



## Compliance Training

Reduce Risk. Improve Quality

### Reduce risk. Improve competency and quality with effective training management.

Regulated organisations are constantly under pressure to maintain compliance and quality throughout their business processes. They must ensure that all staff are aware of, understand and adhere to strict training requirements. As business environments evolve and new regulations come into effect, there is less tolerance for non-compliance. Implementing an automated compliance training system will help manage the process, reduce the risk of non-compliance and provide an auditable training environment.

Cobent's signature product 'Learning Compliance Suite' (LCS), is a compliance training system that provides organisations with the tools to develop, deliver, track and manage training programmes critical to meeting strict training, competency and record-keeping guidelines.



### Why Cobent Solutions?

Cobent has extensive experience in the learning and training industry and continuously works with subject-matter, industry and technical experts to refine and develop solutions that are optimised to meeting compliance and learning requirements.

Cobent training compliance solutions have been built from the ground-up for the regulated environment to provide the flexibility and level of training granularity needed for any business model, while still maintaining strict compliance

features. Cobent has a proven track record of successful implementations throughout the UK, Europe and US; Cobent's regulated clients include: Avecia Biotechnology, Eli Lilly, AAH Pharmaceuticals, Barclays Bank and Norwich Union Risk Services.

Cobent solutions assist regulated organisations to meet compliance, training and competency requirements by providing:

### Competency & Qualification Management

Creating training material is in many cases the easy part, ensuring this training is delivered to the right individuals, at the right time and completed, can be the real challenge - especially for larger organisations. Cobent LCS makes it easy to manage competency and qualification by automating the process with preconfigured workflows and schedules based on your business and operational logic.

- Manage quality control by building in process flow, review, and certification stages with workflows.
- Qualify stages with e-signatures or assessments to ensure key steps are not skipped.
- Assign user notifications based on schedules and pre-defined rules for periodic re-certification requirements.

### On-the-Job & Classroom Management

Many regulated organisations will have staff without ready access to computers, where training must take place either in the classroom or in practical on-the-job (OJT) sessions. Aside from managing e-learning, a key feature of LCS is its ability to also capture and manage 'offline' training activities. From its classroom management feature which allows organisations to manage and assign classroom resources and notify and track attendees; to the OJT feature to manage and record, training completion, supervisor(s) sign-off and evidence upload. LCS automates and manages the entire training process for a complete training history.

### Benefits Highlighted:

- Manage training and competency to industry standards
- Automate and streamline SOP and OJT Training
- Centralised record-keeping and management of training programmes
- Full audit trail and e-signature validation
- Improve training compliance
- Provide learning flexibility to your staff, encourage adoption & understanding
- Reduce costs of training associated with travel and administration
- Easy-to-use and intuitive Collaborative content authoring environment for streamlined development
- Increase performance with competent and confident staff
- Powerful reports and dashboards



## Assessments

Assessments are a rapid and powerful way of measuring the impact and effectiveness of training programmes. Build questions, a variety of assessments and manage the assignment of them via workflows or groups. Run reports and validate completion by the correct person with e-signatures if required.

## Integration with Quality Systems

Integrate LCS with your Quality System to provide full automation of a training requirement to complete the quality management process. Quality processes may be related to audits, deviations, customer complaints, change control, corrective and preventive actions (CAPAs) and company policies and procedures. Automating the training process will close the quality loop and ensure that compliance training is managed through a single process – reducing the risk of non-compliance and the administrative costs associated with managing the process.

## Standard Operating Procedures (SOP) & Process Training

Standard operating procedures provide the guidelines to ensure that quality and compliance requirements are met by individuals, departments and the overall organisation. Manage the training process effectively and ensure that each individual is aware of, understands and adheres to policies and procedures with LCS. Automate SOP training assignment, tracking, sign-off and certification.



## Record Keeping, Archiving, Auditability & Reporting

As part of strict compliance requirements documentation must be auditable to ensure integrity and validity. Cobent's LCS solutions provides a powerful audit trail; changes and updates within the system, are recorded and cannot be deleted or amended and will remain stored in the LCS's database and available for interrogation.

All electronic records generated in LCS are:

- Centrally managed and stored for full control and security
- Maintained in a secure and active database, for easy accessibility, regardless of time-period, even when the software is upgraded.
- Validated through process controls and e-signatures.
- Accessible for auditability and contain the data demanded by regulation e.g. time-stamps, id's, e-signatures.
- Linked to their respective e-signatures. Linking and the electronic signatures cannot be deleted, changed, copied or falsified.



## Avecia - Customer Success Story

Avecia is a leading private biotechnology company focused on the development and manufacture of innovative biotechnology-based medicines, focusing on treating serious illnesses such as cancer and heart disease. The company has 600 employees over three sites.

Following significant growth, Avecia needed to upgrade its method for training and administration to ensure compliance with FDA audits. In 2007, Avecia implemented Cobent's 21 CFR Part 11 compliant 'Learning Compliance Suite'. In order to effectively manage compliance needs, Avecia uses the system to automate and track all compliance training programmes, including Standard-Operating-Procedure (SOP) training.

## Find Out More ...

Visit our website [www.cobent.com](http://www.cobent.com) for further information, to see screenshots and recorded demonstrations. Contact us to see how we can assist your organisation.

## Cobent Services:

- Supply and implementation of fully compliant learning management tools.
- Supply and implementation of collaborative authoring tools.
- Consultancy and advice based on 'best-practice' knowledge and industry experience
- Development of bespoke content based on specific learning and business requirements
- Supply of off-the-shelf content for rapid deployment

## Selected Clients:



*"...the Cobent LCS is crucial because it means we can offer a much better service to our customers, we can get them trained quickly and, with the roll out of National Programmes for IT throughout the UK for primary healthcare, it's key to our business. It also offers AAH real competitive advantage to be able to offer an e-learning solution for our EPS systems."*

### Leon Rudd

Marketing Director  
AAH Pharmaceuticals

