

Roche Carolina Sets the Standard for Quality Control | Case Study

Client

› The **Roche Carolina** campus makes and develops manufacturing processes for active pharmaceutical ingredients (APIs) and intermediate compounds. A division of Roche, with global headquarters in Basel, Switzerland, the facility makes the active ingredients for Xeloda® for breast/colorectal cancer, Xenical® for obesity, Tamiflu® for the flu virus and Pegasys® for hepatitis C. The South Carolina campus includes one of the company's Pharma Tech Centers, a research and process development center that includes a pilot-scale production plant.

Challenge

› Meet or exceed regulatory requirements and release product as quickly as possible.

Solution

› Lab associates implement 5S principles, sorting material and equipment, setting everything in order by storing it in common and highly visible locations, standardizing labels and driving sustainability with daily, weekly and monthly checklists.

Results

QC labs achieved zero observations following their most recent FDA audit. The inspectors even used the laboratories 5S processes to train their staff in best manufacturing practices. From a customer point of view, testing lead times remains constant at industry-leading levels of less than five days, despite a five-fold increase in output for critical drugs.

By applying lean tools, such as 5S and visual management, Roche Carolina laboratories defined good manufacturing practices and has helped the company respond to market demand for critical drugs like Tamiflu®.

When it comes to pharmaceutical manufacturing, the U.S. Food and Drug Administration (FDA) inspects facilities on a two- to three-year cycle for conformance to "good manufacturing practices." This case study explores how Roche Carolina has applied 5S, one of lean manufacturing's core tools, to a laboratory environment. By emphasizing workplace organization, order and cleanliness, 5S helps employees do their job more efficiently and effectively.

"Being regulated, that first impression is absolutely enduring," says Tracy Taylor, Manager of Quality Control at Roche Carolina. "When the FDA walks in, I literally have 10 minutes notice. They arrive at the front gate, security calls, and we bring them in. If they come into a place that's a mess, their impression will be that this is not a well-managed lab. On the other hand, if it looks stellar, if it's clean and organized, that's another story."

The analytical laboratories are outfitted just as you would expect, with benches and a variety of instrumentation, and tons of storage in cabinets and drawers. Applying the 5S principles in this setting proved to be no more difficult, and just as beneficial, as it is in manufacturing areas.

Sort – During the initial 5S implementation, the defining question is, "Do we need it, or not?" The question is asked of equipment, materials or consumables. If the answer is no, it's disposed of.

Set in order – During the sort process, if the answer is, "Yes, we need it," the equipment and materials are moved to a logical place and labeled or otherwise identified.



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Shine – Roche implemented the cleaning and housekeeping aspect of 5S through daily, weekly and monthly audits in each laboratory. Detailed checklists included dusting shelves and cleaning floors, as well as maintenance items such as requesting repairs to lights and fans that were not working.

Standardize – As part of the standardization process, Roche bought new log books and put them in a defined place in each lab so everyone would know where to find them and what instrument they went to. Roche also standardized how they labeled containers of chemical mixtures. The labels were then checked as part of the daily audits.

Sustainability – After six months, Roche cut out the weekly audits and rolled those activities into the daily and monthly checklists. Making a 5S project part of every analyst's annual objectives has been another key to sustainability.

When visitors tour Roche Carolina, they invariably visit the quality control labs. The typical comment, Taylor reports, is that it doesn't look like anyone works there. There aren't a lot of vials and flasks and papers lying about. It looks sterile, as it should. By comparison, the labs, now 15 years old, look just as good as another lab on the site that went through a major renovation last year.

About the TBM Pharmaceutical Practice

TBM Consulting Group is the worldwide leader in lean innovation and rapid sustainable business improvement for manufacturing and service industries. We have helped pharmaceutical companies improve quality, eliminate order backlogs, remove capacity constraints, increase productivity and asset utilization, rapidly integrate new acquisitions, streamline research and development processes and improve customer responsiveness. Visit the *"Industries we Serve"* section at www.tbmcg.com to learn more.

Roche Carolina and TBM Consulting Group

TBM Consulting Group's work with Roche Carolina helped it to win the Shingo Silver Medallion for Operational Excellence in 2008 on a number of process improvement projects and kaizen events. These included:

Manufacturing process changes. By mapping it out and documenting issues, the team consolidated three separate databases into one database, and cut out a number of unnecessary steps. This included all of the follow-up work. The new processes eliminated unnecessary handoffs and reduced delay time total processing time, and overall lead times.

Quality control release time. Release time for a high-demand API ranged from 1 to 12 days and was very unpredictable. The team eliminated redundant checks, excessive material movement, and developed standard work and testing schedule. The end result of this project and related work was a smooth workflow and a 4.9-day average release time (7-day maximum) from the drying stage to product shipment.

Production scale up. This initiative included developing a standardized project plan, visual tracking of project milestones, removal of non-value-added tasks, reducing documentation redundancy, elimination of loop backs and earlier approval of raw material purchases. These efforts collectively reduced and stabilized the time from request for a production campaign to actual production in the pilot plant.

Technician hiring process. The lead time for hiring technicians sometimes took more than six months, including 50 steps, 30 handoffs and 14 different types of delays. New processes designed by the kaizen improvement team reduced the hiring process from 25 weeks to seven.

