



Client Stratus Group
Location West Chester, Ohio

Supplier to pharma industry challenged by owner to develop robust quality program to secure future business

Then passes owner audit and acquires new clients with cGMP compliance program developed by FW Biokinetics.

Situation

One of Stratus's largest customers was Barr Laboratories, purchased by Teva Pharmaceutical Industries Ltd. in 2008. Barr, with operations in both NJ and Cincinnati OH, had been a Stratus client since 1993. Barr grew their business significantly over the years, and Stratus was able to support Barr's growth by expanding along with them. Following Teva's purchase of Barr, an initial cGMP audit of Stratus's printing and packaging operations was conducted. While the quality of Stratus's packaging and label materials had always been superior, Teva's audit revealed that Stratus's quality program was not compliant with their expectations for pharmaceutical suppliers. Although Stratus would not be subject to an FDA audit, TEVA expected Stratus to maintain the same quality systems as a direct supplier to the pharma industry. Additionally, Stratus would need to comply with Teva's quality standards. Teva gave Stratus a very aggressive timeline to achieve these quality standards. To continue as a supplier to Teva, it was recommended that Stratus contact FW Biokinetics for their help in developing a robust quality system to meet the expectations of the pharmaceutical industry.

Background

Stratus Group is a premier printer of paperboard packaging and pressure sensitive labels. It supports four major-market segments: personal care, pharmaceuticals, beverage, and food. Personal care and pharmaceuticals are the company's largest segments, accounting for nearly 80% of its revenue, equally split between paperboard packaging and pressure sensitive labels. The firm employs three technologies: offset, UV flexography, and digital printing. Stratus, founded in 1992, is privately owned and has over 115 employees. Most of its business is located on the East Coast.

Stratus had a quality management system, however, "From a pharmaceutical perspective, Teva's standards were more stringent than Barr Labs," according Curt Curran, Stratus COO. Stratus management felt, "It was imperative to get expert advice in how to meet the expectations of not only Teva, but all the other pharmaceutical companies." Stratus asked Dave Mason, a Teva Project Manager, for a referral. Dave referred Stratus to Christina Dell Cioppia, ChE, who is the Vice President of Validation at Foster Wheeler Biokinetics.





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Solution & Process

The Validation team at FW Biokinetics began working with Stratus to gain an understanding of their quality systems. This included a gap assessment of:

- Qualification/Validation documents for the printing/labeling equipment used for Teva labels
- Qualification/Validation processes
- Change control
- Periodic review
- Process for handling non-conformances
- Training process
- cGMP documentation practices
- Document control
- Calibration and preventative maintenance programs
- Equipment and Quality SOPs
- Process for determining label critical quality attributes and critical process parameters
- Process for determining acceptance criteria
- Batch record documentation
- Actual and theoretical yield calculations
- Warehouse and inventory control practices

FW Biokinetics found that Stratus was consistently making a product that met all acceptance criteria. The issue was in the documentation of their practices.

FW Biokinetics then went to work to put together a plan to bring Stratus into regulatory and customer compliance. Stratus upper management was committed to bringing their facility into compliance and provided full support for the execution of the plan. This included documented training to both management and operating staff in cGMP compliance issues, re-execution of a number of qualification activities to ensure acceptance criteria were rationale, testing was properly documented, and deviations were documented and resolved. FW Biokinetics also worked with Stratus to develop a Site Validation Master Plan, update batch records, rationalize

the calibration and preventative maintenance program, and develop SOPs to fully document equipment operation, maintenance, line clearance, batch record review, non-conformance investigation, periodic review, change control, and warehouse management. To ensure continued compliance, Stratus hired a pharmaceutical product Quality Manager to support the program going forward.

Results

According to Curt Curran of Stratus, “The Foster Wheeler Biokinetics team did a great job of helping Stratus become familiar with and appreciate the importance of cGMPs. The FW Biokinetics team worked with us to develop a practical, sustainable, cGMP compliance program that will help Stratus not only meet Teva’s expectations, but the expectations of other pharma clients in the future.”

Overall Curran’s assessment was, “The project was very successful.” Stratus measured their success by looking at whether they met their objectives: developing more sophisticated quality systems for pharma, and of course the ultimate objective — “We passed our audit, and we were approved by Teva to produce product. We know now that the procedures and systems we have in place will ensure that we meet Teva specifications.” In addition “FW Biokinetics helped Stratus with the Validation of new equipment that was installed in 2009. We now have proactive systems to show not only Teva, but all pharma clients, that we can meet their quality expectations.”

The success of the Teva audit helped Stratus acquire a new pharma client because of their newly improved capability. Now Stratus is in a position to better penetrate and expand this segment. They have recently expanded their sales staff and have a greater marketing push in this direction.

Contact Information

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