

The Foundation of the High-Performing, High-Quality Commercializing Company

BEST PRACTICES FOR TRANSITIONING TO FULL-SCALE PRODUCTION

As emerging Life Sciences companies transition from trials or feasibility studies to commercial production, each executive - from HR to Sales to QA to Corporate Compliance - must deal with hundreds of issues related to scaling up the business: staffing, corporate and GMP compliance requirements, resource allocation and more.

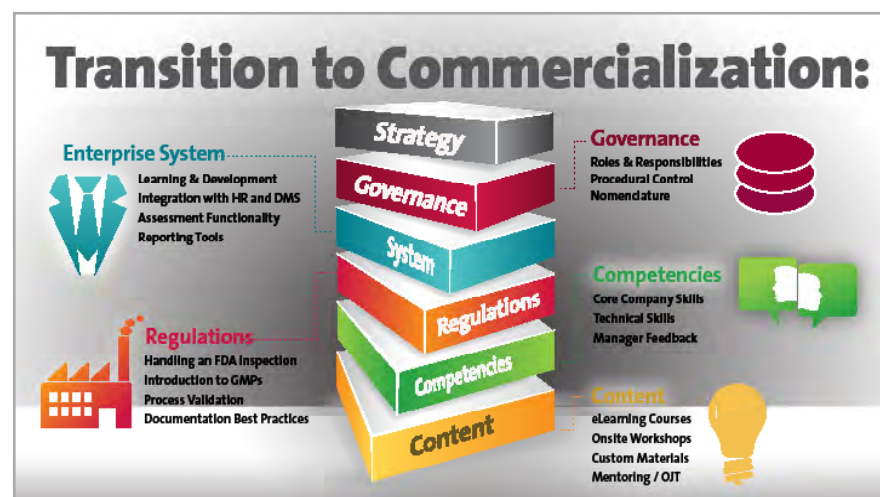
In this brief, we share our model for a learning and compliance infrastructure, which has enabled hundreds of Life Sciences companies to cost-effectively “scale up” their education and compliance programs. These best practices are based on UL projects with hundreds of small to mid-size Life Sciences companies.

UL’s solutions for companies transitioning to commercial operations includes a combination of technology, content and industry experts, who have built learning and development foundations for many emerging Life Sciences companies. As noted in this brief, companies that transition from Phase III trials to commercialization often employ a “siloed” approach to learning and development - in which QA, HR, Corporate Compliance and other departments address their own learning & compliance goals. This approach can put a strain on both budgets and IT resources, but more importantly, it cannot be sustained as the company grows.

Build an Adaptive Learning & Compliance Infrastructure

What UL experts have learned is that clients that transition to the commercialization stage gain long-term value when investing in a holistic and sustainable learning & development infrastructure. The following six elements are part of this infrastructure, which will help all departments better equip themselves to expand into new products and regions:

- Create a Learning and Compliance Strategy that clearly defines the organization’s vision and roadmap for learning and employee compliance, qualification and competency;
- Define a Governance Model that outlines the process, roles, and responsibilities required to execute your strategy;
- Evaluate enterprise learning and compliance systems that address each department’s critical needs; ensure that managers gain visibility into employee compliance and development metrics;
- Conduct on-site, hands-on workshops on GMP regulations and audit readiness;
- Manage competencies that move beyond “check the box” compliance training in order to drive employee competence and performance;
- Leverage “best in class” standard eLearning courses for continuous compliance learning.



Six Key Elements of the Learning & Compliance Infrastructure:

1. **Strategy:** Your organization should include a cross-functional team that devises a business strategy related to compliance, quality, performance and employee development.
2. **Learning Management Governance:** Your learning and development process should include a governance framework, training and computer system policies.
3. **Enterprise System:** Your learning and employee development platform should be scalable, address the needs of HR, QA and Corporate Compliance, and easily integrate with HR, DMS and MES; the platform should minimize IT and Validation resources.
4. **Regulations:** Your QA/RA team should have the tools they need to share critical GxP regulatory training to targeted roles, in concert with SOPs and work instructions.
5. **Competencies:** Your organization should strive to move beyond the basic “check the box” training that is done to meet compliance and audit requirements; this requires that you define the corporate, role and technical competencies that will elevate quality and drive improved business performance.
6. **Content:** You can build your own training content and also rely on third parties for “foundational” regulatory courses and programs, focused on GxP, Ethics, HCP Interactions, etc., so trainers can focus on company-specific topics.

Requirements for Building the Adaptive Learning Infrastructure:



Strategy: Questions to Ask

What are our learning and performance goals?
What does our ideal state of compliance, competency and performance look like?



Governance Model: Questions to Ask

Does our training policy define which personnel must be trained in cGMP?
Do our document and training policies define roles and responsibilities?
Do our document and training policies detail nomenclature requirements?



Enterprise System: Questions to Ask

Does our learning system adhere to 21 CFR Part 11 and Annex 11?
Does our LMS easily integrate with other critical HR and Quality systems?
Can we quickly provide employee qualifications to auditors?
Can we capture role-based qualifications?



Regulations: Questions to Ask

Are our experts prepared for regulatory inspections?
Do our teams know how to write SOPs?
Are our processes and systems aligned with regulatory requirements?
Is our supplier quality system aligned with regulatory requirements?
Are we familiar with regulatory emphasis on data integrity issues?
Have we focused on quality culture throughout the organization?



Competencies: Questions to Ask

Have we defined both core and job-specific competencies?
Have we aligned expected behaviors for each competency?
Can managers easily assess the competencies of each direct report?
Can managers gain visibility into individual competency ratings?



Content: Questions to Ask

Have we prepared product training materials for our sales team?
Have we prepared compliance training for each employee?
Have we prepared a training matrix for each job function?
Have we addressed key training such as PhRMA Code, GMP, etc.?