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Optimizing Pfizer Continuous Drug Product Manufacturing with PCMM

Founded in 1849 and headquartered in New York City, with its research headquarters in Groton, Connecticut, Pfizer Inc. is the world's largest research-based biopharmaceutical company. As of 2020, the company reported annual revenue of $41.9 billion and had 78,500 employees.

This project, which took place at one of Pfizer's two primary research and development clinical supply manufacturing facilities in Groton, focused on the Portable Continuous Miniature and Modular (PCMM) platform, a first-of-a-kind, transportable, manufacturing facility for continuous oral solid dose pharmaceutical development.

PCMM accelerates the speed of tablet production and enables smaller, more flexible continuous processing. It is the epitome of Pfizer's goal to drive for breakthroughs that change patients' lives, because continuous manufacturing enables the company to accelerate the timeline to bring lifesaving therapies to patients.

"The purpose of the project was to maximize capacity on a continuous manufacturing equipment line, which manufactures solid dosage pharmaceutical drug product," said Robert Noack, senior director of drug product manufacturing. "With the technology platform in its infancy, work needed to be done to assess the current state, identify opportunities, and establish realistic numbers."

With demand for PCMM set to double from 2019 to 2020, Pfizer brought in a student team from the Tauber Institute for Global Operations at the University of Michigan, consisting of **Casey Carlson**, working on a Master of Business Administration degree, and **Anubhav Gupta**, seeking a Master of Science in Engineering degree in Industrial and Operations Engineering. The Tauber team was tasked with standardizing efficient work processes, visualizing capacity utilization, and establishing schedule adherence.

With uncertain clinical manufacturing and demand expectations, PCMM faced challenges with establishing and enforcing production schedules. Further, its team did not have formal processes to efficiently update schedules when faced with process upsets and delays.

Above: 2020 Tauber team Pfizer

> "The team showed a great deal of resilience and focus interfacing with all of the stakeholders, asking the right questions, and communicating effectively when they needed support to move forward."
> *Robert Noack*

Additionally, the PCMM team could not view true free capacity and identify process inefficiencies, as they were unable to distinguish between productive and non-productive downtime. With an unreliable view of capacity, the Tauber team focused on delivering a strategy for updating data tracking and establishing scheduling tools.

"The Tauber team developed a model using identifiable benchmarks in current processes and provided targeted recommendations for improvements in the model and improvements in asset utilization," said Noack.

"The drivers around the project involved anticipated demand for upcoming years and needing to have a way to answer capacity

Dr. Ravi Anupindi
Ross School of Business

Dr. Quentin Stout
College of Engineering

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Anubhav Gupta working on-site at Pfizer and remotely.

questions from an ambitious, but also informed and realistic point of view," he continued. "Design drivers involved ease of use and maintainability of those who will utilize it moving forward."

The Tauber team created a flexible Excel-based capacity model to understand capacity limits and schedule demand. The model enabled the team to run scenarios and recommend strategic improvements to improve process understanding of key large batches on the horizon in 2021.

"Realizing allocation of the asset in a manipulatable tool uncovered promising opportunities around better forecasting time needed, based on process knowledge background for a certain drug product and more effective scheduling," said Noack. "The Tauber team identified direct correlations between manufacturing history for a given drug product and time allocations for their manufacture."

The Tauber team also designed a daily downtime tracker to track non-productive delays, which with the scheduling tools, enabled Pfizer to view their true current capacity. Finally, the team created a high-volume production strategy by identifying work processes that warranted updates to enable longer run times required by the high-volume demand that PCMM would encounter in 2021 while increasing production capacity.

"One of the tools delivered, a downtime tracker to improve the effectiveness of the developed model, was piloted," said Noack. "The model was also demonstrated to predict 2021 timelines based on scheduled demand.

"The model itself is capable of being used immediately. Work needs to be done around classifying drug products based on level of process understanding to roll them out within the model. Additionally, targeted recommendations around scheduling structure need to be evaluated and will likely result in SOP/Procedure updates before implementation."

When applied, the dynamic capacity model, downtime tracker, and high-volume production strategy will have the potential to avoid the cost of outsourcing up to 20 batch equivalents to external manufacturers, which could cost upwards of $2 million. This will increase visibility and efficiency in scheduling PCMM operations and clinical manufacturing, with an anticipated 50 percent increase in utilization of yearly manufacturing capacity with the enforcement of the downtime tracker and high-volume production strategy.

"One of the primary challenges of this project was that it was fully remote," said Noack. "The team showed a great deal of resilience and focus interfacing with all of the stakeholders, asking the right questions, and communicating effectively when they needed support to move forward.

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"One of the highlights of the project was how well the Tauber students worked together and complimented each other's strengths. This quality was highlighted by multiple Pfizer colleagues they interfaced with across the duration of the project."

These initiatives with PCMM support Pfizer's strategic goal to lead the industry in rapidly delivering a large portfolio of life changing therapies to market.

"We are a research and development group which has adapted to function under full regulatory expectations after receiving a commercial license from the Food and Drug Administration (FDA)," said Noack. "The technology continues to roll out across commercial sites across the network. As a result, the learning that occurred during this project will have broad impact."

Student Team
Casey Carlson – Master of Business Administration

Anubhav Gupta – MSE Industrial and Operations Engineering

Project Sponsors
Kenneth Nadeau – PCMM Operations Manager

Robert Noack – Sr. Director Drug Product Manufacturing

Paul Stewart – Vice President Drug Product Supply

Faculty Advisors
Ravi Anupindi – Ross School of Business

Quentin Stout – College of Engineering

About Tauber Team Projects

The 2020 Tauber Team Projects resulted in $433.8 million in savings according to sponsoring company calculations, an average of $31 million per project over three years.

Each two to three person Tauber Team consists of graduate engineering and/or graduate business students. Along with receiving high-level corporate support from the sponsoring company, each team is advised by a College of Engineering and a Ross School of Business faculty member and overseen by a Tauber Institute Co-Director. The projects begin on-site in May and continue for 14 weeks. Students present the results of their projects and compete for over $40,000 in scholarships at the U-M Tauber Institute's annual Spotlight! Team Project Showcase and Scholarship event, held each September in Ann Arbor, Michigan. Spotlight! provides outstanding opportunities for students and corporate partners to establish relationships while exploring innovations in operations and manufacturing.

To learn more about the Tauber Institute for Global Operations, visit tauber.umich.edu or contact us at 734-647-1333.

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