CIMCON Software
Compliant Digital Transformation™

API Manufacturer Reaps Benefits of eInfotree Excel Desktop since Nine Years (and counting)

Benefits:

Productivity:

- ✓ Replaces paper-based logs
- ✓ Automated manual processes saving time and money
- ✓ Trending across hundreds of spreadsheets
- ✓ Easy monitoring & tracking of batch inconsistencies
- ✓ Instant reporting on results
  - data compilation
  - graphing

Compliance

- ✓ Audit Trail
- ✓ Security
- ✓ Access Controls
- ✓ Sign-offs

The Customer

The customer is a California-based company that manufactures active pharmaceutical ingredients and registered intermediates for pharmaceutical and biotechnology customers. With more than 70 years of mastering challenging chemistries, the firm safely produces energetic compounds at commercial scale.

Business Drivers

Due to the exacting nature of the manufacturing process and the strict requirements of regulatory compliance, automated systems are rapidly replacing time-consuming and error-prone manual processes. The company implemented the eInfotree Excel Desktop in 2005 to control access and track changes to production spreadsheets that calculate complex final release data as well as simple logging tasks. After years of a very successful implementation, the firm implemented an enhanced version of eInfotree that included a trending feature. The trending feature allows them to track key data points across hundreds of spreadsheets, allowing personnel to easily track inconsistencies in batch processes and instantly report on the results using both data compilation and graphing.

Results

The eInfotree Excel Desktop has been a resounding success for this FDA-regulated customer for over nine years. It has allowed the customer to save time and money, while becoming Part 11 compliant. The Trending/Reporting feature has allowed them to replace another manual process leading to additional productivity benefits. The customer has a stable and well established spreadsheet process that improves security, safety, and controls while enabling compliance.

Customer Testimonial

"CIMCON's **eInfotree Excel Desktop** application for Part 11 control of spreadsheets has and continues to be an important part of our manufacturing process. Since eInfotree Excel Desktop works in the background, users are not required to go through extra training, thus adoption of the application was companywide. We are using Excel spreadsheets for complex calculations of final release data as well as for simple tasks such as logging miscellaneous information. eInfotree Excel Desktop gives us the ability to control access and track the changes that personnel make with the intuitive cell level audit trail functions. With the built-in Trend Reporting feature, we are able to monitor and easily track any inconsistencies in our batch processes across hundreds of spreadsheets; previously this was a time consuming manual process. We always have a positive experience with CIMCON tech support and have high regards for their ability to resolve any issues related to software functions or performance." **—QA/IT Engineer**

About CIMCON Software

CIMCON Software, LLC 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. CSI 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.

einfotree