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This case study shows the impact of an organized and focused continuous improvement effort using teamwork on equipment reliability.

Life-Enhancing Biotherapeutics Company Nets Healthier Equipment

by Kevin Pait and Preston Ingalls

Introduction

The following is a case study of the reliability improvement program utilized by a North Carolina biotherapeutics company in order to reduce equipment downtime thereby increasing the overall throughput of their products. This case study will define the equipment involved and its importance to the production process, identify equipment deficiencies, and explain the methodologies and tools used to achieve greater reliability and accountability.

The Company

The mission of Talecris Biotherapeutics, a global biotherapeutics and biotechnology company headquartered in Research Triangle Park, North Carolina, is "to be the recognized global leader in developing and providing vital protein therapeutics." Achieving this mission involves a firm commitment to customers, employees, and reliable equipment.

Because of the importance of equipment reliability, Kevin Pait, Director of Plant Engineering and Maintenance, implemented Total Process Reliability (ToPR). ToPR is a program developed in collaboration with TBR Strategies,

a consulting firm based in Raleigh, North Carolina.

With the help of TBR Strategies, Pait identified two employees who would serve as ToPR Coordinators, and he also began to assemble an Implementation Team. The Coordinators, employees tasked with running the onsite ToPR program day-to-day, seek to identify the gaps between the current situation and the ideal situation. Next, they discern which ToPR methods and tools will most likely remove that gap. One Coordinator, Richie Hogg, is a Talecris veteran with nearly 17 years of production experience in operations, training, and performance development.

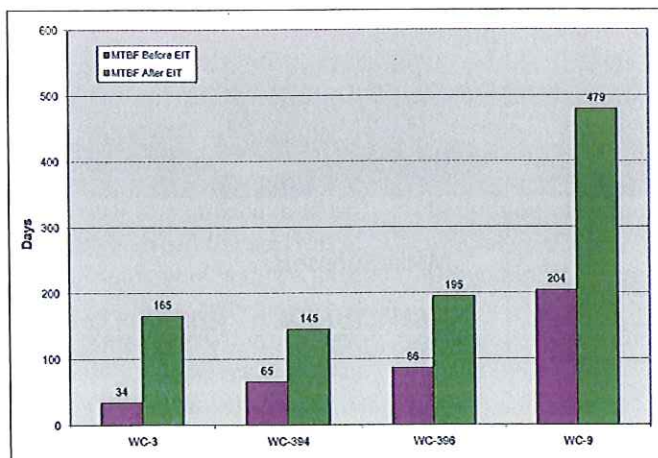
Hogg sees his position today as more theoretical than hands-on. "As ToPR Coordinator, my main responsibility is to promote transformation through collaboration and partnership within the maintenance, operations, and engineering departments. I am a change agent."

Pre-Planning

The Implementation Team, responsible for initiating and guiding cross-functional teams, determines projects based on criticality and historical performance. Criticality is decided by the importance of a piece of equipment to the overall process, and performance is based on uptime or Mean Time Between Failure (MTBF).

Once the Implementation Team has identified the new project, a senior management sponsor meets with a coordinator and team leader to write a charter. The charter includes a description of the initiative, goals, scope, boundaries, and project deliverables. The team leader chooses a group of employees (consisting of representatives from maintenance, operations, and engineering) to serve

Figure 1. Westfalia centrifuge - MTBF.



on the Equipment Improvement Team (EIT).

The benefits of an EIT include creating and improving machine care standards, initiating and maintaining visual controls, restoring equipment to a like-new condition, developing action steps for machine improvements, and tracking and displaying progress of the equipment restoration efforts.

Determining the Issue

One of the main issues identified by the Implementation Team was the equipment reliability of the Westfalia centrifuges. The centrifuges are high speed solid-liquid separators which utilize the differences in density of solid particles to achieve separation. Centrifugal force, created at speeds of approximately 5500 rpm, causes the solid particles to separate and adhere to the bowl wall, while the lighter substances (liquid) pass through.

The centrifuges are used for multiple functions in the Fractionation method, including the process to remove intermediates used in the treatment of Hemophilia A. The centrifuges also are vital in the separation and recovery of proteins used to produce therapies to treat a rare and difficult to diagnose illness caused by genetic emphysema.

So, successful production of the company's life-enhancing therapies greatly depends on the availability of the 13 Westfalia centrifuges. In terms of performance, the centrifuges were requiring excessive maintenance. By examining each

machine's failure report, the Coordinators identified the most problematic centrifuge.

The Process

The EIT process begins in a classroom format with a general safety review. The Coordinators then introduce the basic ToPR concepts to create an appreciation for the overall goals of the program.

The ToPR overview is followed by a discussion of the benefits ToPR can provide to the employee, the department, and the company as a whole. Team members learn equipment reliability principles, including the evolution of maintenance practices (World War II through today) and the theory of equipment operation.

The next step is viewing the equipment. During this time, the team identifies lock-out points and creates a plan of action. A list of cleaning needs and supplies is generated and an initial assessment is conducted on the equipment. The team reviews machine-specific safety information and identifies guard or cover removal points.

The next step of the EIT process takes place once again in a classroom setting. Discussion and lecture topics range from autonomous maintenance to cleaning and countermeasures. The team then moves back into a hands-on situation for a *Clean, Lubricate, Adjust, Inspect, Repair* (minor) and *Eliminate* (CLAIRE). This activity breeds a defect list that

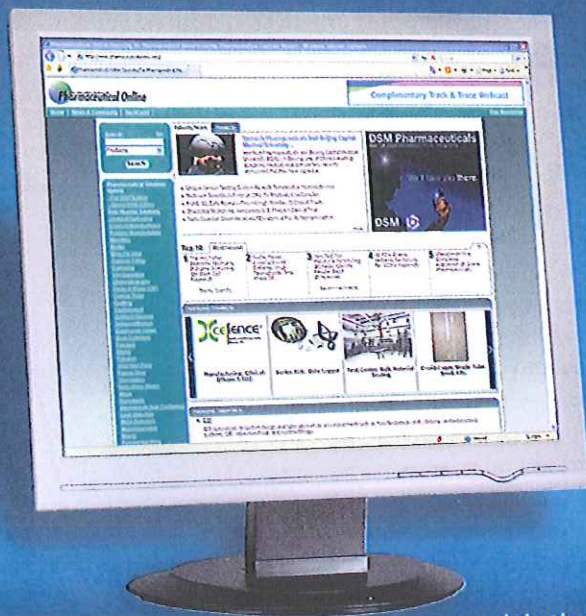
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"Focusing on cosmetic and mechanical order helps establish an operational respect for the equipment and also creates a department-wide sense of ownership."

can be prioritized and corrected using countermeasures, steps taken to eliminate defects. Countermeasures include, but are not limited to job aids, modifications to reduce cleaning and lubrication time, best practices, and single-point lesson plans.

Equipment-Focused Improvement Techniques

One defect exposed by the EIT, seal damage, was the result of "flooding" the Westfalia housing during the cleaning cycle. A countermeasure, in the form of an operator care standard, was developed to eliminate seal failures due to inappropriate techniques.

Countermeasures can be implemented using many tools, such as job aids, which can sometimes be seen in the form of Single Point Lessons. This form of job aid is a one-page document clarifying a single point or task in an operation. Single Point Lessons provide a short, concise description of the task and utilize pictures to illustrate the proper techniques and methods to complete the task.

Some Single Point Lessons are preventive measures, not countermeasures. In the case of the Westfalia, a Single Point Lesson with six steps was developed to disassemble and inspect the centripetal pump to ensure that the inner parts were clean and the seals were in proper working condition.

Best Practice Standards are another type of Job Aid that identifies the "one best way" to complete a task. Best Practices can be used to eliminate defects as well as enhance techniques that improve equipment functionality. They may include, but are not limited to machine care, lubrication, and cleaning. In addition to best practices and operator care standards, the team creates an operator troubleshooting guide and a rebuild parts list.

Employee-Focused Improvement Techniques

Cross-departmental training is another tactic being used to ensure equipment reliability by amplifying the relationship between maintenance and operations. "In addition to participating in the EIT events, the Maintenance Department teamed up with trainers in the Purification Department to provide hands-on assembly training with each operator in the Production Department," explained Maintenance Technician Ronald Crocker. "The training helped improve operating equipment knowledge and resulted in a lower number of assembly errors."

Technician Julie Monteiro realized the value of the collaborative aspects of the ToPR implementation:

"Having the operators and mechanics working together to refurbish the Westfalias bridged a gap between us. Operators are on the front-line of manufacturing, and now a ToPR trained operator understands how and why

a piece of equipment works. Because of this program, operators and mechanics are speaking and understanding the same language."

Another component of the team's training involved "5S" events, which stands for *Sort, Set in order, Shine, Standardize, Sustain*. Through these events, team members make equipment and workplace upkeep a priority. Focusing on cosmetic and mechanical order helps establish an operational respect for the equipment and also creates a department-wide sense of ownership.

Inspect What You Expect

Monthly inspections in the form of audits are performed to ensure that the desired level of equipment stewardship is sustained. Equipment audits are used to ensure that whatever the team evaluates – in this case Westfalias – is maintained at the highest level of Tighten, Lubricate, Clean (TLC). Fasteners, such as gaskets, nuts, and bolts, must be in place, including the right quantity and type to ensure the equipment is tight. Lubricants, such as oil, must be at the right level and quality. In addition, the equipment and its parts must be clean. Deficiencies discovered during the audit require immediate follow-up and corrective action.

Results

At the completion of the EIT, the Westfalia was tested in the maintenance shop. Each component was inspected by the team members. In addition, vibration readings were recorded by predictive maintenance technicians for baseline data and trending. The team goals (to restore the Westfalia to like new condition, develop best practices and operator care standards

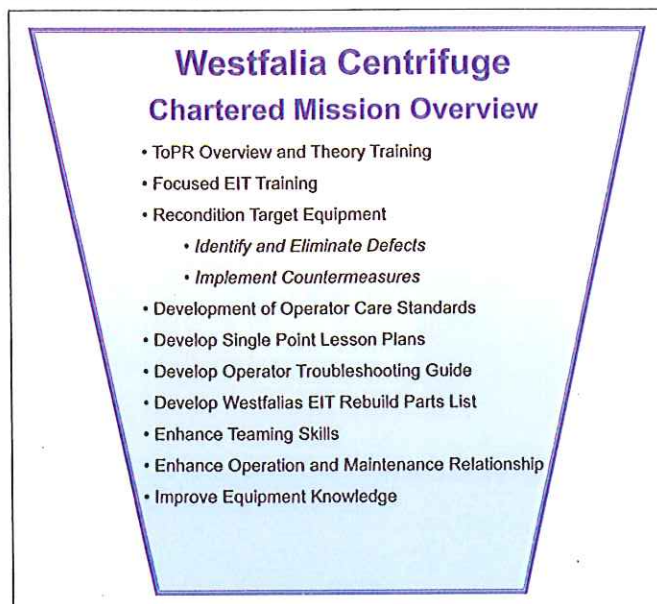


Figure 2. Westfalia centrifuge chartered mission overview.

and to measure MTBF to show results) had been achieved. Each team member participated in a debriefing with senior management to share their experiences from the event.

As a result of the EIT, the Westfalia centrifuge's MTBF increased from an average 34 days between failures to 165 days and counting. Following another EIT, a second Westfalia centrifuge's uptime is 479 days where, at one time, it was functioning at 204 days. In total, the performance of four Westfalia centrifuges has improved through EIT activities.

Summary and Conclusion

Total Process Reliability facilitates a cultural change at every level. It emphasizes leadership and the communal ownership and stewardship of equipment. ToPR also assists employees in providing therapies that improve people's lives, a vision that they believe in.

With a two-fold improvement in the performance of one centrifuge and an almost five-fold improvement of another, it becomes clear that the Total Process Reliability program yields exceptional results. The production of life-enhancing therapies at Talecris is more efficient, orderly, and productive, directly reflecting two of the company's seven core values: Operational Excellence and Teamwork.

About the Authors



Kevin Pait has more than 30 years of experience in plant maintenance and engineering, production management, process development, and strategic planning in the pharmaceutical, specialty chemical, utility, and biotechnology industries. He has extensive experience in plant and fleet maintenance. He is the Director of Plant Engineering and

Maintenance for Talecris Biotherapeutics, located in Clayton, North Carolina. His educational background includes a BS in chemical engineering and an MS in financial management, both from North Carolina State University. He is a registered Professional Engineer in the State of North Carolina. Pait can be contacted by telephone: +1-919-359-5028 or by email: kevin.pait@talecris.com.



Preston Ingalls is the President and CEO of TBR Strategies LLC, a maintenance and reliability consulting firm located in Raleigh North Carolina. He has more than 37 years in the field of maintenance, engineering, and reliability. As a consultant for the last 20 years, he has implemented maintenance improvement efforts with numerous manufacturers,

construction companies, oil and gas producers, and public utilities across 27 countries. Ingalls holds undergraduate degrees in manufacturing engineering and engineering operations, as well as a master's in organizational development. He can be reached by telephone: +1-919-341-1387 or by email: pingalls@tbr-strategies.com.

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