



FDA Regulated

Effective Training Compliance

Reduce risk and improve compliance training effectiveness with Cobent's 21 CFR Part 11 compliant learning solution.

FDA & MHRA regulated organisations are required to ensure that their staff are aware of, understand and adhere to strict compliance guidelines.

Regulated organisations must implement systems that allow them to easily manage compliance training requirements while being flexible enough to grow and change with the organisation.

Cobent's flagship product, 'Learning Compliance Suite' (LCS), is a 21CFR Part 11 compliant system that provides organisations with the tools to develop, deliver, track and manage training programmes ; critical to meeting FDA's strict guidelines on security, accountability and auditability.

WHY COBENT SOLUTIONS?

Even though many organisations we work with have had an existing system, they chose to explore our solution because we specialise and are therefore at the forefront of assisting FDA regulated organisations to streamline training processes. Cobent works continuously with subject-matter, industry and technical experts to refine and develop solutions that are optimised to meet compliance and learning requirements.

Our solutions are 21 CFR Part 11 compliant and have been built from the ground-up to provide the flexibility needed by our diverse client base, whilst maintaining FDA compliance. With a proven track record of successful implementations throughout the UK, Europe and US, Cobent has helped organisations to cost-effectively fulfil and exceed their training and compliance objectives. Cobent FDA regulated clients include: Dentsply, Avecia Biotechnology, Eli-Lilly and AAH Pharmaceuticals.



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

21 CFR Part 11 COMPLIANCE

The requirements for converting 'paper-based' training procedures into an electronic format are not straightforward. Electronic learning management systems must meet FDA's strict guidelines, specifically 21 CFR Part 11, in order to be compliant. Cobent LCS provides organisations with an easy-to-use, automated system to manage all types of learning; elearning, classroom and on-the-job.

Cobent's LCS meets all 21 CFR Part 11 compliance guidelines and also offers: assessments management, classroom management, collaborative content authoring and integration with other QMS and HR applications.

STANDARD OPERATING PROCEDURE (SOP) & OTHER CONTROLLED DOCUMENT TRAINING

Maintaining and managing training documentation and ensuring employees are supplied with and trained on the latest revisions can be a time-consuming exercise. Cobent solutions integrate with document management systems to provide access to training documentation; ensuring that personnel are always trained on correct versions and meet certification and compliance requirements.

Benefits Highlighted:

- Fully FDA 21 CFR Part 11 Compliant System
- Automate and streamline SOP and OJT Training
- Centralised management of training programmes
- Human-free auditability 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, intuitive, LMS
- Collaborative content authoring environment for streamlined development
- Increase performance with competent and confident staff

Synchronisation with a centralised document management system provides:

- Version and quality control over training documentation such as operation procedures, manuals, and policies
- Evidence-backed assurance that employees are trained only on the correct documents and notified if they need to be updated
- E-signatures to validate that individuals understand and comprehend new documentation
- Easy and secure access to documentation relevant to the individual, regardless of location

Standard Operating Procedures are fundamental to ensuring that quality and compliance requirements are met by individuals, departments and the overall organisation. However, managing that process and ensuring that each individual is aware, understands and adheres to policies and procedures is difficult, especially without a formal management system. Cobent solutions make it effortless to manage SOP and On-the-job training by automating the reporting, tracking, sign-off and certification process.



ON-THE-JOB TRAINING (OJT)

On-the-job training is an effective method of training and often the fastest way to ensure behavioural change post training. However efficiently capturing and managing the OJT process and its related data, is difficult.

Cobent LCS provides the ability to manage OJT effectively. As practical activities are completed and assessed, details are added to an employee's personal training record. This information is then updated and automatically sent to qualified personnel for validation and sign-off. Reports and alerts can be created to notify of any changes or non-compliance of personnel.



AUDITING, ARCHIVING & REPORTING

As part of FDA compliance requirements, documentation must be auditable to ensure integrity and validity. Cobent's LCS solutions provide powerful 'human-free' auditability and traceability. Changes and updates within the system, are recorded and cannot be deleted or amended, and remain stored in the LCS's database and available for interrogation.

All electronic records generated in LCS are

- Stored and managed centrally
- Maintained in a secure and active database, for easy accessibility.
- Validated through process controls and e-signatures.
- Accessible for auditability and contain all data demanded by regulation.
- Linked to their respective e-signatures.

AVECIA – CUSTOMER CASE STUDY

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 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

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