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Fortune 500 Pharmaceutical Company Partners with LCE to Improve OEE and Save Millions

The Situation

A biotechnology and pharmaceutical company was struggling to meet customer demands and keep costs down. The company's products treat genetic diseases, multiple sclerosis, cardiovascular disease and other rare diseases.

Drug shortages, tight regulations, pricing challenges, patent cliffs, ebbing cash flow and shareholder pressures have presented a challenging environment for many executives in the pharmaceutical industry. As competition increases and emerging market demands rise, CEOs and COOs are shifting focus to the manufacturing sites for greater efficiency and improvements in Overall Equipment Effectiveness (OEE). When treating rare diseases it's not just financial ramifications associated with missing production numbers – lives are at stake when market demands go unmet.

The Challenges

The pharmaceutical company had exceeded its budget by \$2.1 million due to inefficiencies in manufacturing. Approximately 40 percent of overtime was necessary to meet production targets and 50 percent excess production hours were needed to achieve goals. Manufacturing data indicated that the Overall OEE on a critical packaging line was approximately 25-30%.

The manufacturing facility was plagued with chronic reactivity and an inability to stay within budget while also maximizing asset health over time. Historical equipment performance data, specifically downtime codes, was limited, which led to unexplainable performance loss (production loss) and an inability to define failure modes.

The following areas were identified as targets for improvement:

- Increase OEE
- Budget compliance
- Improvement in year-over-year site financials
- Decrease loss attributable to unplanned downtime
- Decrease the amount of unknown loss (performance loss)
- Inventory management
- Hourly performance metrics capture

The Approach

The company partnered with Life Cycle Engineering (LCE) to target a critical manufacturing line with risk-based asset management services - an engineering-based approach to equipment failure remediation and elimination of loss due to habitual poor maintenance and operator care.

After analyzing the equipment capacity, unexplained downtime and failure modes, it was determined that a five percent increase in OEE would support the

production goals of the site. In dollars, this equates to a cost savings of \$1.0 million a year and a 50 percent increase in equipment availability which offers scalable production potential if market demands rise. The percentage increase for OEE was determined based on available time, equipment maximum capacity (rate/min), production capacity time and market demand.

A structured change management process was implemented along with the tactical remediation activities to address the people side of change and ensure long-term success.

To achieve the outlined goal, LCE initiated a three-phase Line Performance OptimizationSM plan on a critical packaging line. Line Performance Optimization (LPO) is a process that identifies and pinpoints reliability trouble areas that lead to poor quality, downtime, waste and regulatory problems.

The first phase was the planning phase which included outlining the business case, current and future state, and key performance indicators of success. A review of all maintenance and operator processes was conducted to identify performance gaps. Failure Mode and Effects Analysis (FMEA) and value stream mapping were performed to pinpoint areas of vulnerability in production.

During phase one, LCE helped construct cross-functional focus teams to establish a plan around the following core areas:

- Employee engagement and adoption of change (change management)
- Consistent data entry and analysis
- Failure mode and effects capture process and analysis
- Reliability engineering (preventive and predictive maintenance best practices)
- Accurate inventory management

A holistic approach to managing the people side of change was incorporated into the entire engagement. This included a communications plan, sponsorship map, an integrated change competency and coaching as well as education. Leadership played a critical role in determining plant-level metrics while providing functional and moral support to the focus teams.

The second phase was the implementation phase, which included capturing data to more accurately categorize downtime and identify where areas of opportunity existed to decrease rate loss and increase production time. Hourly production boards were utilized for consistent tracking to minimize unknown losses. LCE facilitated an improvement in maintenance activities to mitigate failures that would have a significant impact on the line.

The last phase was the reinforcement phase. During this phase LCE and plant leadership analyzed new data, identified any existing gaps and established actions to close the gaps. Initial goals were reevaluated and modified as needed. The recommendations for improved preventive and predictive maintenance activities to sustain the assets at a higher level of reliability were instituted with expected long-term benefits. A plan was set forth to address the gap found in inventory management.

A comprehensive list of critical spares was created based on OEM manual specifications, asset criticality, risk priority number, cost and availability. Reinforcement of positive behaviors in compliance with industry best practices

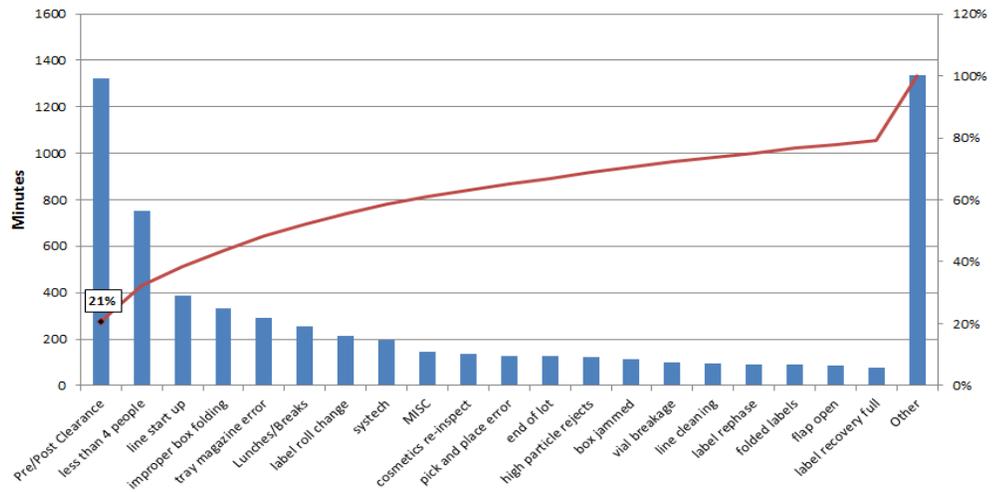


and LCE recommendations was incorporated into this stage to facilitate long-term sustainable change.

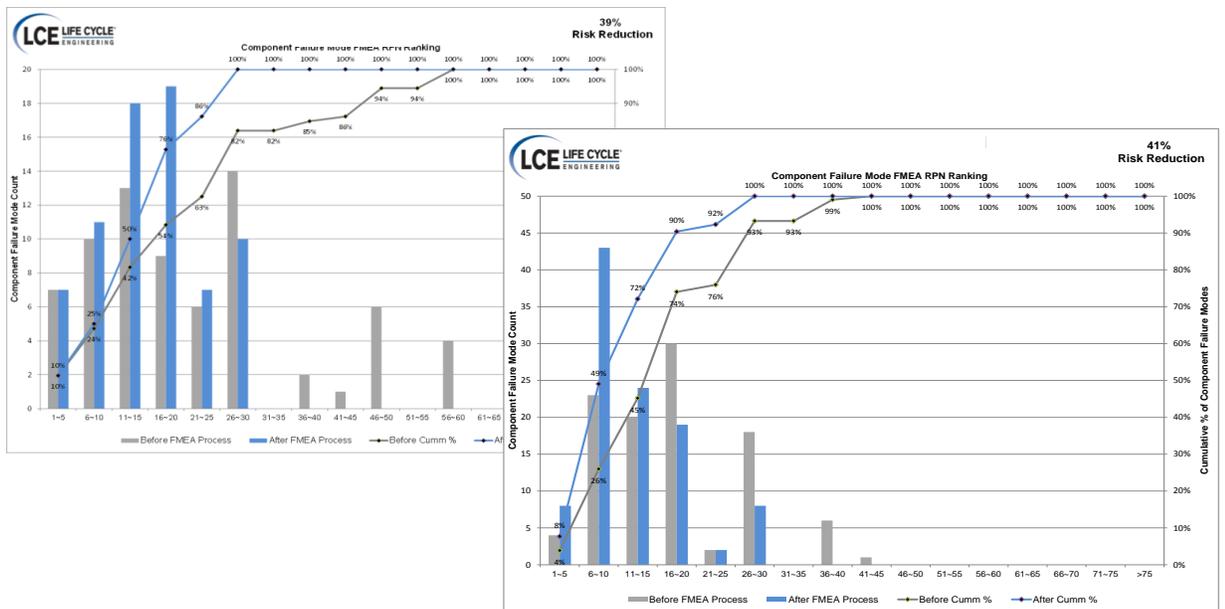
The Results

As a result of the reliability-focused asset management efforts, consistent data entry is now mandatory and hourly production targets are understood. Data collection and Pareto analysis enabled the team to identify where loss was occurring and resultant corrective actions have led to a 10 percent improvement in OEE in less than six months.

Top 20 Downtime Codes
(Jul 16th 2012)



FMEA activities identified equipment on the manufacturing line that was at high risk for a debilitating failure. Maintenance and inventory recommendations for two critical assets decreased the risk level by a cumulative magnitude of 80 percent.



Data analysis and remediation has resulted in a 70 percent decrease in rate loss and Overall Equipment Effectiveness has increased by 10 percent which translates to millions of dollars in product sales. The ability to scale up production based on market demands offers exponential financial benefits as well as increased customer satisfaction.

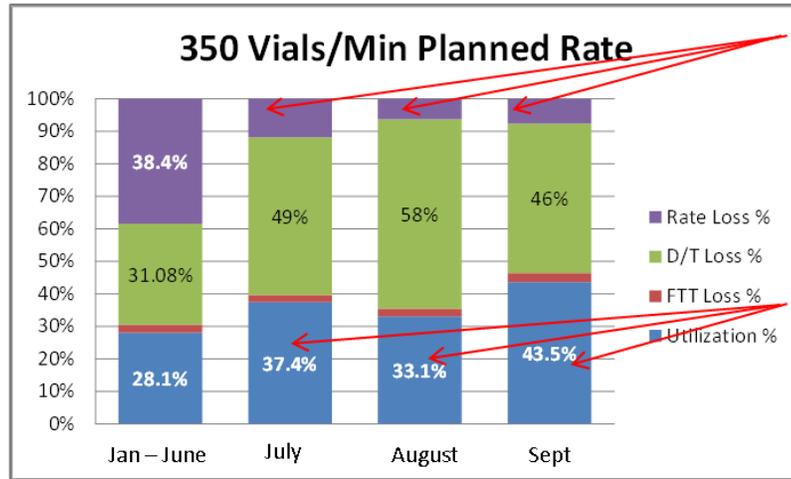


Figure 3.
 Historical rate loss (unknown loss) of ~40% has been sustained at < 10%.
 OEE has shown an average performance increase of ~10%.

Conclusions

Only one year after implementation, the plant met demand goals within budget with minimal overtime, which translated to savings of approximately \$1.0 million. The decrease in overtime hours opens the opportunity for more production should the demand increase.

Issues such as emerging market pricing obstacles, rising production demands and regulatory pressures continue to dominate the attention of pharmaceutical executives. This pharmaceutical company embraced the manufacturing sector of the business to remediate inconsistencies and inefficiencies so executives could focus on other strategic growth initiatives. The investment in asset reliability is part of a long-term vision: a transformation to a data-driven environment where employees are aware of business objectives and impacts of missing target production numbers. Improved manufacturing capabilities will facilitate continued growth and enable the company to better serve its customers.

The plant continues to develop and improve processes and business practices to further increase the savings and avoidance of costs associated with unplanned downtime and inefficiencies at the site. With more efficient processes in place, the company can focus on what they do best - delivering treatment for rare diseases and improving the quality of life for patients.



About LCE

As a leading maintenance and reliability solution provider for over 30 years, Life Cycle Engineering (LCE) (www.LCE.com) helps public and private enterprise gain increased profitability through greater capacity, lower operational costs, and decreased downtime. By combining a range of industry experts, unique processes with proven success, and a comprehensive array of educational courses, LCE has gained reputable status as the premier provider of innovative and successfully executed reliability and maintenance solutions worldwide.

