



Waters High-Performance Liquid Chromatography

Waters Corp., a publicly traded corporation (NYSE:WAT) headquartered in Milford, Massachusetts, holds worldwide leading positions in complementary analytical technologies – liquid chromatography, mass spectrometry, rheometry and microcalorimetry. Specifically, the company designs, manufactures, sells and services ultra performance liquid chromatography (UPLC), high performance liquid chromatography (HPLC), chromatography columns and chemistry products, mass spectrometry (MS) systems, thermal analysis and rheometry instruments.

Business Benefits

- Reduced manufacturing costs while maintaining quality
- Focused attention on chosen core competencies
- Gained perspective on continuous improvement culture in manufacturing operations
- Achieved delivery to commitment target of 100% every month
- Achieved zero returns in the first year

The Product

High-performance Liquid Chromatography (HPLC) is used to separate and then sequentially detect different molecules in a liquid sample mixture (e.g. drug formulation, cell culture extract). Fundamental components of the instrument include a sophisticated pump to deliver a “pulse free” and continuous flow of liquid at high pressures, a valve (injector) to introduce the sample into the stream and carry it over the column and a detector that converts the chemical data to electronic signals.

Project Scope

Waters Corporation sought a strategic foothold in Asia from a competitive sourcing and fulfillment perspective for manufacture of highly complex medical equipment without the requirement of ramping a new factory with Waters. In 2005-2006, Solectron built from the ground up a Medical Manufacturing Center of Excellence, which has since been integrated into Flextronics' global footprint that met Waters manufacturing needs. Waters has two primary requirements:

- The need to support full system build, final assembly and wet chemistry tests
- The ability to maintain quality in all aspects of production, including high-precision machining, fluids and optics

Challenges

Due to the sophistication of Waters' product, the company faced several challenges to their outsourcing initiative. The largest were:

- The optimal strategy to source, manufacture and fulfill demand for its HPLC systems needed to be determined
- The low volume, high mix profile of the product families does not fit a traditional high volume outsourcing model
- The supply chain leverage is much more difficult to achieve and is less of an advantage, since much of the medical supply base is proprietary
- The need for regulatory compliance, ISO 13485 certification, and relevant expertise on the part of the outsourcing partner often limits a medical company's ability to find a viable partner

What is HPLC? Modern High Performance Liquid Chromatography came into prominent use in the 1970s, evolving from technology roots that date back to the early 1900s. HPLC has become a primary analysis tool used in research, development and quality control in virtually all pharmaceutical companies. HPLC is also relied upon heavily in biomedical and life science research, as well as some industrial chemical/petrochemical applications.

HPLC is used to separate, then sequentially detect different molecules in a liquid sample mixture (e.g. drug formulation, cell culture extract). Sample mixtures are introduced in a liquid stream that is forced through a packed bed of fine particles (the "column").

Fundamental components of the instrument include a sophisticated pump to deliver a "pulse-free" and continuous flow of liquid at high-pressures, a valve (injector) to introduce the sample into the stream and carry it over the column, and a detector that converts the chemical data to electronic signals. Samples are introduced one at a time with the complete separation and detection process usually taking five to 20 minutes. Waters' Alliance system incorporates an "AutoSampler" that allows an operator to load numerous samples to be analyzed automatically.

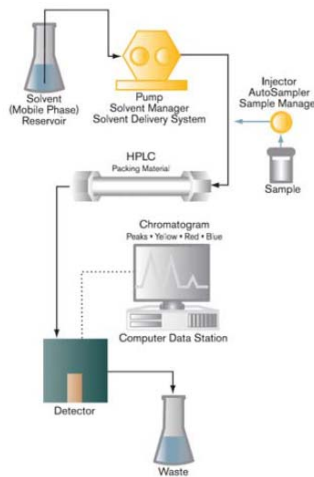
Solution

- Dedication of a customer focus team and a global team to understand Waters' needs
- Expansion of medical manufacturing operations with a new site in Singapore dedicated to medical device manufacturing
- Intense collaboration on every discipline involved in the technology transfer, including supply chain, product knowledge, manufacturing and commodity management
- Implementation of production in "U-shaped" cells, one system at a time, under stringent quality standards
- Investment in a chemistry lab to maintain and use calibration standards in the final functional test of the completed system
- Close proximity to an established Waters Singapore-based distribution center for fulfilling customer orders worldwide

Results

The business relationship began with the manufacturing of Waters' HPLC pump modules and ultimately moved to full system build, final assembly and wet chemistry functional test on Waters' market leading Alliance® System, ahead of schedule. Through the two companies' collaboration, Waters:

- Reduced manufacturing costs while maintaining quality
- Focused attention on chosen core competencies
- Gained perspective on continuous improvement culture in manufacturing operations
- Achieved deliver to commitment target of 100 percent every month
- Achieved zero returns in the first year



QUALITY
INNOVATION
SPEED
COST

For more information, please visit www.flextronics.com or contact medical@flextronics.com

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