

# Learning Management System EVALUATION GUIDE

***With more than 400 companies with sites in 30 countries, and over 35 million training assignments completed, UL EduNeering is in a unique position to share best practices for global quality and compliance training for regulated companies.***

***In fact, under a unique partnership with the agency, the FDA uses our ComplianceWire® learning management system (LMS) to train more than 36,000 inspectors.***

## **How to Use this Guide**

We developed this evaluation guide to help our prospective clients refine their own evaluation process and provide a starting point for comparing learning management systems. This ensures that these organizations receive the functionality they need in order to make their compliance and quality training effective. Our system, ComplianceWire, meets all of the requirements listed here. Beyond the specific “line item” functionality requirements outlined in this guide, we also believe that core requirements should include:

- 1) A Software as a Service (or hosted) LMS that reduces both IT costs and validation burden, while supporting training to non-employees;
- 2) Designed to be compliant with EU Annex 11 and 21 CFR Part 11 requirements;
- 3) Designed to support the language needs of global learners;
- 4) Designed to be flexible and scalable to respond to evolving training and productivity goals.

## **Core Training Recommendations**

From a training role and regulatory perspective, the LMS should support a company’s objective to standardize qualification and compliance learning, thus reducing the risk of non-conformity. At the same time, quality groups and departmental training teams should be able to gain the freedom to focus on the unique operational and cultural issues that will make training more effective in that facility or area of operation.

We believe a training management system should also provide a method for capturing a “role” or title and the other aspects of that role that you can’t see in the title itself. For example, a “Line Operator” on the second shift in one facility may need to understand the operation differently than the “Line Operator” on the first shift at another site.

Our global clients use ComplianceWire to define role-based “User Groups,” which automate membership based on an employee’s title or role. If the employee receives a new title, he or she is placed into a new User Group and the learning plan is automatically updated.

## **Contact Us for More Details**

Let us know if our Business Solutions Group can evaluate your business and training requirements. Contact us at 609.627.5300 or [uleduneering.com](http://uleduneering.com).





<b>EVALUATION GUIDE SCORING:</b>	<b>3 = FUNCTIONALITY IS AVAILABLE</b>	<b>2 = FUNCTIONALITY REQUIRES CUSTOMIZATION</b>	<b>1 = FUNCTIONALITY IS NOT AVAILABLE</b>
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<b>CLOUD/SOFTWARE AS A SERVICE TECHNOLOGY</b>	Vendor 1	Vendor 2	Vendor 3
Online Learning Management System			
Available to users 24/7 (except for scheduled maintenance)			
Wholly-owned hosting and maintenance of hardware			
Ongoing technology support and maintenance			
Ongoing technology enhancements and upgrades			
Ongoing data storage and security			
All data for active and inactive users always available			
24/7 on-site physical security at data center			
Multiple security layers (including 40/128 bit Secure Socket Layering [SSL] encryption) and user authentication			
Fully redundant network architecture and enterprise-class servers, redundant key networking components (routers, firewalls, data arrays, etc.), all monitored 24/7			
Full application security including security enforcement at every login and page request			
Data backup several times throughout the day. Regular backups made and stored off-site in fire-resistant vault			
Production servers housed in secure and proprietary data center with redundant climate control, power feeds and generator capacity			
TOTAL:			

<b>CLASSROOM (INSTRUCTOR-LED) COURSES</b>	Vendor 1	Vendor 2	Vendor 3
Build multiple classes for a single course			
Enable learners to self-register from a list of available classes			
Classroom waitlist feature with administrator tools			
Instructors can retrieve training item			
Capture attendees via an electronic class roster			
Integrate class registration with Outlook calendars			
TOTAL:			



<b>REPORTING CAPABILITIES</b>	Vendor 1	Vendor 2	Vendor 3
Reporting functionality tool to create standard reports on users, completions, training activities, courses and qualifications			
Automated scheduling and e-mail reports to users and non-users			
Available on mobile devices			
Separate reporting database			
Qualification Matrix reporting			
Flexible design of organizational structure			
Customized login screen with company-branded logo			
Ability to schedule report delivery to senior level management			
Qualification and resource management			
Comprehensive event log of system activities			
Tracking functionality for all users, training and curricula			
=====	=====	=====	=====
TOTAL:	=====	=====	=====

<b>MANAGING ROLE-BASED QUALIFICATIONS AND TRAINING TYPES</b>	Vendor 1	Vendor 2	Vendor 3
Set up automatic e-mail notifications regarding assignments (introduction, pending and overdue) that list actual training items assigned			
Develop role-based qualification and certification programs			
Tracking of equivalencies (eg, an SOP is equal to a classroom event)			
Ability to manage User Profiles, assign course credit and add, modify or deactivate users			
Ability to maintain qualifications (JD, CV, Certifications)			
Qualification record must indicate to a user when a “read, understands and signs” is required			
Ability for both the department manager and training manager to view associated users qualification records			
A user’s training record displays the “read, understood and signed” date of the qualification record			
Score history and report access (allows learners to view progress)			
Define groups of users based on specific department, role, etc.			
Build role-based qualification curricula that includes multiple types of training items			
Establish “assignment” rules so that qualification-related refresher training is automatically set by curricula at a future date			
=====	=====	=====	=====
TOTAL:	=====	=====	=====



<b>MANAGING THIRD PARTY CONTENT</b>	Vendor 1	Vendor 2	Vendor 3
Ability to link to third party courses that have been developed utilizing AICC, HACP and SCORM methodology			
Ability to author course content			
Build stand-alone online exams that store numerical scores			
Ability to have SCORM courses hosted on the learning platform for easy access by learners			
=====	=====	=====	=====
TOTAL:	=====	=====	=====

<b>MULTIPLE LANGUAGE SUPPORT</b>	Vendor 1	Vendor 2	Vendor 3
Interface available in multiple languages			
Launch a single training item that can be displayed in multiple languages			
=====	=====	=====	=====
TOTAL:	=====	=====	=====

<b>CONTROL DOCUMENT TRAINING</b>	Vendor 1	Vendor 2	Vendor 3
Assign internal documents via e-mail notification			
e-Acknowledgement and e-Signature of receipt and understanding			
Ability to link the assignment to the actual internal document and track completions (assignments link directly so learner can review actual files)			
Ability to add a quiz to measure comprehension of document assignment (without requiring programming skills)			
=====	=====	=====	=====
TOTAL:	=====	=====	=====



<b>ADMINISTRATOR SECURITY ROLES</b>	Vendor 1	Vendor 2	Vendor 3
Ability to assign security settings for different levels of system administrators			
Users with appropriate security rights can assign courses to individual students of groups of students			
Ability to limit access to specific data and function based on security rights associated with the user role in the system			
<b>TOTAL:</b>			

<b>JOB SKILL, CREDENTIALING AND COMPETENCY ASSESSMENTS</b>	Vendor 1	Vendor 2	Vendor 3
Ability to create surveys and assessments			
Creation of job-skill and verification checklist with dual signatures			
Record learner feedback on surveys			
Ability to automate risk and competency assessments			
Ability to build user groups based on individual learning assessments			
Electronic storage of curriculum vitae or background			
Health Care facility credentialing program for sales representatives			
<b>TOTAL:</b>			

<b>LEARNING AND COMPLIANCE SOLUTIONS FOR EXTERNAL PARTNERS</b>	Vendor 1	Vendor 2	Vendor 3
Ability to train external vendors, suppliers and non-employees			
Ability for third parties to self-register to receive training			
Ability to upload bulk training items, third-party users and scores			
Ability to assign a third party intermediary within the organization			
Ability to perform risk assessments driving learners into appropriate roles for targeted training			
<b>TOTAL:</b>			



<b>ONLINE COURSE LIBRARIES</b>	Vendor 1	Vendor 2	Vendor 3
Standard Course Libraries: <ul style="list-style-type: none"> <li>• Quality &amp; Good Manufacturing Practices for Medical Device, Pharmaceutical &amp; Dietary Supplements</li> <li>• Global Clinical Management and Site Training for Medical Device and Pharmaceutical</li> <li>• Sales &amp; Marketing (Pharmaceutical/PhRMA Code, Medical Device/AdvaMed Code)</li> <li>• Ethics &amp; Corporate Responsibility</li> <li>• HR Compliance and Risk Management</li> <li>• Health Care (General, HC Industry Reps, HIPAA, Medicare Advantage, Part D)</li> <li>• Energy Operations (OSHA)</li> <li>• Environmental Health and Safety</li> <li>• Personal Care</li> <li>• FDA Inspections and Enforcement</li> <li>• Food Safety</li> </ul>			
Ability to have custom courses developed			
Mobile content available for end users			
Access to UL's Subject Matter Experts for content development			
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<b>DEPLOYMENT AND ONGOING SOFTWARE SUPPORT</b>	Vendor 1	Vendor 2	Vendor 3
Deployment and subsequent work order projects: <ul style="list-style-type: none"> <li>• Project management provided throughout deployment</li> <li>• Promotional and Communications services</li> <li>• On-site kickoff meeting and workshop</li> <li>• Weekly status updates</li> <li>• On-site Systems Administration training</li> <li>• Train the Trainer session</li> </ul>			
Ongoing implementation of enhancements and upgrades			
Quarterly account review sessions			
Training related to new feature enhancements			
Client Service support available 24/7 (phone & email)			
Ability to link to client's internal documentation and support teams			
<hr/> <hr/> TOTAL:			



<b>DATA INTEGRATION</b>	Vendor 1	Vendor 2	Vendor 3
Training data migration from legacy training systems			
Integration with Document Management Systems			
Integration with Manufacturing Execution Systems and Biometrics link to LMS			
Integration with Electronic Data Management Systems			
Integration with Human Resources Systems			
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<b>VALIDATION</b>	Vendor 1	Vendor 2	Vendor 3
Fully-documented, validated system that ensure compliance with 21 CFR Part 11 requirements (FDA regulations for electronic records and electronic signatures)			
A validation process has been implemented, covering planning and execution of validation activities / including required roles			
A 21 CFR Part 11 assessment is in place			
A distinct qualification documentation process is in place, addressing different levels of requirements and design documentation			
A process to ensure traceability			
Audit trails have been implemented and provide information about what data has been changed, by whom and when			
A structured change approach is in place for infrastructure, applications and interfaces, covering the change process (planning, execution and documentation of changes), change logs and different involved roles			
Electronic signatures, if used in the application, are used to sign all regulated documents and activities are tracked with the audit trail			
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## About UL EduNeering

UL EduNeering provides knowledge and expertise that empowers Life Sciences organizations globally to accelerate growth and move from compliance to performance. Our solutions help companies enter new markets, manage compliance, optimize quality and elevate performance by supporting processes at every stage of a company's evolution. These solutions are a combination of advisory solutions with a strong modular SaaS backbone featuring ComplianceWire®, our award-winning learning platform.

UL EduNeering is a business line within UL Ventures. 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.

For more than 30 years, UL EduNeering has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), EduNeering has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations.

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