

Caution: New Regulations Ahead

Get Ahead of the Curve with a Learning Management System



Congress passes a \$2.7 billion dollar FDA budget for 2009 representing a 5.7% increase over the previous year, making more audits a likelihood and compliance a top issue for executives of every regulated organization.

President Obama proposes a 19% hike to increase the FDA 2010 budget to \$3.2 billion, as his administration hopes to fortify inspections with the additional budget allocation among other items.

The U.S. Department of Health & Human Services states that with the additional funds and resources, the FDA will be able to conduct an additional 1,000 domestic inspections of food and medical products.

The FDA is favoring more of a “prevention strategy” than an “intervention strategy” for the near future.

What does this mean for companies that fall under the close scrutiny of the FDA? They can anticipate more inspections with even greater stringency. With the current state of the economy, companies simply cannot afford to be out of compliance. When profits are soaring, writing the check for a penalty is less painful or threatening than when times are tight. By contrast, when profits are down, that same penalty has a greater percentage impact on earnings or can make the difference between profit and loss.

With the looming prospect of increased FDA audits for 2009 and beyond, organizations must ensure all of their training records and paperwork are up-to-date, organized, and readily available. One way an organization can help manage compliance requirements, in addition to tracking records, is through a learning management system (LMS). Many organizations have specifically mandated training courses that employees are required to complete to maintain regulatory compliance. Training programs create well-informed employees who are more prepared to perform their daily tasks. The likelihood of an employee mishap that puts consumers at risk or of a fine or lawsuit can be greatly reduced through comprehensive education.

Additionally, an LMS implementation has an immediate return on investment - 65% of individuals reported their satisfaction with the ROI after an LMS implementation, per the eLearning Guild Research group¹. The business case for the investment is easy to make with the benefits of an LMS far outweighing the costs. Compliance benefits include:

- Authenticated and centrally-maintained training records,
- Qualifications tracking by individual or teams for shift-planning, performance management, and employee development,
- Immediate training availability to ensure individual qualifications are maintained, and
- Facilitated reporting for auditing.

Beyond just the compliance benefits, additional benefits include enhanced training accessibility for a distributed workforce, reduced travel costs related to training, and customized training content by individual job responsibilities. These benefits are realized immediately after an implementation with no additional investment of time or money needed. According to Bersin Associates research, a learning management system enables 25-35% improvements in learning operational effectiveness and efficiency².

“The difference between the employees that work for a regulated company that have an LMS versus those that do not is the level of preparedness during a regulatory audit.”

Another integral benefit is that an LMS is a key part of a comprehensive talent management strategy. In fact, the FDA recommends proactive measures related to talent management including succession planning and training as essential tools in proper quality systems management³.

According to Mike Leary, a partner at Clarkston Consulting with over 13 years experience in management consulting and practical systems, “It is nearly impossible to just expect employees to ‘do the right thing’ and stay abreast of all the possible training changes in their company without an LMS.”

Marie McDonald, an associate partner at Clarkston with expertise in regulatory compliance and auditing, added, “Without having a well- defined and readily accessible LMS, it’s difficult to provide evidence to auditors that their employees have been trained effectively.”

In this VIEWpoint, we sat down with Mike and Marie to get a better idea of why an LMS is important for regulated companies; the consequences that might occur for a company that does not have one; how an LMS helps with quality control and process improvement, as well as some of the major compliance requirements companies are facing today.

Per the FDA, “...continued training is critical to ensure that the employees remain proficient in their operational functions and in their understanding of CGMP regulations⁴.” The FDA expects managers to establish training programs that include the:

- Evaluation of training needs
- Provision of training to satisfy these needs
- Evaluation of effectiveness of training
- Documentation of training and/or re-training”

An LMS enables you to meet these compliance requirements easily through competency management, skill-gap analysis, training evaluation, and centrally-maintained, authenticated training records.

Why is an LMS especially important for companies that must survive in a compliance-driven environment?

Mike: The goal of any regulated company should be: “say what you do and do what you say.” Companies need to have a clear definition of policy, as well as the intent of that policy. An LMS gives companies the flexibility to establish a curriculum and manage the training associated with it, allowing the business to gauge compliance with its stated policy. The most successful companies have used learning management systems to aid employees by performing both of those functions effectively.

Marie: One of our clients received a warning letter from a regulating agency because they were having an issue adhering to product packaging regulations. When the client began to investigate the source of the issue, they realized that people were not being trained adequately. Additionally, no single location existed where upper management could track who has been

Learning Management System (LMS)

In addition to supporting your compliance needs, an LMS is a key part of a comprehensive Talent Management strategy. It can be a low-cost investment to quickly enhance your talent management capabilities and internal services.

An LMS is a complete software package that enables management and delivery of learning content and resources to students and/or employees. A typical LMS provides functionality in six areas: registration management, competency definition and management, skill-gap analysis, training delivery, training pre- and post-assessment, and compliance (notifications, tracking, and reporting).



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trained, when the training took place, and what courses were covered. The client began to realize that if a robust LMS system had been implemented, a lot of issues they faced could have been prevented. Companies should be considering an LMS long before they are issued a warning letter.

What are some of the consequences for a company if they do not implement an LMS?

Mike: Without an LMS, it is possible to ensure training manually, but it is far more costly and time consuming. Companies spend way too much time tracking and ensuring compliance. Often, the first thing an auditor will ask to see is a site’s training records. An LMS helps to manage those records and would allow a company to provide employees’ training histories at its fingertips. An LMS can help identify the specific courses and curriculums offered, in addition to tracking employee performance.

Marie: Even without a negative event, a company can be audited by a regulating agency and asked for their training records. If a company can’t provide their records quickly, the likelihood that an

auditor will look at other quality systems to uncover additional gaps is very high. The auditor might think, “If they can’t find this for me, what else are they not keeping track of?” Every time I was at a client site when an audit was occurring, one of the first things the client would do is require its employees to update their training records.

What are some of the major compliance requirements companies are facing today that are driving them toward LMS? Is there any new policy that is moving companies toward LMS?

Mike: The current FDA guidance is to look at compliance in a risk-based manner. Before that approach was taken, there were tremendous inefficiencies in regards to training. If an employee played a role in a process they often had to be trained on everything—including responsibilities that were not applicable to his or her position within the company. The risk-based approach allows an organization to choose the curriculum specifically designed for an employee’s role. With an LMS, you can fine-tune and be a little more creative in your approach without the added administrative burden.

How does a Learning Management System help to manage an organization’s training compliance requirements?

Mike: First, an LMS enables a more customized curriculum. Second, an LMS allows the tracking, administration, and analysis of that curriculum.

Marie: The reality is audit-preparedness is overwhelmingly enhanced when you know you can offer correct records. If a company does not have a robust system to facilitate an audit situation, then it is going to be painful.

Is there a notable difference between regulated companies that use an LMS versus those that do not? Do regulating agencies look more favorably on companies that implement an LMS?

Mike: There is a notable difference. With an LMS, a company is able to report quickly and establish control. It is important during an audit to be able to show an establishment of control. It is commonly understood in the industry that the FDA might shorten an intensive audit if a company can prove effective management, control and organization.

Marie: The difference between the employees that work for a regulated company that have an LMS versus those that do not is the level of preparedness during a regulatory audit.

If an auditor asks questions related to an LMS and the company is able to give answers readily, it enhances regulatory agencies’ confidence in those companies. It could be argued that companies would be audited less or the audit wouldn’t last as long. If they don’t answer readily, the agency may return for more (and lengthier) audits.

Why should a company consider implementing an LMS now during difficult economic times?

Mike: There is a huge wasted effort in training costs associated with not having a well-thought-out curriculum. Without the ability to manage training performance, a company could potentially be sending their employees to useless training. A company could jeopardize a product release because their workforce isn't trained adequately or documented appropriately. It is imperative that a company shows that not only the appropriate training took place, but that it was done well. Without an LMS, a company will find it much more difficult to guarantee that training was done correctly.

How can Clarkston help?

Mike: LMS is at the intersection of the three things we do really well: human capital management, quality systems and regulatory compliance specific to life sciences. An LMS is a core component of ensuring your company is

forward thinking in those three areas. It helps in managing people to achieve maximum results and ascertaining that compliance measures are being met.

Clarkston offers strategic and implementation services to aid you in an LMS implementation including:

- Business case development
- Talent management strategic roadmap development
- Software vendor selection
- Comprehensive systems implementation services such as change management, training, validation, and support

Clarkston also has deep experience supporting life sciences companies with all of their quality systems process improvement endeavors. In addition to Learning Management, our experience spans across several quality systems including Change Control, Content/Knowledge Management, Laboratory Management, Batch Management, CAPA, and Packaging and Labeling.

References:

- 1 Adams Miller, D., Grey, N., Nguyen, F., van Barneveld, A. "Learning Management Systems: the good, the bad, the ugly...and the truth." May 2008
- 2 Bersin, J., Howard, C., Mallon, D., and O'Leonard, K. "Learning Management Systems 2009: Facts, Practice Analysis, Trends, and Provider Profiles." April 2009.
- 3 "Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations." <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070337.pdf>
- 4 Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations." September 2006. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070337.pdf>



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