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As a major international safety consulting and certification company, can you talk about the role that UL plays in the pharmaceutical industry here in India?

UL works with a diverse international array of companies and stakeholders every day to make the world safer and provide quality assurance. We work with more than two dozen pharma companies in India, ranging from the ten largest in the world to smaller startups. Our vision for UL EduNeering in India is to expand that presence in the area of quality and regulatory compliance learning in keeping with our company's vision of working for a safer world. We aim to provide a good example of corporate citizenship and social responsibility by partnering with pharma, government agencies, and medical device companies to promote safe and effective regulatory standards.

How has this helped pharmaceutical companies to comply with the recent domestic regulations and reach out to regulated markets?

UL EduNeering has a 15-year learning partnership with the U.S. FDA, which includes global commitment to consistent GMP standards. By using and offering content authored by FDA, we bring a high level of consistency and credibility to a globally applicable standard for regulatory and compliance training. We prepare companies not only to have standardized processes, but also an audit readiness while demonstrating superior compliance practices. Our expertise in systemic and content leadership, our FDA-authored library of more than 200 courses, our 700+ course library, including recent topics such as Sunshine Act, and our multilingualism and global approach all enable us to help companies comply with domestic and global regulations.

Can you talk to us about the primary problems that you encounter in a typical Indian company inspection and how these problems may differ to problems encountered in Western companies?

The biggest challenge in India today is a mindset issue on quality. What will make us succeed will be companies not looking at quality from the point of view of regulation alone. Any inspection should reveal consistent quality. It is, after all, a patient safety issue, not an Indian or a U.S. issue. The common thread is the lack of a consistent approach to quality processes and implementation. The second challenge is the lack of a robust training ecosystem to bring professionals across various functions up to speed on compliance processes. There is very poor management of training records for employees. The industry lacks a systematic way of monitoring the levels of individual preparedness for compliance. Let me also share another cultural interpretation of compliance, which can use a re-visit. I am privy to closed door meetings with industry leaders and have found that sometimes, an absence of records is also a function of unwillingness to share what may be "incomplete" records, as opposed to seeing that as a work in progress. Ironically enough, it is a cultural focus on academic excellence rather than misrepresentation of data that drives this, but with unpleasant consequences. The challenge is not so much of intent but of globally shared perception of records, knowledge and awareness.

So what can we do about this?

According to our recent annual survey, The Product Mindset, globalization is a core business reality that is increasing in importance and influencing priorities. The supply chain is a significant priority and increasingly global. 48% of manufacturers state they will increase global sourcing

over the next five years. Consumers globally are well-informed about the complexities of the supply chain. They understand manufacturers are sourcing pieces and parts globally and want visibility and insight into that. We saw in our study that supply chain transparency is a rising priority among consumers and manufacturers. It was also an area of disconnect between manufacturers and consumers. 84 percent of manufacturers agree that stakeholders are increasingly demanding supply chain transparency. Yet, 42 percent of consumers believe that manufacturers do not provide sufficient transparency into their supply chains. To compete globally, many companies must adopt a “quality first” culture. This starts with regulatory knowledge, then moves to more rigorous production systems, and a top-down quality mind-set. Often, this investment into quality is surrounded by education, quality-based compensation incentives and governance policies. The rollout of the Affordable Care Act and increased cost of healthcare in the United States will lead to additional pressures in production costs globally.

India is currently the third largest manufacturer of pharmaceuticals. What is your opinion of India’s role in the global market?

Our customers face challenges in navigating regulatory requirements and ensuring that their products perform as expected, are safe and meet market demands. Technology helps businesses and consumers better understand and enhance supply chain visibility which can be a competitive advantage for businesses. As I have mentioned earlier, our offering to R&D, product realization, packaging etc., is driven by the larger goal of providing the right training to the right people at the right time. Hence, we provide learning solutions globally as a one stop shop, where we have over 700 courses, an audit readiness for training records, and a validated Learning Management System, a 21 CFR Part 11 compliant system which is easily accessible over the Internet while being fully secure and complying with FDA’s electronic signature governance requirements.

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