MEETING THE QUALITY CHALLENGE

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Effective training in Good Manufacturing Practices helps ensure top-quality products and can prevent product-recall blindsides

Every year U.S. consumers buy approximately 10 billion personal care products, from toothpaste and sunscreen to skin moisturizers, bandages and pain relievers. For the most part, consumers don't care if a product is regulated as a drug or not. They aren't concerned if Good Manufacturing Practices, or GMPs, are required by regulation. They expect quality and hold manufacturers – not regulators or regulations – responsible for any quality defects, safety issues or product recalls.

Quality and safety form the cornerstone of the Personal Care Products Council and are the foundation of a unique alliance between the Council and UL EduNeering, a developer of learning solutions designed to assure regulatory compliance, minimize risk and improve business performance. Through that alliance, Council members can benefit from online training courses for essential GMPs in areas including microbiology, toxicology and failure investigations.

GMPs: The Basis of Quality

GMPs are required for the manufacture of products regulated by the U.S. Food and Drug Administration, but they also serve as a useful road map of quality assurance, operational efficiency and employee performance for all manufacturers of personal care products.

Adherence to the standards of GMPs requires employees to have working knowledge in essential areas, including proper documentation, standard operating procedures (SOPs), how to resolve out-of-specification test results, vendor certification, calibration, and maintenance and cleaning of manufacturing equipment. Training should target product- and job-specific knowledge needs, with learning programs tailored to the product types, processes, regulatory requirements and risk areas. Cosmetic manufacturers, for example, will benefit from programs such as maintenance and cleaning of cosmetic manufacturing equipment, while manufacturers of pharmaceutical and over-the-counter drugs are best served by courses such as GMP principles of SOPs for an FDA-regulated environment.

UL EduNeering's new "Introduction to Microbiology" delivers that training, setting the groundwork for more advanced coursework in topics including toxicology.

Behavior, Not Hours

Until recently the FDA and other regulatory agencies emphasized the number of hours required for GMP and other training. Now they evaluate the effectiveness of training by what is *learned and applied*, not by the number of hours or courses delivered.

FDA-regulated and nonregulated companies have spent millions of dollars on training, confidently checking the boxes of each required course and duration, only to be blindsided by a product recall or enforcement report. Effective training targets the needs of the learner, recognizing the individual's job function, knowledge needs and proficiency level. It uses techniques such as role-based models to drive comprehension and application of the new knowledge.

Competency must be taught, tested, repeated and reinforced. Simply "checking the training box" won't deliver the results needed for compliant or efficient operations.

Ellen Leinfuss, Senior Vice President,
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Personal Care Products Council
Committed to Safety, Quality & Innovation

Quality and safety form the cornerstone of the Personal Care Products Council. They also set the foundation for PCPC's alliance with UL in the development of a quality and regulatory training solution. As PCPC's exclusive online training partner, UL provides PCPC members with access to the same training, documentation tracking and 21 CFR Part 11-validated technology used by the FDA at its virtual university, ORA-U, to train FDA inspectors. Courses are customized and approved by the Council to meet the needs of the cosmetic and personal care products industry. In addition to its online learning library, UL's technology platform, ComplianceWire® enables companies to improve and expand their enterprise-wide management of SOP delivery, training and efficient resource use.

About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a global independent safety science company offering expertise across five key strategic businesses: Life & Health, Product Safety, Environment, Verification Services and Enterprise Services.

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.