

## Life Science Case Study

# “Operation Excellence”

## Leveraging Lean Techniques

By Mike Gadway and Rafi Maslaton

In today's business environment, operational challenges such as cost reduction, cycle time reduction, improved efficiency, Right First Time, and schedule adherence are critical issues for site existence. Operation excellence Excellence has become an umbrella for many initiatives and approaches such as “Lean Operation,” “Six-Sigma” and “Lean-Sigma.”

These approaches aim at improving the overall operational performance, reduce variability and institute a solid foundation for cultural changes that drive continuous improvement. Shire Pharmaceuticals, a leading global specialty biopharmaceutical company focused on attention deficit hyperactivity disorder (ADHD), human genetic therapies (HGT), gastrointestinal (GI) and renal diseases, leveraged lean and six sigma techniques to improve its overall operational performances.

### Operation Excellence Journey

The journey for operation excellence at Shire began in the first quarter of 2006. Shire is a UK-based company with North American headquarters in Wayne, Pa. Shire's primary manufacturing facility in Owings Mills, Md., currently employs approximately 300 people. Shire and cResults, a New Jersey-based operations consulting firm (an affiliate of NJTC-member Integrated Project Services), sought out to streamline and improve Shire's Owings Mills site, making it the manufacturing facility of choice for Shire's existing and future products through.

The plan set out to: enhance quality, streamline processes, improve capacity and improve cost competitiveness. The operation excellence team goals were broad and challenging and included:

- Increase profit margin
- Improve material usage and consumption
- Reduce cycle time and improve OEE
- Increase yields
- Improve material and process flow
- Establish safety stock aligned with inventory strategy to ensure product supply and outstanding customer service performances
- Reduce non-value added activities
- Build quality into the overall process

### A Strategic Approach

Shire's executive team defined goals and objectives specific to the Owings Mills site that were essential to maintain its competitiveness compared with contract manufacturers with similar capabilities. The operation excellence (OE) team initiated an assessment to determine drivers/projects and expected ROI to meet the site goals and objectives. The assessment team selected Key Strategic Projects (KSP) based upon the selected projects and skill set required. A project team was established for each KSP with support and facilitation of the external consultant,

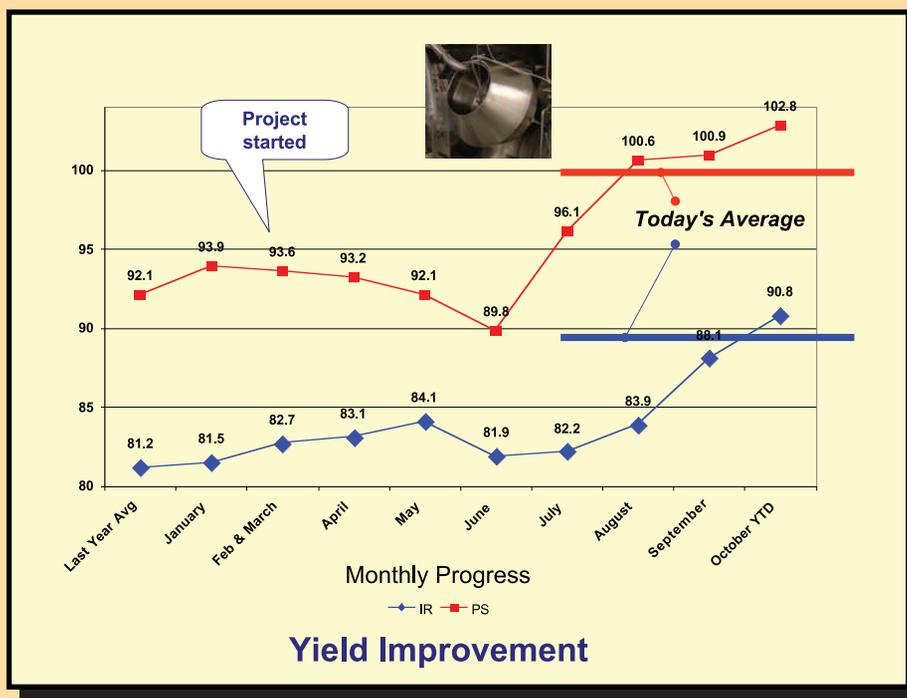
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cResults. A detailed schedule was developed for each initiative and lean and six sigma tools were implemented. The team's timeline was established around a six-month implementation plan followed by transition toward a continuous improvement mode of operation. The project team held workshops, weekly meetings, action items / meeting summaries to govern each KSP and the overall project.

The success of lean manufacturing is highly dependent upon the involvement of employees from all levels of the organization from project onset, and incorporated that approach in their plan.

In addition, the team frequently involved Shire front line manufacturing team members throughout the assessment and during the analysis stage. The OE project team understood that the success of lean manufacturing is

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## Life Science Case Study continued

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The main focus of the OE team was Pan Coating operation. The key bottleneck was identified in a "six coating pans" suite. The focus was to eliminate process variability, improve yield, OEE (overall equipment effectiveness) improvement, change over reduction, material flow and visibility improvements, and cost reduction. The OE team met all of its goals. And, this tremendous success story has made Shire more competitive with bottom line impact on profit margin. Due to the major cost reductions that were a direct result of the OE team's effort, a portion of the savings could be directed toward promotional efforts in new markets.

### Summary

This project resulted in, among other successes, an increased awareness on cost effectiveness and overall efficiency improvement by the entire team.

In fact this "Journey To Operation Excellence" yielded a variety of key learning points well worth sharing:

1. Leveraging lean techniques and statistical analysis leads to major improvements and culture changes.
2. Operation excellence is a result of a combination of multiple challenges and solutions that contribute to the overall operational improvements requiring a coordinated effort between various stakeholders (i.e., QA, QC, Manufacturing, PharmTech, Material Management).
3. Standardizing the work environment is a key enabler to sustain improvements.
4. Ownership and accountability are imperative to continuous improvement.
5. Executive support is an essential component in the journey to operation excellence.

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