UL Signs MoU with Gujarat Government to Train FDCA Inspectors on Audit Regulations

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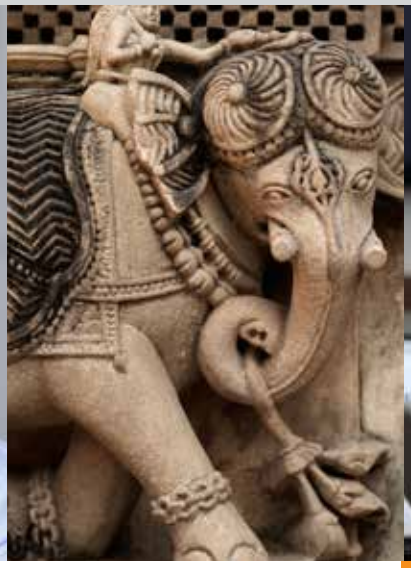
In order to provide robust regulatory and compliance training to government investigators covering critical areas including GMP, GCP, audit-readiness and remedial training, the US-based global leader in safety science Underwriters Laboratories (UL) has signed a memorandum of understanding (MoU) with the Gujarat government to train Gujarat Food and Drug Control Authority (FDCA) inspectors.

UL will be using specially designed online programmes in keeping with international regulatory guidelines, to help ensure the quality and safety of pharmaceuticals manufactured in Gujarat. UL EduNeering, the compliance education and training services business division of UL Life & Health, will lead this initiative.

The goal of this effort is to empower the FDCA investigators with the same source of knowledge that is currently accessible to US Food and Drug Administration (US FDA) investigators. In the first phase, training was conducted in December with 45 inspectors from the Gujarat FDCA, and featuring 20 online modules. UL EduNeering will continue training throughout the year utilizing a blended approach to learning through continuous improvement and training.

Says Dr HG Koshia, Gujarat FDCA Commissioner, "To meet the challenges of matching the complex regulatory environment, Gujarat FDCA is committed to provide high-quality educational opportunities to its investigators, scientists, analysts, state and local regulatory officials. UL EduNeering's rich modules of training programmes that are followed by US FDA would definitely help our inspectors understand the nuances of global regulatory requirements and ensure a high degree of quality control for pharmaceutical manufacturers in Gujarat."



Last year, pharmaceutical exports from India to the United States rose 32 per cent to $4.2 billion. India accounts for about 40 per cent of generic and over the counter (OTC) products and 10 per cent of finished dosages used in the US. Given these numbers, it is not surprising that the Government of India and foreign regulatory agencies are emphasising the need to ensure consistent quality of the country's drug products. This move by the government of Gujarat is a step in the strategic direction to bring Indian pharmaceutical standards on par with the US FDA's and enables India to maintain a competitive advantage.

Explains Dr Kavita Mehrotra, global strategic head, UL EduNeering, "UL EduNeering's ongoing commitment is to bring in expertise to Indian life sciences and healthcare companies. Through this strategic partnership with Gujarat FDCA, for the first time in India, UL aims at bringing in good manufacturing practices (GMP) by empowering the regulatory authorities with the right kind of training which would enable them to guide drug manufacturers in adhering to necessary standards."

She further adds, "From a strategic perspective, this is very important, because ultimately, not only does this contribute significantly to patient safety but also influences the quality of exports of pharmaceuticals and other related products, thereby accelerating business results as well."

"UL offers innovative technologies that prepare companies to have standardised processes, as well as audit readiness, by adhering to GMP requirements, so that the best practices exist at every level in the organisation," concludes Suresh Sugavanam, managing director , UL India and South Asia.

About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.