



We Innovate Healthcare

Roche Carolina Inc.

Company Profile

SC Shingo Prize 2008

Roche Group

Headquartered in Basel, Switzerland, Roche has been discovering and providing novel healthcare products to the world for over a century. Roche is one of the world's leading research-focused healthcare groups in the field of pharmaceuticals and diagnostics. With a broad spectrum of innovative solutions, Roche's integrated approach is not only the diagnosis and treatment of disease, but also the early detection and targeting of diseases when their damaging effects can still be prevented. Roche employs over 76,000 personnel worldwide and in 2005, was selected as one of the best 100 companies to work for by Fortune[®] Magazine. For more information, see www.roche.com.

Roche Carolina

Located in Florence, South Carolina, RCI (Roche Carolina Inc.) has 310 employees and is a strategic process development and manufacturing facility in the pharmaceutical division of Roche. Our state-of-the-art laboratories and world class production facilities have a challenging mission: to develop efficient pharmaceutical manufacturing processes so that innovative new drugs can be produced to reach the global market place in the shortest possible time. Our unique flexible operations allow us to adapt quickly to new product development and production needs. Our employees work diligently to ensure that our products are of the highest quality, with the knowledge that the products we make every day allow patients around the world to lead healthier and productive lives. Manufacturing

activities began in 1996. For more information, see www.rochecarolina.com.

Site Recognition

- South Carolina Governor's Gold Award by South Carolina Quality Forum (2006)
- Roche Olympiad Gold Medal for Tamiflu Supply Chain Expansion (2006)
- South Carolina Silver Crescent Award for Manufacturing Excellence (2005)
- South Carolina Manufacturer of the Year (2001)
- Roche Responsible Care Award for eight consecutive years (2000-2007)
- American Chemistry Council Energy Efficiency Award (2000)
- South Carolina Chamber of Commerce Award for Safety Excellence (1994-2007)

Achievements

- RCI was able to react to the pandemic supply for Tamiflu with global leadership and flexibility to meet five times the normal demand.
- RCI led the effort to reduce the global lead time and inventory levels for the Xeloda supply chain by 40%.
- RCI is the only Roche chemical site to be honored eight consecutive years with the Responsible Care Award for EH&S.
- Since 2005, RCI has conducted over 40 Kaizen events to implement Lean principles in a wide range of processes.

People

RCI employs highly trained personnel in a wide range of technical disciplines whose knowledge, experience, and passion ensure that rigorous quality standards are upheld at all times. Roche has also



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recently developed High Performance Work Teams to shift more ownership to the floor level. RCI developed a six-month Process Technician training and apprenticeship program, which became a federally licensed apprenticeship.

Process

RCI's Pharma Tech Center (PTC) is a premier development center for pharmaceutical products and production processes, which includes a pilot scale production development plant. Here, processes for the manufacture and analysis of new active pharmaceutical ingredients (API) are developed.

The Manufacturing facility contains reactor sizes ranging from 300 to 3000 gallons. With its world leading flexible multi purpose unit (MPU) concept and its partnering relationship with the PTC, Manufacturing's primary goals are to respond quickly to market demands for new compounds and provide flexible commercial production capacity. The Manufacturing facility is capable of parallel multi-step organic synthesis from small lots to metric ton commercial scale production. The facility is FDA registered and fully compliant to meet the most stringent production, quality, cGMP (current Good Manufacturing Practices), safety and environmental standards. The latest in computer-controlled reaction systems and equipment have been synthesized with a new concept in multi-product plant design to provide the ability to rapidly campaign different products while providing minimum downtime for cleaning and plant reconfiguration.

Products

- Xeloda[®] for breast/colorectal cancer
- Xenical[®] for obesity
- Tamiflu[®] for the flu virus
- PEG for Pegasys[®] for hepatitis C

Various other commercial drug products are manufactured as well. In addition to the products above, the development group produces clinical supplies for approximately ten new investigational drugs each year.

2007 SQDC (Safety, Quality, Cost, Delivery)

- **Safety** – 1.67 OSHA Total Recordable Rate; 6 OSHA Recordable Injuries
- **Quality** – 97.9% Right First Time (*our metric includes non-production related problems for the batch*)
- **Cost** – 83% Overall Equipment Effectiveness, 6% Cost Reduction
- **Delivery** – 100.8% On Time In Full

Community Involvement

RCI is committed to developing and manufacturing life-saving medicines for patients around the globe. We also recognize the importance of being an exemplary neighbor in our own community. To that end, we have provided financial and in-kind resources to many charitable organizations that improve quality of life and make a positive impact to our communities. Roche Carolina's focus areas of commitment are Education and Healthcare.

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