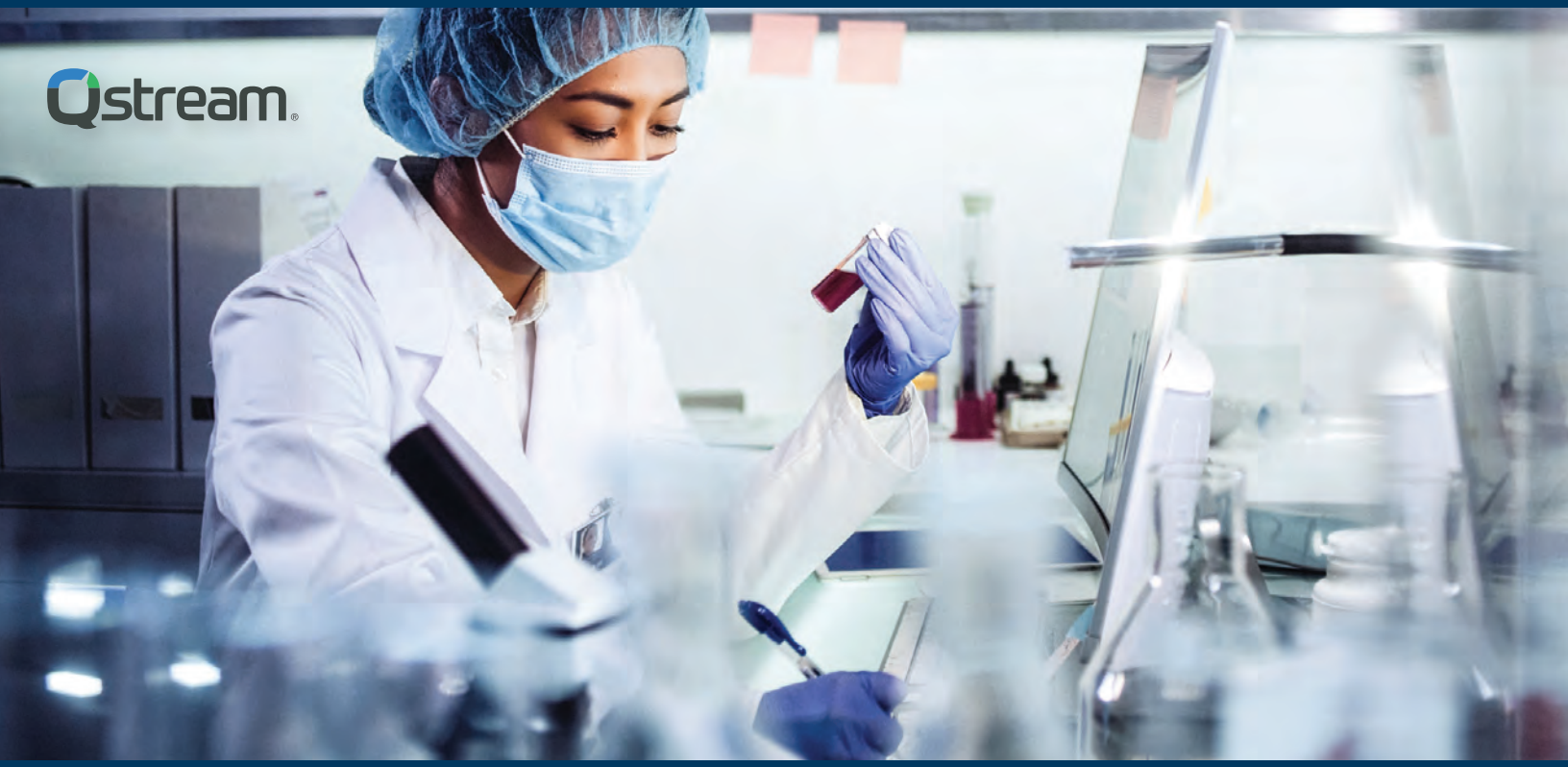

Modernizing Compliance Training To Meet The Evolving Demands Of Life Sciences

The life sciences industry is introducing more complex products, experiencing frequently changing markets and seeing ever-increasing expectations from healthcare providers and patients. This is the reason why leading pharmaceutical, medical device and biotechnology companies are using microlearning, a modern solution to make training more accessible, less disruptive and adaptable.

In the life sciences industry, regulatory compliance training is rarely seen as more than a "check-the-box" exercise measuring completion instead of proficiency in a particular subject area. But in this high-stakes environment, failing to follow the industry's copious rules and regulations can be costly.

Companies are routinely the targets of penalties. According to a study of 26 large drug firms published in the *Journal of the American Medical Association*, 85% received financial penalties over a 14-year period. Fines for activities like pricing violations, off-label marketing and kickbacks cost the companies $33 billion combined.[1]

Mistakes made during clinical trials can also damage companies by delaying when a product reaches the market. Each day that a trial is delayed costs companies between $600,000 to $8 million, according to *industry estimates*.[2]

Whether a life sciences company is training its sales force on rules about off-label promotion or trying to improve the competencies of its clinical operations team, regulatory compliance training can be the key to mitigating risk and protecting investments. Here, we offer suggestions for modernizing your compliance training strategies to ensure your employees are up to speed on any new (and existing) regulations so that business expectations are met and your brand reputation is protected.

[1] DG Arnold, OJ Stewart, T Beck, *"Financial Penalties Imposed on Large Pharmaceutical Firms for Illegal Activities,"* JAMA 2020;324(19):1995–97.

[2] *"Accelerating Study Start-Up: The Key to Avoiding Trial Delays,"* Association of Clinical Research Professionals blog, Feb. 1, 2017.

Make sure compliance training results in business impact

When regulatory compliance training isn't optimized for learning, it is quickly forgotten. And as a result, it rarely has a business impact.

That was the case for one biopharmaceutical company that was struggling to improve the proficiency of its site monitors, specifically related to their risk-based monitoring (RBM) practices. Traditional training had failed to achieve the desired outcomes, and the success of the product was on the line.

When the company implemented a microlearning platform that enhanced knowledge retention and provided real-time proficiency data for each site monitor, compliance with regulations and standard operating procedures (SOPs) improved. Within a year, the company achieved an average proficiency increase of 9.7%, directly correlating to a return on investment.

Improve knowledge retention up to 170%

Increase proficiency by 17%

93% **engagement** rate

Deliver compliance training in the flow of work to not kill productivity

No function in a life sciences organization can afford to waste time, particularly today's clinical operations teams, who must meet tight deadlines to keep trials on track while adhering to scores of FDA regulations, good clinical practices (GCPs) and other country-specific rules.

To effectively train employees in much less time than traditional training programs, many life sciences companies use microlearning strategies that allow employees to "learn in the flow of work." For time-pressed clinical operations teams, microlearning can help them quickly build the knowledge they need to help prevent mistakes during clinical trials that can compromise patient safety or data accuracy, or cause research and development (R&D) costs to escalate.

The most effective microlearning uses a spaced learning model that applies principles of the testing effect, which shows that learning is enhanced when training programs provide immediate answer feedback. This has been shown to improve knowledge retention by up to 170%. Greater knowledge retention can help clinical operations teams achieve better compliance with SOPs so their studies can be "inspection ready" at a moment's notice.

Create compliance training courses that provide job-relevant context

In the life sciences industry, regulations are constantly changing, affecting every aspect of product commercialization from R&D to sales. On the sales side, for example, many organizations have been training their commercial teams about new changes to the PhRMA Code that affect company-sponsored speaker programs and other sales activities.[3]

However, training programs in the life sciences industry often use stale, generic scenarios that don't mimic the true challenges faced by representatives interacting with clinicians in the field. The same is true for scenarios designed to train employees in other functions, including production supervisors overseeing good manufacturing practices (GMPs) on the floor of a manufacturing facility.

Yet when training is designed by experts who understand the life sciences industry, the scenarios are not only relevant and timely but can also lead to meaningful behavior change. Through scenario-based learning, leaders can quickly hone their team's critical thinking abilities so employees can apply what they have learned to a variety of complex situations in the real world. Teams also benefit from practicing in a low-stakes environment first so they can avoid making mistakes on the job, which could result in severe clinical and financial consequences.

[3] Pharmaceutical Research and Manufacturers of America, *Code on Interactions with Health Care Professionals* (PhRMA, July 2021).

Using scenario-based questions to improve critical thinking skills and on-the-job behaviors has been shown to increase job proficiency by 17% on average. For sales teams, this may translate to more ethical interactions with healthcare professionals and fewer financial penalties, as well as better reputation management. For production supervisors, higher proficiency may result in more efficient completion of their production timelines and greater ROI on expensive manufacturing equipment.

Think past completion data, collect actionable analytics

Cross-functional collaboration is required throughout life sciences organizations, whether teams are working together on quality assurance, logistics or market access. If just one employee has low proficiency on a particular topic, the entire team's performance can falter.

A recent example concerns reporting to meet new drug price transparency laws that vary by state.[4] To meet the various reporting requirements, leaders from compliance, legal and brand teams must work together effectively. For cross-functional teams working on drug price reporting, better proficiency can ensure that the organization meets state requirements in a timely and efficient manner. If they fail to report complete and accurate pricing data, they could face hefty penalties, as much as $10,000 per day in one state.

Identifying the "weak link" on a cross-functional team can be difficult without sophisticated, real-time analytics that can alert managers to opportunities for targeted coaching for each employee. In-depth analytics provide granular insights into an employee's proficiency and performance by topic. By identifying skill and knowledge gaps, leaders can direct future training only where it is needed (at the individual, team, department, regional or country level). In this way, proficiency analytics can help leaders avoid costly errors and deliver true ROI on their compliance training for their organizations.

Turn compliance training into engaging learner-centric experiences

Whether they work in a lab or a manufacturing unit, employees say life sciences organizations waste their time on regulatory compliance training that is dull and not tailored to their individual needs. In contrast, personalized regulatory compliance training shows employees in every function they are respected and valued.

Rather than a one-size-fits-all approach, the most effective microlearning is personalized to the needs of each unique audience. Employees in life sciences organizations appreciate this type of personalized training because they recognize it makes them better at what they do. For example, it can help quality control teams promote good laboratory practices (GLPs) to ensure the safety and quality of chemicals used during manufacturing. It can also help regulatory affairs specialists ensure more accurate regulatory filings to obtain faster product approvals so a product reaches the market sooner.

Personalized training promotes better engagement. Creative gamification strategies, such as utilizing a point system and leaderboards, also keep employees interested by fostering friendly competition amongst peers. Research has shown that microlearning including these elements can achieve a 93% engagement rate.

Your Strategic Partner for Regulatory Compliance Training

In order to modernize your compliance training, look for a partner who understands the life sciences industry and can help you meet the needs of your employees as well as your internal stakeholders. At Qstream, we recognize the unique challenges of life sciences companies. We can optimize your existing regulatory compliance training to make it more impactful, or our instructional design experts can create brand-new learning content for you.

[4] *"Prescription Drug Pricing Transparency Law Comparison Chart,"* National Academy for State Health Policy, Nov. 1, 2021.

Developed at Harvard Medical School, Qstream's simple, scalable mobile microlearning platform can help you reinforce the competencies that matter most to your team. Qstream's scientific approach has been validated in more than 22 randomized controlled trials to improve performance and sustain behavior changes.
Our team of content experts can help you build effective regulatory compliance training programs on topics such as:

- Site monitoring and clinical trial management
- SOPs and protocols
- International Council for Harmonization (ICH) E6(R2) compliance
- Off-label marketing
- Anti-bribery laws
- Safety regulations
- Good manufacturing practices (GMPs), good laboratory practices (GLPs) and good clinical practices (GCPs)
- Adherence to RBM practices and processes
- Sponsor management
- Field operations monitoring
- Intellectual property rights (IPRs)
- Antidiscrimination and unconscious bias

Within the life sciences industry, Qstream's platform can help speed the commercialization of your products by improving the proficiency of employees in critical functions including R&D, manufacturing, quality assurance and control, technical services, logistics, regulatory and medical affairs, supply chain, marketing and sales.

We're already working with the leading pharmaceutical, medical device and biotechnology companies of the world and it is possible that your organization is utilizing and seeing substantial results using the Qstream microlearning platform.

Qstream®