



Pharmaceutical Manufacturer uses Life Cycle Spreadsheet Management Tools for 21 CFR Part 11 Compliance

The Customer

This customer is a research based international pharmaceutical company serving customers in more than 150 countries. With a focus on the generic pharmaceutical sector, the company produces a range of quality, affordable medicines using innovative, safe, environment-friendly and cost effective global technologies to deliver high quality APIs.

Project Drivers

The manufacturing of pharmaceuticals is carefully regulated by the FDA and requires an exacting level of precision. Because of this, spreadsheet errors in a GxP environment, can lead to serious consequences including improper release of a batch or erroneous clinical trial results. There was an immediate need to address manufacturing compliance gaps through the use of uncontrolled spreadsheets in multiple locations.

Business Benefits

This client chose CIMCON Software for their quality product and superior support. They had confidence that all of their critical GxP spreadsheets once controlled by **eInfotree Excel Desktop** would meet the strict requirements of 21 CFR Part 11 regulations. The software ensures that a controlled environment is consistent across all users and provides authenticity, integrity and confidentiality of the electronic records. The convenience of not having to migrate files to a new system and that no additional hardware or software was required translated into a short learning curve and no slowdowns in the production environment.

About eInfotree Excel Desktop

eInfotree Excel Desktop is a plug-in to Excel providing a controlled Part 11 environment for any spreadsheet. The application creates an irrevocable audit trail, air tight security and e-signature functionality and provides many business process improvements.

About CIMCON Software

CIMCON Software delivers proven and mature 21 CFR Part 11 compliant software solutions that improve business productivity. In business for over 25 years, we have a large installed global client base in over 30 countries. We deliver solutions that are developed using a well established Quality process, speed user adoption and implement quickly using validation packages and tools. Please contact us to see how we can help your organization work **smarter and faster**.

eInfotree Excel Desktop

- ✓ Audit Trail
- ✓ Electronic Signatures
- ✓ Security

