

Life Sciences

Seven step quality process eliminates field failures for global biotechnology company

“Segue Manufacturing Services provides our company with components critical to the success of our products in the life sciences market. Their quality processes, problem solving skills, and engineering expertise re-confirms our commitment to outsourcing contract manufacturing and engineering services to Segue and expanding our relationship with them in the future.”

Director of supply chain at a Global biotechnology company

Quality issues resulted in 50% field failure rate

In a business that helps scientists, researchers and humans work towards a better life, the quality of the company's products is paramount to its success. However, when the company chose to outsource the manufacturing of a critical sub-assembly component of one of its systems, it underestimated how vital the engineering and problem solving skills of the contract manufacturer were to the success of the program. It wasn't

until the system was utilized in the field, that the company started learning about a significant problem and high failure rates. Upwards of 50% of the systems were leaking in the field. The contract manufacturer was approached to resolve the issue but an undefined method for discovering and evaluating the problem was unsuccessful and the expense of the failure was quickly mounting.

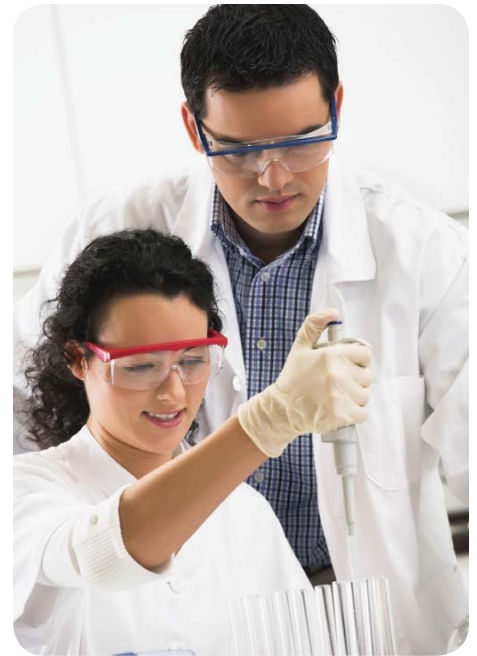
Segue eliminates failures and jumps to preferred vendor status

The company approached Segue Manufacturing Services (Segue) to help solve the problem. Immediately Segue chose to utilize the seven step quality manufacturing method as a roadmap for solving the complex problem. The seven step approach helps Segue employees standardize the approach, achieve greater team participation in problem-solving exercises, and develop faster, more effective solutions to the problem. The first step was to properly define the problem and assign an engineering owner. Next, Segue developed a containment plan. They utilized an in-house mass spectrometer helium leak detector and determined the leak came from a purchased solenoid valve.

A failure analysis was conducted on the leaking valves. Parts were sectioned for examination and a weldment in the valve was found to be inconsistent, thus causing the leaks. Segue approached the valve manufacturer with the problem, a modification was made to the manufacturing of the valve

and now 100% of the valves are passing the leak test and meeting the application requirements. Lastly, as part of the seven step process corrective action, process documentation was modified to include 100% leak checking of the valve prior to assembly in the manifold.

Since completing the analysis, the biotech company has shifted the manufacturing of the critical assembly over to Segue and field failures have dropped to zero. “Typically, when new vendors start working with this large biotech company, they start as a probationary vendor, then move to an approved vendor, preferred vendor and finally a partner,” comments Peter Frasso, president and CEO of Segue. “Because of our quality processes, our ISO 13485 registration and our ability to demonstrate engineering expertise, we leaped immediately to a preferred vendor status and continue to demonstrate our commitment to this customer and others in the medical and life sciences markets.”



Benefits:

- Field failures reduced from 50% to zero
- Achieved preferred vendor status
- Increased customer satisfaction

Vertical:

- Life Sciences



**Your Partner for
Global Competitiveness**

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Seven Step Quality Manufacturing Process

STEP	ACTION
1. Problem	Define the problem and the goal
2. Data	Analyze data; contain the problem
3. Cause	Determine verifiable root causes
4. Solution	Identify, plan, and pilot a solution
5. Results	Validate effectiveness of the solution
6. Deployment	Make the solution permanent
7. Debrief	Learn from the problem & 7S process

About Segue Manufacturing Services

Segue Manufacturing Services is one of New England's leading contract manufacturers, providing a wide range of services that include Turn-Key Manufacturing, Electro-Mechanical Assembly, Cable Design and Fabrication, Global Sourcing, Machining and Product Engineering. Segue is the prime supplier to some of the region's most innovative companies in the military, solar, medical, semiconductor and industrial markets. The Company's success is based on its ability to provide high value, cost effective manufacturing solutions from its modern 44,000 square foot manufacturing facility and through leveraging its engineering services and global sourcing capability. For more information about Segue Manufacturing Services, please visit at www.segue-mfg.com.



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