

## Discovering Peak Performance at Supelco with Minitab



Supelco, headquartered in Bellefonte, Pennsylvania, provides HPLC columns and other chromatography products worldwide.

### KEY FACTS

#### ORGANIZATION

Supelco, a part of Sigma-Aldrich Corporation

#### OVERVIEW

- Supelco provides chromatography products for analysis and purification
- Approximately 250 employees
- Annual sales approximately \$64 million

#### PRODUCTS USED

Minitab® Statistical Software

#### RESULTS

- Pass rates for HPLC columns now exceed the 95 percent target rate.
- Cpk, a measure of how well a process meets specifications, improved from -0.01 to 1.74.
- Column production and testing processes have been made more efficient.
- Losses from failed columns have been drastically reduced.

Supelco manufactures chromatography products, including columns used in the pharmaceutical industry. One of Supelco's products is their Discovery line of high performance liquid chromatography (HPLC) columns, which aims to provide performance levels that surpass all other products on the market. To meet that high standard, the company invests significant resources into quality assurance. When problems are detected, the company's scientists turn to Minitab and continuous improvement methods to find solutions that ensure the quality of their products.

### Challenge

Scientists use HPLC to analyze substances by separating them into their individual components. The process uses a column that holds chromatographic packing material, a pump that moves the substance being tested through the column, and a detector that shows the retention times of the different molecules in the substance. Because their performance is critical to valid analyses, Supelco produces and tests its Discovery columns under strict ISO 9001 conditions to ensure that they meet specifications.

When the pass rate during performance testing for one of their columns fell to 80 percent, well below their goal of 95 percent, production manager John Rumbaugh and a team of scientists and quality professionals set out to optimize the production processes in order to increase the pass rate to 95 percent and reduce the costs associated with column failure, which ranged from \$40 to \$85 per column.

First, they developed a cause-and-effect diagram to find potential root causes of column failure in four areas: column production, packing operations, testing, and final product packaging.

They identified several key variables that influenced the production throughput. One was the type of quality assurance instrument used to test the columns. Supelco used two types of testing stations: multi-testers that

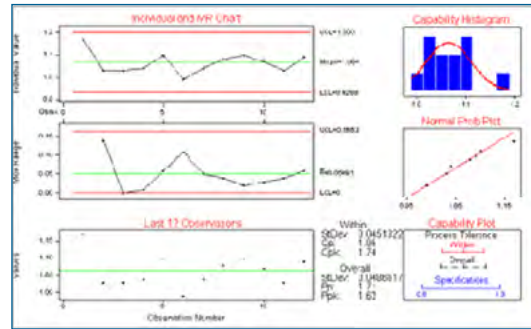
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handle six columns at once, and single column testing stations.

Another variable was the slurry, the mixture of solvents used to pack the columns with silica. Slurry packing involves suspending the silica in solvents and pumping it into the columns at high pressure. Supelco used a 90:10 ratio of acetone to methanol. The project team compared this mixture to a 50:50 toluene and acetone mixture to see if manipulating this ratio could increase the pass rate.

A third variable was the level of packing pressure used to pack the columns. The last variable they tested was machinery. The team wanted to see whether using automatic or manual machines to pack columns would produce more reliable parts.

The dependent variables were efficiency, with a specification greater than 3700, and peak asymmetry, with a specification between 0.80 and 1.30. Asymmetry describes the shape of a chromatographic peak, which should be symmetrical. A value greater than 1.0 indicates a tailing peak, while a value less than 1.0 is a fronting peak.



Minitab's Capability Sixpack™ displays the values of Cpk and Ppk, which are measures of how capable a process is of meeting specifications. Supelco's Cpk for asymmetry, a key measure of column performance, improved from -0.01 to 1.74, exceeding their Cpk goal of 1.2.

## How Minitab Helped

Now the team needed to design an experiment to test the effects of these variables and determine which factors would boost the quality of the columns. If the team could discover how much each variable affected the pass rate of the columns, they could refine the settings to achieve optimum quality and performance.

Minitab's Design of Experiments (DOE) capabilities allowed Supelco to screen the factors and quickly identify which were most important—and most likely to yield improvements. Two key variables were proven to have significant impact: pressure, and the type of quality assurance instrument used to test the columns. Using Minitab, the team also was able to determine optimum conditions for these two important variables. An increase in the pressure used during the column packing process reduced variation, while switching from a normal testing instrument to one optimized for shorter columns resulted in a more accurate measurement system. The team ran a test of 12 more columns using the proposed conditions to confirm that the pass rate would increase if the experiment's results were used in production, and they found that the Cpk improved from -0.01 to 1.74. This large increase in the column pass rate, to greater than 99 percent, translated into cost savings in both materials and man hours. In addition, the chromatograms produced using the new process have a more ideal peak shape, one closer to the 1.0 target.

## Results

Based on these results, Supelco revised their control documents to reflect the new packing conditions. The column is now being packed at 7,000 psi and tested on an optimized measuring system, with all other factors remaining as they were prior to the experiment. Pass rates for the column have increased beyond the goal of 95 percent. "Without Minitab, we probably would have changed one thing at a time and the whole process would have taken significantly longer," Rumbaugh notes. Supelco hopes to increase sales and profit via increasing the throughput of the column production process. As the company analyzes future opportunities to design and launch new products and to make improvements on existing products, Minitab will be part of Supelco's strategy to develop production methods that ensure high pass rates.

*Supelco is a part of Sigma-Aldrich Corporation, which also includes Sigma Chemical Co., Aldrich Chemical Co., Fluka Chemie AG, Riedel-de Haen, and Genosys. The corporation has subsidiaries in 26 countries and more than 50 distributors worldwide.*