HOW EMERGING COMPANIES GAIN COMPLIANCE EFFICIENCIES

BEST PRACTICES FROM 80+ EMERGING LIFE SCIENCES COMPANIES

In this Knowledge Brief, we share best practices from the "compliance" efficiencies of 80+ emerging companies in 2016.

For many of these companies, the challenge was reducing the compliance risk associated with key areas: HR, Clinical Operations, Health & Safety, and Sales. Reducing these risks is critical to continued growth of these companies, as new products are gaining approval, and facilities and sales teams are expanding globally.

For many of our emerging clients, the challenge is building a learning and development program that focuses on high-risk compliance topics in an engaging manner, so that knowledge transfer is effective and compliance risks are reduced. UL has categorized the compliance challenges into three areas:

- **HR High-Risk Topics:** *"how can we deliver and track critical high-risk topics related to anti-bribery, discrimination and FMLA?"*
- **GMP and Health & Safety:** *"how can we meet global regulatory requirements around GMP, hazard communication and other topics mandated by US FDA, OSHA, DOT and other agencies?"*
- **Sales Compliance:** *"how can we provide proactive compliance training related to high-risk topics such as anti-bribery, interactions with healthcare practitioners, and vendor credentialing?"*

HR Compliance:

1. Sexual Harassment Awareness for Employees
2. Discrimination & Harassment Free Workplace
3. Diversity in the Workplace
4. Antitrust Law and Competitor Relationships
5. Family and Medical Leave Act (FMLA)

GMP & EHS Compliance:

6. Introduction to GMPs
7. Good Documentation Practices
8. Change Control
9. Hazard Communication
10. Bloodborne Pathogens — General Industry
11. Personal Protective Equipment
12. Fire Extinguishers

Sales Compliance:

13. Global Anti-Bribery
14. Basics of PhRMA / AdvaMed Code
15. Physician Payment Sunshine Act
16. Reporting Adverse Events

Addressing Challenges with Off-the-Shelf Courses

Emerging companies have shared these business benefits to leveraging off-the-shelf eLearning content:

1. Reduced Development Effort: UL has estimated that a learning and development team can save 50 hours by replacing a 60-minute classroom training event with a 3rd Party-developed eLearning course;
2. Learner Convenience: Employees can take the training at their own individual pace, as opposed to completing all learning within a structured classroom environment, and content is available at anytime, for reference support at a later date;
3. Improved Retention: eLearning can be highly engaging and visually interesting, which improves retention;
4. Consistent Delivery: All learners receive the same material when an online class is taken; the quality of instruction spans multiple shifts, enabling managers, trainers - and auditors - to grasp exactly what was covered.

Building the Compliance Competency Matrix

Department Owner	Business Risks	Target Learners	Topics	Recurring (Y/N)
Human Resources	Harassment Training Required by Many US States	All employees	- Harassment - Discrimination - Family Medical Leave Act (US)	Yes
Quality Assurance	GMP Awareness (Required by US FDA, EU and other global agencies)	QA, GxP employees, Management	- Introduction to GMP - Change Control - Inspections (QSIT for medical devices)	Yes
Environmental, Health and Safety	OSHA and DOT Training Requirements	Production, Operations, Management	- Introduction to GMP - Change Control - Inspections (QSIT for medical devices)	Yes
Corporate Compliance and Sales Operations	DOJ and OIG interactions with Heath Care Practitioners	Sales and Marketing (including 3rd Party Distributors)	- Anti-Bribery - Adverse Event Reporting - Interactions with HCPs - Bloodborne Pathogens - Operating Room Conduct - Industry Codes (PhRMA, AdvaMed, MedTech)	Yes
Clinical Operations	GCP Education and Clinical Site Management	Clinical Managers, CROs and clinical site personnel	- Introduction to GCP - Informed Consent - Roles of CRA and CRC - Adverse Event Reporting	Yes

Demo the UL Standard Online Courses

UL Compliance to Performance provides more than 500+ courses used by hundreds of Life Sciences companies of all sizes to manage these business challenges:

- **Improve GMP Awareness and Quality Culture**
- **Manage Clinical Provisioning of Site Personnel**
- **Reduce EH&S safety incidents**
- **Manage Vendor Credentialing (Medical Device Sales)**
- **Reduce Sales Compliance Risks**

Contact Pat Thunell to discuss these programs and view the courses: pat.thunell@ul.com