Product Launch Puts Compliance Training on the Fast Track

PHARMACEUTICAL BEST PRACTICES

Life & Health

Executive Summary

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In April 2013 Raptor Pharmaceuticals hit an important milestone when the 50-employee company received approval from the U.S. Food and Drug Administration (FDA) for its first product, PROCYSBI®, for management of nephropathic cystinosis in adults and children over the age of six. Celebration quickly gave way to planning for commercialization of PROCYSBI. The first order of business was compliance.

Paul K. Ross, Vice President, Chief Compliance Officer, had experience working with young companies with limited resources and early-stage risk management structures in place. He was brought into Raptor shortly prior to the FDA approval with a straightforward charge: Get the organization's compliance processes "launch ready" ASAP. The schedule left no time for delays or missteps. "Under the best of circumstances, building a fully functioning compliance program takes 18 to 24 months," said Ross. "We had a week to assess the risk management needs and begin implementing the basics before the launch of our first commercial product."

Gearing Up

Ross was armed with a proven checklist from past experience. First, he drafted and operationalized a suite of health care compliance policies. Then, he and his small team partnered cross-functionally across the company to develop a plan for training. "As one of the seven critical elements of an effective compliance program, it was a priority for us to build a compliance training capability." Raptor's small size proved advantageous for initial training. "In the early months I did a lot of face-to-face training but we always knew that wouldn't be sustainable as the company grew. We needed to implement a system that was both scalable and enduring."

Ross had worked with ComplianceWire® and UL EduNeering's library of compliance courses earlier in his career. "Leveraging that experience, we met with UL, laid out a curriculum that fit the company's current and future needs and set out to deliver a system that could grow with our company." In addition to training on the company's Code of Business Conduct and Ethics and suite of health care compliance policies, the initial training curriculum included standard training modules from UL on compliance topics including global anti-bribery, FCPA, HIPAA, Insider Trading and the PhRMA Code. All courses were scheduled, distributed, tested and documented in ComplianceWire.

Based on the system's success, other departments within Raptor such as Human Resources and Quality are now collaborating with Compliance to incorporate their training needs into the program. HR has added courses on General Harassment, Sexual Harassment (Employees) and Harassment Avoidance (Managers). At the same time, the Quality Department has added its own curriculum that includes Recalls, Introduction to GMP, Orientation to GMP Compliance and QA Complaints. Future plans include the addition of GxP SOPs and expanded health care compliance topics.

Compliance Training Best Practices

The development, implementation and expansion of Raptor's compliance training program illustrates a series of best practices that can provide guidance to other life science companies in building and managing their own systems.

1. Control the Startup

Raptor began its training program with six core training modules. "The easiest way to stumble during the launch of a training solution is to inundate people with too much too quickly. Balancing the need for immediate training with the burden of the initial bolus of on-line assignments is sometimes an art when considering the success of adoption," said Ross. "We initially focused on core health care compliance topics to bring employees up to speed with compliance basics and then paced additional modules with the organization's bandwidth and needs."

2. Build in Scalability

When Raptor launched its compliance program, the company had 50 employees. By the end of 2014, that workforce had grown to 240 employees and the company's operations had expanded from its original US facility to offices in the Netherlands and Germany. "We knew we wanted a system that was scalable," explained Ross. "ComplianceWire distributes training regardless of geography. Currently, all full- and part-time employees across the globe are captured in our ComplianceWire system and we are looking to make the system available to our third parties in the near future."

3. Demand Versatility

"Our system is designed to be flexible," noted Ross. From its compliance training launch, Raptor's training system has grown to meet additional needs for its HR and Quality Departments. "ComplianceWire has a number of additional capabilities and applications which we are currently exploring for expanded use, including distribution of training to our contracted partners and further utilization of metrics and ComplianceWire dashboards."

4. Aim for Proficiency, Not Just Training

"While it was obvious that we needed a training system, our executive leaders were eager to put something in place that exceeded the bare minimum requirements. We wanted a system that would demonstrate learning proficiency even before the field teams were given permission to call on customers," said Ross. "We wanted a demonstration of training proficiency that would weather any regulatory inspection."

5. Ditch the Paper

"The training system is very efficient, and that efficiency was not a hard sell," explained Ross. "Every employee had a thick paper training binder sitting somewhere on their shelves. So when we asked, 'How do you feel about training at your fingertips, on any device?' there wasn't much opposition." FDA's emphasis on electronic recordkeeping is likely to drive even greater support for expanding the use of ComplianceWire.

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Looking Forward

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Since FDA approval for its PROCYSBI, Raptor has racked up a row of successes. The company received approval for PROCYSBI from the European Commission in September 2013 for the treatment of proven nephropathic cystinosis. Raptor has active clinical development programs based on its proprietary extended and delayed release formulation of cysteamine bitartrate for the potential treatment of Huntington's Disease, Nonalcoholic Steatohepatitis (NASH), Leigh Syndrome and other Mitochondrial Diseases.

"We're a global company that is growing very fast," said Ross. The challenges of that growth include managing the training and compliance of a dispersed workforce. "We have a system in place that meets our current needs and allows for future scalability." As a further validation of Ross's enthusiasm for UL's solutions, he commented, "I'm continually impressed with ComplianceWire and would recommend it as a staple of any growing organization's compliance program."

About UL EduNeering

UL EduNeering is a business line within UL Life & Health's 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®.

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.

202 Carnegie Center
Suite 301
Princeton, NJ 08540
609.627.5300

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