# Building Your Compliance Training Infrastructure
## UL'S TURNKEY APPROACH

*As emerging Pharmaceutical and Biologics companies transition from successful Phase III trials to commercial production, they deal with hundreds of issues related to product scheduling, manufacturing, distribution and resource allocation.*
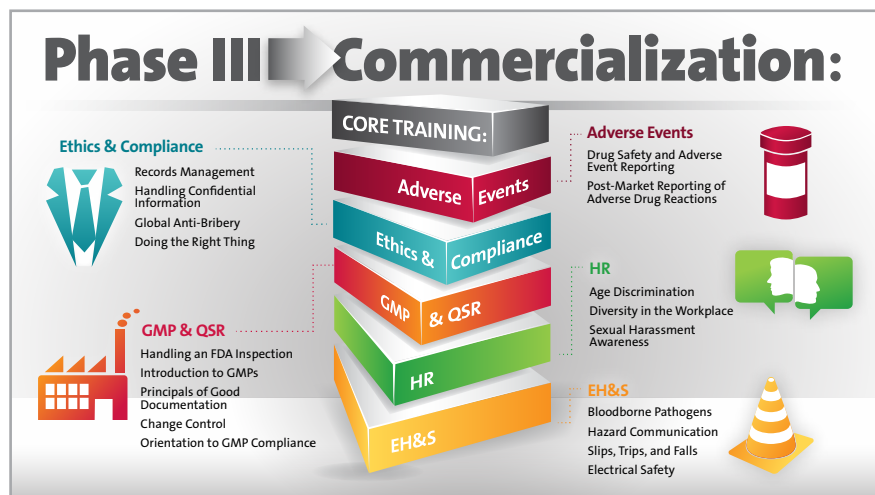
*In our industry, another key challenge is building a proper training infrastructure based on best practices.*

*UL EduNeering has worked with dozens of emerging companies to develop and deploy cost-effective compliance training programs. Our turnkey solution for managing compliance education for employees and third parties enables your team to focus on critical product launch milestones.*

## Let UL Build Your Compliance Infrastructure

Our team of experts includes Corporate Compliance and Quality Executives who have developed and managed programs in the field. By leveraging our program elements, listed on the next page, our turnkey solution has enabled clients to realize these benefits:

- Meet aggressive product launch compliance and certification goals;
- Minimize financial and compliance risks;
- Assure that employees and third parties are qualified to represent your organization;
- Improve employee performance and satisfaction related to training;
- Improve audit readiness;
- Empower managers with visibility into employee compliance metrics.



**Phase III → Commercialization:**

**CORE TRAINING:**
- Adverse Events
- Ethics & Compliance
- GMP & QSR
- HR
- EH&S

**Ethics & Compliance**
- Records Management
- Handling Confidential Information
- Global Anti-Bribery
- Doing the Right Thing

**GMP & QSR**
- Handling an FDA Inspection
- Introduction to GMPs
- Principals of Good Documentation
- Change Control
- Orientation to GMP Compliance

**Adverse Events**
- Drug Safety and Adverse Event Reporting
- Post-Market Reporting of Adverse Drug Reactions

**HR**
- Age Discrimination
- Diversity in the Workplace
- Sexual Harassment Awareness

**EH&S**
- Bloodborne Pathogens
- Hazard Communication
- Slips, Trips, and Falls
- Electrical Safety

## UL's Turnkey Approach: Program Elements

- **Advisory Services**: Our experts will work with your team to build your compliance and quality program to meet regulatory requirements as well as your organization's objectives; this effort can include development of a training matrix that spans all roles within your organization.

- **Cloud-Based Technology Infrastructure**: You will rely on the same training and compliance management system that is used by US FDA to train the agency's investigators; this scalable, cloud-based learning system minimizes IT resources while delivering dozens of features focused on compliance.

- **Distribute and Track Content**: Your organization will gain the ability to organize and distribute a wide range of organizational content, including internal policies, procedures, slides, classroom materials, videos, etc., to targeted employees within the organization.

- **UL's Course Libraries**: You will gain access to our standard online compliance courses, written by industry experts and spanning areas such as Sales & Marketing compliance, FDA Inspection and Enforcement, GxP, Ethics, HR Compliance, EH&S, Adverse Events and more.

- **Risk Assessment Tools**: You can capture and store compliance feedback electronically from employees and third parties, which automates remediation notifications and additional compliance activities.

## We Recommend the Following "Core Courses:"

### GMP – Core Training (Pharmaceutical/Biologics)
Maintenance and Cleaning of Drug Manufacturing Equipment
Conducting Annual Product Reviews
Writing and Reviewing SOPs
Understanding GMPs for Facilities and Equipment
Introduction to GMPs
Implementing an Equipment Qualification Program
Conducting Annual Product Reviews
Implementing an Equipment Qualification Program

### GMP/QSR – Core Training (Medical Device)
Introduction to the Quality System Regulation (QSR)
QS Regulation 3: Design Controls
Writing and Reviewing SOPs
An Introduction to ISO 13485 – The Quality Management System for Medical Devices
Introduction to GMPs
Implementing an Equipment Qualification Program

### EHS – Core Training
Bloodborne Pathogens – General Industry
Hazard Communication
Slips, Trips, and Falls
Personal Protective Equipment
Ergonomics: Body Mechanics and Fitness
Electrical Safety

### Adverse Events – Core Training (Pharmaceutical/Biologics)
Drug Safety and Adverse Event Reporting
Post-Market Reporting of Adverse Drug Reactions

### Adverse Events – Core Training (Medical Device)
Reporting Adverse Events for Medical Devices
Medical Device Safety Reporting

### Ethics – Core Training
Doing the Right Thing – Our Shared Commitment (Mastery)
Records Management
Handling Confidential Information
Global Anti-Bribery

### HR – Core Training
Age Discrimination
Diversity in the Workplace
Sexual Harassment Awareness for Managers
Substance Abuse