

A Quality and Compliance Training Road Map for Emerging FDA-Regulated Companies



Emerging Company Training Road Map



Executive Summary

Quality and compliance leaders within emerging life science companies face the same compliance and regulatory pressures as larger life science companies.

Often compounding this issue are lean business models in which key production, sales and operational functions are outsourced. This results in the need to disseminate training on key policies, procedures and regulations to a wide audience without the benefit of a dedicated training team.

What these companies demand are solutions that automate the quality training effort without compromising the entire quality program.

Further, paper-based programs have proven to be unsustainable, leaving an organization vulnerable to audit findings and product quality issues.

Kaplan EduNeering has successfully delivered compliance training programs to hundreds of life science companies, including many small to medium organizations. These companies now have world-class quality and compliance programs that automate training, communication and record-keeping.

Stage#1: Move from Paper to Electronic Platform

Many small to mid-sized companies struggle just to meet ongoing global quality and compliance regulations. As such, the challenge of developing a well-defined training management process may be sitting on the back burner.

Unfortunately, what many executives have learned is that a paper-based training and record keeping program can quickly become costly, error-prone and time consuming. The effort spent generating reports for audits and organizing training content is ineffective. By moving to an electronic platform, multiple cost and efficiencies can be recognized:

- Organizational roles are aligned with the training and qualifications;
- Audit reports can be generated in minutes, as opposed to the hours needed with a paper-based system;
- Assessments can be delivered to measure knowledge retention, thereby improving the training experience;
- Learners gain visibility into their progress on all activities, from SOP reviews, to classroom activities, to computer-based training;
- Training costs related to travel and expenses are reduced.

Stage #2: Standardize Training Content

Once the “paper to platform” transition is defined, the company must identify a process that standardizes training content. How an organization defines “qualification requirements” and how the electronic platform executes on this process may be two different things. The platform should contain efficiencies that can help shape the processes by which training content is controlled “outside” of the platform.

For example, quality and compliance teams must define the role of the training content owners. These individuals must ensure that policies and related training are current, consistent and targeted to the right employees or contractors. The content owners are expected to know how often to review content, when to add new procedures, how to leverage nomenclature, how to build assessments, etc.

Finally, content owners must define the appropriate criteria or user attributes that apply to the curricula that they manage.

Because content owners may be dispersed throughout an emerging company, quality and compliance leaders should develop a coding structure of all the training materials to ensure accurate assignments and reporting.

Stage #3: Improve SOP Retention

After the content has been standardized, emerging companies need to focus on SOP training management. Regardless of size, companies in the life science industry have upwards of 100 SOPs that require training. It is critical that a risk assessment be conducted to determine which of these documents can be treated with “read and understand” and which require more formal assessments -- to ensure that learners comprehend the material.

FDA has specifically identified operational areas that fall under cGMP and — by extension — SOP regulation. The components for which employees must have sufficient knowledge to perform their job functions adequately, range from buildings and facilities to equipment, complaint management, components, packaging and labeling, laboratories, and returned products. Many emerging companies have addressed SOP compliance by including activities that include:

- Creation of a quality control unit responsible for ensuring SOP compliance;
- Writing SOPs for each job task that are updated and understandable to employees and contractors;
- Accurate, timely distribution of SOPs to all responsible parties, and validation that the SOP has been received and understood;
- Assessments that ensure employee comprehension of the SOPs and the ability to apply the knowledge contained in the SOP;
- Comprehensive corrective and preventive action.

We’ve learned through hundreds of deployments that an online learning platform can significantly improve SOP distribution and comprehension through online assessments that are linked to the SOP assignment.

Stage #4: Align the Training Matrix by Role

At first glance the training matrix is simply an inventory of the curricula that will be delivered to specific roles. But the success of the online learning platform depends on how well this matrix is defined. The ideal training matrix contains a list of role-based curricula that lists each relevant training item: classroom events, on-the-job observation, podcasts, online courses, synchronous training, job-aids, simulations, and more. This content then is a reflection of the defined qualifications or certification of each role within the organization.



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White Paper

Emerging companies must review their existing training matrix and alter their internal processes to align with platform functionality (how the system automates group membership based on criteria, for example).

Quality teams must ensure that a curricula's assignments are of a manageable size for the individual learner; due dates, retraining periods, and sequencing should be automated within the platform. What's more, organizing user groups by a specific hierarchy type (Facilities, Departments, Roles) can further automate the training matrix management.

Contractors and suppliers shouldn't be neglected. In some cases, emerging companies should focus as much as critical knowledge to third parties as they do their employees, given the integrated roles that contractors and vendors play in functions such as production and sales.

Stage #5: Provide Management Visibility into Training

An emerging company's training program should stress accountability, and this means delivering training and performance reports to senior managers and department heads. For example, a company may define a process in which managers must review incomplete training assignments of their team members.

Two other metrics that are used by small to mid-sized organizations to measure enterprise-wide effectiveness are: 1) the training completion rate (overall percentage of user completions); and 2) the qualification completion rate (how far along the employees are to completing a curricula).

Conclusion

As emerging companies create their road map for growth, they need to include the impact that training can have on standardizing their entire business operations.

Using these five stages, an emerging company can transition from a paper-based filing training management process into a scalable electronic platform that grows with the company, while leveraging the technology that's offered through the LMS itself.



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About Kaplan EduNeering

Kaplan EduNeering (www.kaplaneduneering.com) is part of Kaplan, Inc., a worldwide education services leader and a subsidiary of The Washington Post Company (NYSE: WPO). Kaplan EduNeering develops technology-enabled knowledge solutions for improving business performance and assuring regulatory compliance. For more than 30 years, the company has served corporate and government clients in the life sciences, healthcare, energy and industrial sectors using proprietary learning management platforms that integrate business, learning and technology.

For more than 10 years, under a unique partnership with the FDA’s Office of Regulatory Affairs (ORA), Kaplan EduNeering has provided the online training, documentation tracking, and 21 CFR Part 11-validated technology system for ORA-U, the FDA’s virtual university.

Kaplan EduNeering is also the exclusive online partner for compliance solutions to AdvaMed and the Medical Technology Learning Institute (MTLI), delivering compliance education to AdvaMed’s members, including an engaging online course on the AdvaMed Code.

Kaplan EduNeering and the Drug Information Association (DIA) formed a strategic alliance to create online educational offerings for biotechnology, pharmaceutical, academic, and regulatory professionals around the world. DIA members gain access to Kaplan EduNeering’s online compliance solutions, which are used by over one million individuals in more than 50 countries.

Kaplan’s Worldwide Offices

Headquarters

202 Carnegie Center
Suite 301
Princeton, NJ 08540
Tel: 609-627-5300
Fax: 609-627-5330

EMEA Office

52 Grosvenor Gardens
London
SW1W 0AU
United Kingdom
+44 (0) 207 811 3041

Beijing

Yufei Tower, Rm 1516
42 Dongzhimenwai Avenue
Dongcheng District
Beijing 100027 China
+86 10 8454 9958

Houston, TX

3700 Bay Area Blvd.
Suite 550
Houston, TX 77058
Tel: 281-709-0900
Fax: 281-709-0907

Hong Kong

Room 601-6, 6/F
Harcourt House,
39 Gloucester Road,
Wanchai, Hong Kong
+852 2116 3308

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