

## Business Use Case: Growing Contract Research Organization (CRO)

# ePath Learning's LMS Technology Provides an Ideal Solution for CROs Key Training Challenges

Growing CROs are turning to technology to develop and deliver a consistent training experience while alleviating the worry of being compliant.

### Overview

The FDA has numerous regulations that govern clinical research. Time and time again the FDA cites facilities for the same issues which can result in warning letters, debarments, or a shutdown of the clinical trial. In fact, according to [PricewaterhouseCoopers and the law firm of McDermott Will & Emery](#), the most common violations of FDA regulations are too often caused by poor recordkeeping and lack of training.

Training is a key component of conducting clinical research. It's essential to have comprehensive and standardized training requirements to ensure your team has an understanding of the regulations governing clinical

research. At a high level, these trainings may include protection of human subjects, Good Clinical Practice (GCP), Health Insurance Portability and Accountability Act (HIPAA) privacy and security and laboratory safety training for handling of biological specimens.

It's also critically important to have processes in place for training study teams on individual study protocols, and amendments to those protocols, in order to meet the expectations of the Food and Drug Administration and study sponsors. Therefore, accurate training records that meet FDA guidelines are considered essential documentation to any clinical trial study.



In today's economic environment, more and more pharmaceutical companies are using the services offered by CROs. It's the pharmaceutical sponsor's responsibility to select study monitors that are qualified by training and experience. In this competitive field, it's imperative that CROs establish themselves as trustworthy and reliable partners with their sponsors. Those CROs that demonstrate a commitment to service excellence are likely to be successful, and as such, they know that responsiveness, reliability, and accountability help to define their level of commitment to service excellence.

The CRO is responsible for monitoring all aspects of the study, including proper planning, timely completion and thorough documentation. Monitoring is a quality control activity and a function of auditing. Inadequate monitoring can directly impact the quality of the trial and jeopardize the safety of study participants.

## The Business Case for Implementing Validated LMS Technology

For a small but growing CRO with a decentralized team of predominantly contracted employees, gathering, tracking, and managing essential documentation is challenging. The number of employees on record changes from project to project, as do their contracted hire and expiration dates. The CRO must ensure that their contracted employees' credentials and certifications are always up to date. Distributing SOPs and obtaining employee signatures across multiple locations is time consuming. The type of training and training assessments that need to be delivered also varies. With the exception of employee onboarding training, all other employee training is role specific and study specific. Once a project is started, often study protocols change and these changes need to be effectively communicated and understood by the employees working on the project.

Maintaining a paper system to deliver and track employee training in this type of business environment is wrought with the potential for human error and is only sustainable for so long. A paper system is administratively time consuming and costly, can be inconsistent, and records can easily become misplaced or lost. Paper systems are simply not efficient and aren't worth risking a hard earned reputation on. Furthermore, sponsor companies are looking for CRO partners they can trust and that have top notch quality systems already in place.

Growing CROs are turning to technology to develop and deliver a consistent training experience while alleviating much of the worry of being compliant. They understand that transitioning from paper to an electronic system is cost effective, improves efficiency, quality and accuracy of their training records, as long as the records meet 21 CFR Part 11 requirements put forth by the FDA. A validated LMS that conforms to 21 CFR Part 11 is the ideal solution for managing and delivering employee training online and can be an integral part of the quality system for CROs.

# ePath Learning's Validated LMS Technology Provides an Ideal Solution to Address CROs Key Training Challenges

## Key CRO Training Challenges

### Limited Resources to Devote to Manual Processes

### Deliver Role-Specific Training Content

### Managing and Tracking Training for a Decentralized Team

### Integrity of Data – 21 CFR Part 11 Compliance

### Unique Reporting Requirements

## ePath Learning LMS Technology Solutions

Transitioning from a paper-based system to an LMS increases operational efficiencies, thus saving you time and money. Furthermore, ePath's validated LMS comes backed by a team of regulated industry veterans. We ensure rapid implementation with a high-touch, ongoing client support model. We act as an extension of your team and are committed to seeing your training initiatives through to success.

LMS technology automates the assignment of training based on job role, project, or even location. Assessments can be incorporated to measure the effectiveness of your training materials. It's easy to manage content from multiple sources including content you create or license. ePath's LMS technology supports SCORM, AICC, Word, PDF, PPT, video, and web sources. Our technology fully supports blended learning and tracks both eLearning and Instructor-led training events.

Decentralized teams can login into ePath's LMS at any time, from any location, while using any mobile device. Training is readily available on demand, when and where your team needs it the most. Outside employee certifications are easily tracked and notifications can be set to remind users of necessary training/certification renewal requirements.

ePath's LMS technology supports the software validation requirements defined by the FDA, including robust features such as electronic signatures, automated versioning, data security, and a fully documented SDLC. Furthermore, our validation package speeds up your software validation process so that you can expedite the implementation of your LMS.

LMS technology provides real-time visibility into your training activities and comprehensive employee training records. Our custom reports builder allows the flexibility you need to generate meaningful reports.

In the competitive marketplace of CROs, leveraging validated LMS technology can enhance competitive value, and help growing CROs earn a reputation for trust, quality and reliability. To learn more about ePath Learning's learning management technology and services, contact us today: [sales@epathlearning.com](mailto:sales@epathlearning.com), or call us at 860.444.8090.