

Pharmaceutical Technology Electronic, May 2005
“Technology Helps Manufacturers Create a Manufacturing Compliance Platform” by Joseph Vinahais
<http://electronic.pharmtech.com>

Case study: creating real value.

“Division X” is a \$1.2-billion division of a pharmaceutical manufacturer that was not fully meeting the company’s manufacturing objectives because the technologies and processes in place did not effectively support the division’s growth. FDA compliance costs were rapidly increasing, along with the number of products and manufacturing volumes, and several key issues needed to be addressed.

First, Division X needed to transition from long campaign runs to controlled-order quantity batches. Second, it needed to lower the cost of compliance while continuing to improve quality. Finally, it needed better data collection, as well as full data genealogy and reporting to support FDA compliance. Division X also wanted to optimize efficiency and improve overall quality by improving integration with enterprise planning systems.

Division X addressed this challenge by integrating a manufacturing execution system (MES) with its current enterprise resource planning (ERP) system to integrate recipe management with order management. To further support this transition, MES was integrated with the division’s laboratory information management system (LIMS) to help plant manufacturers gain better visibility of first-pass yields, which significantly reduced the wait and hold time for certificates of analysis. These changes cut the cost of compliance by producing electronic batch records, thereby eliminating costly paperwork and manual data entry.

By integrating a new MES with its ERP and LIMS, Division X reduced its compliance cost by 43% and increased its internal rate of return by 67%. As a result, the division’s MES paid for itself in less than two years.