

Identifying the “Right-Sized” Learning & Qualification System

BEST PRACTICES FOR TRANSITIONING TO FULL-SCALE PRODUCTION

In our previous Knowledge Brief, we shared the “governance” element of the learning and compliance infrastructure.

In this brief, we focus on the Enterprise System element. As an organization gains regulatory approval, and ramps up the manufacturing and sales effort, they often seek a system that can replace a paper-based process and automate employee training and qualifications. For these companies, the governance model lays the groundwork for the enterprise learning and qualification system needed for key areas: HR, QA, Corporate Compliance, Sales, Operations, R&D, and more.

In some cases, the QA team may require a quality management system, which often provides a training module that can record SOP training activities. Unfortunately, this module may not support the needs of other departments. In this brief, we discuss the requirements that UL has gathered from commercializing companies to meet regulatory requirements (GxP, procedural training, etc) plus other departments’ employee development and competency management programs.

The key is that the enterprise learning system must be “right-sized” for an emerging company with tight budget constraints, and still be able to scale as the company’s product pipeline and distribution network expand.



Benefits of the “Right-Sized” Enterprise Learning Platform

There are several business benefits to selecting a sustainable enterprise learning platform that can grow as the company grows:

- Fits the existing training budget without concerns that a new system will be required during the post-commercial stage;
- Addresses current functionality requirements of QA, HR, Sales, Corporate Compliance and other departments;
- Features can be “enabled” as needed with minimal configuration or IT programming;
- Provides functionality “best practices” based on the needs of larger firms in the Life Sciences industry.



Evaluating the “Right-Sized” Enterprise Learning Platform

Many companies about to encounter a period of fast growth have sought a system that can accommodate the changing organization structure.

That means that from the outset, the system must adhere to strict system validation requirements, while also delivering functionality that meets baseline regulatory requirements (SOP versioning control, audit trails, record retention, and more).

The ideal “right-sized” system must also meet the current priorities of key departments, which we have noted in the image below, and include additional features that can be “enabled” as the company adds new employees around the world.

Over the course of a commercializing company’s growth in the first few years, UL has helped clients address these additional learning platform functional requirements:

1. **Expanded Training Matrix & Modalities:** ability to develop more sophisticated curricula, languages and user group hierarchies to support new product lines, facilities, etc.
2. **System Integration:** integration with document management, HR and MES to reduce administrative effort and improve data accuracy.
3. **Expanded Third Party Networks:** ability to educate and certify suppliers, vendors, contractors and even health care practitioners.
4. **Reporting:** as data accumulates, QA and HR need to analyze trends using sophisticated reporting tools.

Enterprise Learning Platform Priorities for the Commercializing Company:

