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When considering employee training, many Life Science organizations make the decision to leverage the training modules offered within a Quality Management System (QMS). QMS applications enable the QA team to record and track quality issues in the manufacturing and operations areas. Many of the top QMS vendors offer applications that include six to seven modules to help QA teams manage documents, CAPAs, change controls, suppliers, training and more.

As these Life Science companies grow and commercialize more and more products, the complexity of employee training increases and organizational training needs stretch beyond the needs of the quality organization. Throughout this growth track, the QA team manages training via the QMS training module: tracking document training and CAPA-related training, etc. However, for larger organizations, there are many limitations utilizing QMS training modules across departments as illustrated on the reverse side.

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Top five limitiations for larger organization when utilizing QMS training modules across departments:

- 1. The QMS training module is often limited in providing the ability to record formal assessments and on-the-job observations; these tools are critical for QA to measure training effectiveness;
- 2. The QMS training module cannot provide tools that enable QA to "segment" learners by specific job function; along the same lines, content cannot be grouped by key product lines or regulatory topics;
- 3. The QMS training module typically offers limited support for "multi-modal" training, so QA cannot move beyond basic SOP and CAPA training; eLearning modules, webinars, classroom events, and other activities often make up rolebased curricula assigned to specific employees across operations;
- 4. Limitations in how you translate your training matrix into a QMS Training Module – you can't set up training by roles and product lines or build "pre-defined" user groups;
- 5. Finally, and perhaps the biggest limitation of the QMS training module, is that it cannot support the diverse needs of other departments, such as HR, Engineering, Corporate Compliance, EHS and Sales; these areas need tools to manage their specific "learning and talent" programs. It's becoming ever more critical that specific departments track performance, development and competency management.

As a company grows, the IT procurement and/or sourcing team has two options:

- 1) Allow each department to select and purchase their own learning system, or;
- 2) Consider a single enterprise Learning Management System (LMS) that can meet each department's needs.

Choosing the second option provides a single solution that can be segmented into "mini learning systems" for each department, removing application redundancy, as employee profiles are stored and maintained in one database; further, IT support and administrative costs are greatly minimized.

Overall, QA needs to be able to integrate QMS document management modules with an LMS to automate the "training assignment" when an SOP is up-versioned. An important note is the regulatory obligation of QA's. Therefore, choosing an enterprisewide learning management system that supports the data integrity requirements of 21 CFR Part 11 and Annex 11 will ultimately save QA departments the time and cost of "retrofitting" these requirements into other systems.

## About UL EduNeering

UL EduNeering is a division within the UL Ventures business unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

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®. In addition, UL offers a talent management suite that provides companies the ability to improve workforce skills & competencies within established role-based talent training programs to drive business performance.

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, 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.