

PAR STERILE PRODUCTS: REDUCING WASTE ONE VILE AT A TIME

ABOUT PAR STERILE PRODUCTS. Par Sterile Products specializes in modified-released oral solid dosage forms and non-oral dosage forms, including nasal sprays, inhalers, patches and other alternative drug delivery platforms. Their focus is on therapeutically equivalent ANDA-based products (abbreviated new drug application) and others on a case-by-case basis. Par Sterile develops, manufactures and markets a broad portfolio of branded generic aseptic injectable products. With a sterile manufacturing facility located in Rochester, Michigan, Par Sterile employs 620 team members.

THE CHALLENGE. Par Sterile Products knew they had an excess of inside-filled losses, which are units containing product that have been discarded from the sterile filling process inside the aseptic area. These losses occurred on lines 1, 6 and 9 resulting in 44%, 78% and 66% of waste. Par Sterile knew that to grow their business and improve production, they needed to find a way to create less waste.

MEP CENTER'S ROLE. To help solve the problem, Par Sterile reached out to the Michigan Manufacturing Technology Center (The Center), part of the MEP National Network™, for training in data-driven techniques and a certification in Six Sigma Black Belt to help improve the effectiveness of operational processes. The Center's experts were able to guide Par Sterile's Black Belt candidate in how to ask the appropriate questions, identify and validate ways to measure the critical outputs, and then study the process to find factors which resolved the problem.

Following the steps outlined in the training by The Center, Par Sterile began by defining the project specifics into a charter, process mapping the current process, and then working out exactly how to measure inside-filled losses. This allowed them to create and validate the measurement method which would be used to resolve the problem.

Next, Par Sterile clearly defined where the current process was operating in a baseline capability study. They now had a basis to make comparisons to during the analysis of factors. Then The Center and Par Sterile began analysis by studying the various potential factors uncovered during process mapping. A design of experiments (DOE) was used to study these factors. This culminated with creating a fill check calculator to allow the operators to independently adjust the fill levels. The calculator now provides the settings they should use based on the product they are making.

Finally, Par Sterile and The Center implemented controls so the improvements can stand the test of time. They also updated their standard operating procedures and trained operators on the new changes. Following implementation, fill check data was monitored for approximately three months to confirm improvements.

"The Six Sigma Black Belt program proved to be extremely useful for our company, as it provided us with a systematic method to develop and implement improvements. In business, not every idea is a 'good' idea, but having no ideas is always a bad idea."

-Jeff Eastman, Principal Engineer, Operations Support

RESULTS



\$1,200,000 in cost savings



19.9% reduction in variation



Setup time reduced from 0.86 hours to 0.30 hours



Received Six Sigma Black Belt certification

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