning platform.

Designed specifically for Indian life science industry, the Learning Management System (LMS) called ComplianceWire is built on a Cloud-based model which helps reduce IT and validation costs. Capable to cater globally in 34 languages, the system helps in audit readiness for training records while being fully secure and complies with US FDA's electronic signature governance requirements. Equipped to provide SOP management, it adapts well to the strategic agility of the growing business needs of the organizations.

UL has trained over 30,000 US FDA inspectors till date. "As a statistical testament to our product leadership in this area, in 2013, we recorded 23 million training completions by our global audience, with four hundred clients in pharma and medical device area and government agencies," she adds.

With the coming of Obama Care and exports of generics, Active Pharmaceutical Ingredients (APIs) and finished drug products from India to the US projected to grow by 40 per cent, Indian life science companies are in dire need to achieve regulatory compliance to minimize organizational risk and improve quality and business performance through training on GMP compliance.

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