

EduNetwork

A Blueprint for Managing Third Party Compliance Risks



The Growing Need to Identify Third Parties

Around the world, regulatory agencies and industry associations are focusing on the risks posed by non-employees who are acting on a company's behalf.

For example, Medical Device advocacy organizations AdvaMed and EucoMed have released *Joint Guidance on Ethical Third Party Sales and Marketing Intermediary (SMI) Relationships*, which encourages companies to adopt a Third Party SMI Management Compliance Program. The suggested program includes several elements, including anti-corruption policies, regular risk assessments, an ongoing diligence program, and an ongoing training program.

Overcoming the Hurdles

There are several external factors that prevent a compliance team from putting in place a rigid, tightly controlled third party audit process and training program. Most common is a lack of information around those individuals, as well as frequent turnover that makes ongoing compliance challenging.

Today, companies must demonstrate to internal and external auditors that they have conducted anti-corruption and other compliance programs to their global distributor network. This can only be accomplished when third party “end users” – each individual reseller, agent, advisor and/or consultant – has demonstrated that they understand your anti-corruption policies. You may even need to drill down even further, and deliver targeted compliance activities to a specific “role” such as a service technician or an agent focused on government-related clients.

A Blueprint... and a Solution

UL Quality, Compliance and Learning has successfully implemented third party training solutions that focus on two key steps:

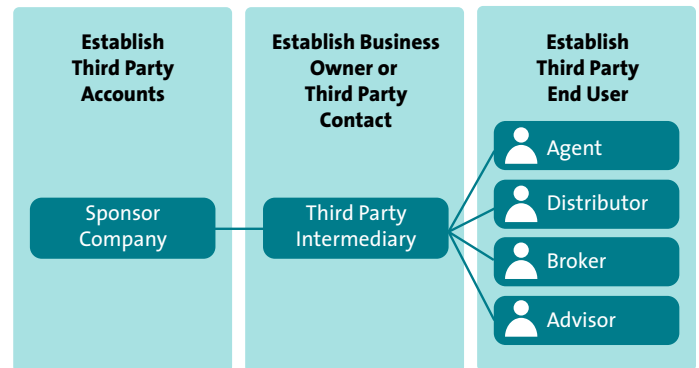
- 1. Identifying** and categorizing third party end users;
- 2. Managing** the ongoing compliance program. Compliance teams can rely on our EduNetwork tool to fulfill these requirements, as it provides a knowledge repository of third party end users, enables you to conduct risk assessments, delivers critical compliance training materials, and captures completions for audit purposes.

In this way, sponsor companies can demonstrate to internal and external auditors that they have conducted anti-corruption due diligence programs that span across the third party network.

Step 1. Define Third Party Management

The first step is defining the type of third parties that will be part of the program, and how your organization will manage the relationships.

As this chart demonstrates, one best practice is to leverage Third Party Intermediaries (TPI), who are often your company's business owners for third parties. These business owners will be responsible for managing the communication and administrative effort related to this third party.



Requirements for Third Party Management

Q. Which Third Parties Will be Included?

For many organizations, any non-employee may be considered a third party. However, casting this wide net may result in unnecessary training and communication to “low-risk” third parties, such as those that don’t interact with the sponsor’s clients. Compliance teams may decide that sales agents and service teams represent the highest risks and focus their attention on these types.

Q. Who Are the Business Owners?

Once the third parties have been identified, compliance teams need to identify which employees will serve as “business owners” of that third party. The business owners will already have specific duties that revolve around contractual obligations, scheduling of activities, budgeting issues and more. Compliance teams can include compliance-related communication and training into this set of responsibilities.

The business owners may also be tasked to identify the number of learners required within each entity. They must also notify the third parties about taking training and policies, thus removing the burden from the compliance team.

Q. What Activities and Items Will be Included?

Once the third parties have been identified, compliance teams need to map information and training requirements to each category. A reseller may receive different anti-bribery training, while an advisor may receive training on education events, for example.

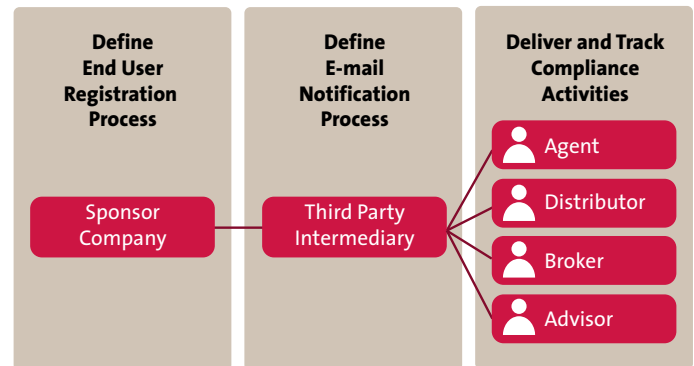
As you consider these activities, and these training items, you need to ensure they are delivered securely.

As explained on the next page, a secure compliance and learning management system enables you to identify and categorize users, then organize your computer-based courses, corporate policies, live classroom events, webinar events and more, without interfering with your company’s IT firewall policies.

Step 2. Manage the Compliance Program

The second step is to define the processes that will enable your organization to manage third party compliance in a way that is sustainable and consistent.

As this chart demonstrates, the sponsor company needs to capture the third party end user registration, to ensure proper training and audit reporting outcomes. In addition, the sponsor must define a notification process and training schedule for each end user.



Requirements for Managing the Program

Q. How Will End User Data be Captured?

Your company may have unique information to capture about each third party, to help with assignments and reporting purposes. With EduNetwork, you can have these unique attributes built into the self-registration page, such as “Type” (supplier, reseller, contractor, etc). This drives specific training to those groups based on the type of end user, and also helps build targeted reports.

An optional SmartForms tool enables you to automate risk assessment, in which learners will be added to a “low risk” or “high risk” user group, based on answers they provide in an electronic form. The specific user group receives the appropriate materials.

Q. What are Business Sponsor Responsibilities?

In the first step, you have identified a business sponsor at your company who is responsible for the third party relationship. Alternatively, you may have defined a relationship manager within the third party itself.

The compliance team must define a procedure that outlines the responsibilities of the business owner, such as notifying new end users and “retiring” end users.

Q. How are Notifications Managed?

The business owner initially records general third party information into EduNetwork. But the third party end users must be responsible for their own data. EduNetwork accommodates this task by allowing a number of “learner seats” to be defined. The business owner can then share unique authentication codes to the third party so end users can “self-register” within EduNetwork.

Business owners and end users can then be notified automatically on when to register. When the end user successfully registers, the account is activated and training is then assigned based on the attributes entered by the end user.

Q. How are Critical Information and Training Delivered?

Your compliance training programs may contain a wide range of content: anti-corruption policies, FCPA or UK Bribery computer-based courses, technical specifications, or an electronic consent form, etc.

Designed to meet stringent 21 CFR Part 11 requirements for electronic signatures, EduNetwork enables the compliance team to build “curricula” that are then assigned to each end user to complete via the web.



About UL Quality, Compliance and Learning

UL Quality, Compliance and Learning 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 Quality, Compliance and Learning 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 Quality, Compliance and Learning 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.