

Austin Pharma Reaps Productivity and Compliance Benefits from eTraininfo Training Management System



eTraininfo Features:

- ✓ Trainer- Led
- ✓ Ad Hoc Training
- ✓ Self Training
- ✓ Security
- ✓ Audit Trail
- ✓ eSignature
- ✓ Detailed Reports

The Customer:

Austin Pharma specializes in the manufacture of difficult or complex active pharmaceutical ingredients with expertise in controlled substances. They have the capabilities to provide early phase R&D, pre-clinical, clinical and commercial drug substances from small scale to large scale production

Business Drivers:

Two important drivers under consideration were the replacement of a paper based process with a fully electronic process and ensuring that CFR 21 Part 11 compliance requirements were being met. Training was a hybrid of paper documents and spreadsheets. Tracking of requirements, storage of effective versions and reporting were challenging. The goal was to merge those two formats into one easy to use and install electronic training management system that was Part 11 compliant.

Results:

Tracking of training documents, versions, employee training and retraining requirements became far easier with **eTraininfo**. All documentation was either stored in the database or linked from secure file shares. Training on the appropriate version was no longer difficult to track since the application will prompt for a replacement document when versions are incremented. Notifications kept employees and stakeholders abreast of changes in requirements.

Testimonial from the Customer:

We purchased the eTraininfo software about 3 years ago and couldn't be happier with the results. Aside from keeping us part 11 compliant, the solution has made record keeping and reporting significantly easier and more time efficient which is key in a regulated environment. The technical support response is always prompt and helpful in resolving any issues we encounter. I would definitely recommend them to anyone looking to transition from paper to software based systems." - QA/QC Manager

About CIMCON Software

CIMCON Software (CS) provides a wide range of software solutions and compliance services that reduce costs and improve operational efficiency while complying with 21 CFR Part 11 and GxPs. CS anticipates, defines, evaluates and solves the technical and regulatory issues that arise in a constantly changing environment to help clients achieve their business goals. The firm brings to bear 25 years of innovation, experience and knowledge in designing, developing and implementing technology solutions from the plant floor to the top floor.

