

Supplier Qualification & Education Solutions

EXCHANGING KNOWLEDGE TO ENGAGE SUPPLIERS AND IMPROVE RELATIONSHIPS



With increased regulatory scrutiny on the Life Science supply chain, many organizations are seeking more formal methods to share critical regulatory knowledge and policies with their suppliers, while also capturing self-assessments and other information.

Supplier relationship teams often struggle to deliver training and communication to suppliers and even sub-suppliers, as this contact information is often not stored on enterprise HR or even the Supply Chain Management System. Rather than deliver this information via e-mail or via conference calls, supplier relationship teams are seeking tools to structure “knowledge exchanges” that convey regulatory issues, policies, product changes and materials to improve knowledge flow to suppliers.

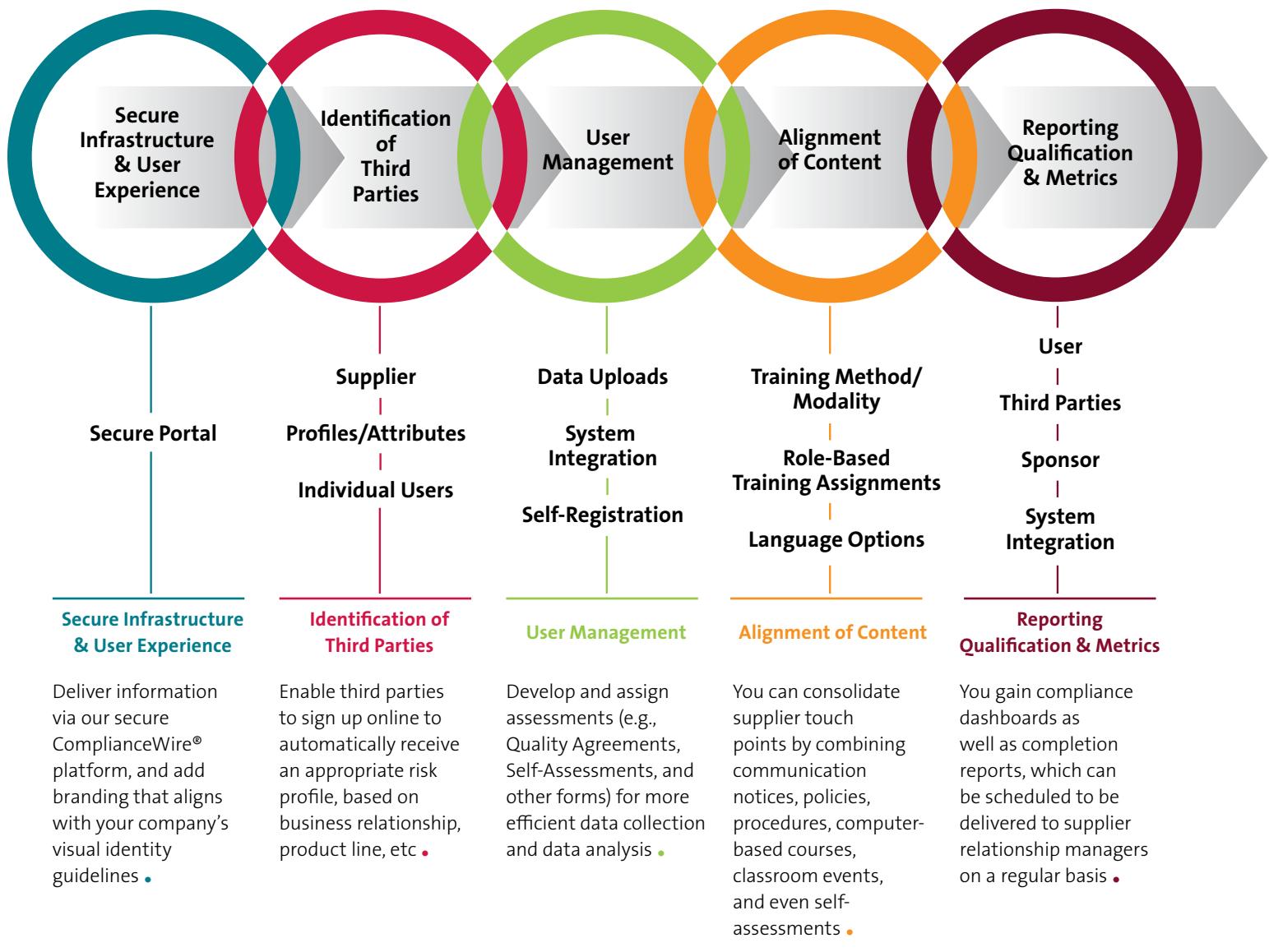
To build an effective supplier qualification program, supplier quality teams need more effective methods for sharing critical information and educational activities with suppliers.

That’s why many compliance teams rely on UL EduNeering’s Supplier Qualification Services, which are centered around our leading web-based platform and quality and regulatory courses. Through this service, leading Life Science organizations can deliver training, send self-surveys for suppliers to complete, conduct ongoing monitoring and deliver critical notifications with electronic receipt to suppliers around the world.

“For example, during the inspection, you indicated that your firm failed to obtain a completed Supplier Self Evaluation from your supplier of [a raw material] used to manufacture your [products]... Your response indicated your firm will ask all approved suppliers to complete revised Supplier Self Survey forms with 3-4 weeks.”

Source: FDA Warning Letter, 2013 <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013>

UL EduNeering's turnkey Third Party Solution, EduNetwork, follows a proven process for delivering training and communications across a secure web platform, based on our experience with leading Life Science companies in capturing third party information. This process is displayed here, with an explanation of each step below.





Additional Benefits Include:

Send Communications & Notifications

Send critical communications and notifications to capture receipt as well as feedback from third parties.

Capture Electronic Signatures

With each activity, ComplianceWire captures the individual's electronic signature, which is unimpeachable and secure, while also simplifying recordkeeping and compliance status reporting.

Receive Full Audit Trails

The system generates an audit trail of all changes made to training items and user accounts, namely the field that was changed, the old value, the new value, the user who made the change and the date/time of the change.

Off-the-Shelf GMP/FDA Courses

Deliver UL's standard online courses covering many GMP and FDA regulatory topics; in addition, our Learning Services team also can develop a custom online course such as "How to Submit a Corrective Action" and other topics.

Leverage UL Audit Services

Leverage our global supplier quality experts who perform on-site assessments locally, saving your audit team travel costs and time away from the office; UL Life & Health experts can also perform RoHS testing & validation, UL rating/certification and other services.

Leverage Our System Administrators

Our experienced administrators can maintain users, content and reports to reduce your administrative effort.

Our Standard Quality courses, which can be used to educate suppliers and build stronger relationships, are self-paced and written by renowned quality and regulatory experts.

- Basics of GMPs
- GMP Principles of SOPs
- Introduction to ISO 13485
- Principles of Good Documentation
- Change Control
- Conducting Annual Product Reviews
- Introduction to QSR
- QSR: Overview and General Provisions
- QSR: Quality System Requirements
- QSR: Document and Purchasing Controls
- QSR: Design Controls



To learn more about our Supplier Qualification & Education Solutions, contact Pat Thunell at pat.thunell@ul.com



Online Self-Assessments for More Accurate Data Analysis

Our Supplier Qualification Solution enables you to capture self-assessments from suppliers. This enables you to review supplier assessments to identify risks and additional activities your company may take as a result.

You can even add rules to self-assessment questions so that suppliers automatically receive new information based on their answers. For example, if the supplier responds “Yes” to the question “Do you use subcontractors” then that supplier automatically receives your policy on notifying your company about these contractors.



About UL EduNeering

UL EduNeering is a business line within UL Life & Health’s Business Unit. UL is a global independent safety science company offering expertise across five key strategic businesses: Life & Health, Product Safety, Environment, Verification Services and Enterprise Services.

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®.

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, UL 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.