

## CASE STUDY



Cambrex gains FDA compliance with single 3-month project from Xelocity Limited. Life sciences innovation company, Cambrex, used a Xelocity project to gain compliance with FDA regulations requiring electronic audit trails for transactions involving changes to food and drugs.

## THE CUSTOMER

Based in the U.S., Cambrex is an innovator in the Life Sciences industry. New opportunities for pharmaceutical, bio-pharmaceutical and bio-technology companies have resulted in thousands of promising new compounds progressing along the drug development path. Cambrex offers a portfolio of technologies, resources and services to help these companies reduce time-to-market. Annual revenue exceeds US\$500 million, Cambrex is listed on the NASDAQ exchange.



## BUSINESS CHALLENGES

- Comply with FDA regulation 21 CFR Part II, which makes electronic “audit trails” of changes to drugs, products, recipes and their verifying transactions, compulsory.
- Upgrade and modify dated Ross ERP system.

## XELOCITY SOLUTION

- Automate a former manual system for FDA compliance.
- Ongoing remote support.
- Off shoring to New Zealand.

## ROI / BENEFITS

- Compliance with FDA regulation 21 CFR Part II achieved within 3 months.
- Successful pass of FDA audit.
- New reporting functionality assists compliance with Sarbanes-Oxley legislation governing financial reporting requirements.

Breakout Quote:

“ I would definitely recommend them (Xelocity) for any Ross Systems-related development.  
Cambrex Development Manager , Susan Lake.



**XELOCITY**  
Powerful Business Results



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## PROJECT SUMMARY

Introduced in 2003, FDA regulation 21 CFR Part II requires companies to shift away from paper-based systems when recording changes to FDA-regulated substances. Electronic audit trails of changes to drugs, products and recipes along with verifying transactions are now compulsory.

If audited, companies must be able to produce full electronic records verifying that FDA procedures governing changes have been strictly followed. The level of detail required is exacting including data such as the names and electronic signatures of scientists approving the changes.

Cambrex found that the fastest and most cost-effective way to achieve FDA compliance was by validating its ERP system to fit the FDA's regulatory framework. Xelocity created a single project to perform the validation of Cambrex's ERP system, plant by plant.

Drawing on its extensive experience working on FDA regulatory projects, Xelocity worked with the Cambrex team to design software to capture all the additional information needed to meet the regulations. Xelocity then used its off-shore facility in New Zealand, to make modifications to the Ross ERP system, referencing the new software.

Working with Cambrex's development group, Xelocity successfully delivered the project inside the tight 3-month deadline. As work progressed, Xelocity worked with the core Cambrex team to audit the changes to the ERP system and verify that they met the FDA's 21 CFR requirements.

Xelocity also wrote software to take Cambrex's heavily modified dated ERP systems to the latest version, with all customisations intact. Data conversions formed part of this phase.

Cambrex has re-used some of the programmes developed by Xelocity for the FDA project to meet new Sarbarnes Oxley regulations governing financial disclosure.

Although Sarbarnes Oxley compliance relates solely to financial information, the capturing and reporting functionality it demands, is very similar to that required by the FDA project.

*"From a technical standpoint, they put together a good project team and worked with us to successfully complete a complex project to tight time frames".*

*I've always been very pleased with our working relationship - we've hit them with short time lines on several occasions and they've always managed to give us what we need".*

**Cambrex Development Manager, Susan Lake.**

## CONTACTS

XELOCITY: [www.xelocity.com/](http://www.xelocity.com/) [info@xelocity.com](mailto:info@xelocity.com) /+64 9 363 6700

CLIENT: Cambrex: <http://www.cambrex.com>