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Evolving the Pfizer Drug Product Supply Informatics Strategy

Founded in 1849 and headquartered in New York City, with its research headquarters in Groton, CT, Pfizer Inc. is one of the world's largest pharmaceutical companies. As of 2016, the company reported annual revenue of $52.82 billion and had 96,500 employees.

Pfizer's Drug Product Supply (DPS) group had been developing and piloting a new manufacturing method, the Portable, Continuous, Miniature, and Modular (PCMM) process, which uses various advanced technologies to transform powders into uncoated tablets in minutes.

At the same time, Pfizer's Technology & Innovation (T&I) group was in the process of implementing the Scientific Data Cloud (SDC) as a new data management system.

These two technologies are well suited to each other, as PCMM generates huge amounts of data that current systems are unable to handle. Using these two technologies together is the best way to fully take advantage of both, helping to move Pfizer forward, shortening development timelines and getting medicines to those in need faster than ever before.

In order to improve informatics by leveraging these recent manufacturing and technology developments, Pfizer's DPS and T&I groups brought in a student team from the Tauber Institute for Global Operations at the University of Michigan, consisting of Pradeep Gopalsamy, working on a Master of Supply Chain Management degree, and Katherine Lobaza, a member of the Engineering Global Leadership Honors (EGL) Program, which leads to BSE and MSE in Mechanical Engineering degrees.

"The purpose of the project was to create an informatics strategy for the Pfizer DPS group, and then implement a solution to help meet this strategy using technologies from the Pfizer T&I group," said Lobaza.

"A holistic informatics strategy for storing, using, and re-using scientific and manufacturing data in real time must be built and use the wealth of data now available to make smart and effective decisions, allowing all resources to be fully leveraged," she continued. "As a systematic framework to improve data exchanges and collaboration, transform operations, and add value to an organization, an informatics strategy will help to speed the process of drug development and continue advancements in the manufacturing process."

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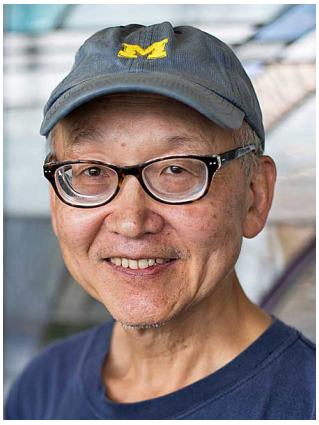

Above, right: Pradeep Gopalsamy and Katherine Lobaza onsite at Pfizer.

Jun Li
Assistant Professor of Technology and Operations
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Henry Wang
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In order to give a clear and comprehensive view of how these technologies can best be used, the Tauber team first created an informatics strategy specific to DPS. Then, the current state was analyzed in terms of this informatics strategy and gaps were identified.

"We created an informatics strategy for DPS that incorporates key features of centralized data, decision making, knowledge base, and delivery," said Lobaza. "Data is shown at the center of the strategy to represent how it is used in each of the other three areas, which form a cycle, and each pull on and feed back into data. First, a decision is made. Then, a solution is delivered. Finally, the knowledge base is grown from the previous steps, so that the next time through the cycle a better decision and more seamless delivery can be made.

"Data is used during each of these steps. Before a process, data is used to make smarter and more effective decisions. During a process, data is used to provide a streamlined and seamless delivery. After a process, data is used to learn from the experience."

Lobaza noted, "This informatics strategy was used to analyze the current state of DPS. Through stakeholder interviews, the Tauber team developed an architecture of current systems, which was analyzed in terms of data connectivity, visualization, and knowledge management to identify gaps."

For the purpose of this project, the area of visualization was selected and solutions were implemented to fill these gaps. Specifically, visualizations were created for PCMM using

SDC as a data source, with the goal of helping scientists focus more on the science and spend less time gathering and analyzing data.

"The SDC's goal is to improve data management, specifically how data is captured, stored, used, and reused," said Lobaza. "Currently, data from lab instruments and manufacturing equipment is saved in multiple file formats and manually extracted and entered into systems and reports. From these reports, data is extracted and analyzed. For computational models, data is extracted from raw data files, extracted from systems and reports, and tweaked based on analysis. There is little standardization, and finding information is a time-consuming process.

"The goal of SDC is to simplify data management. Data from lab instruments and manufacturing equipment will be automatically swept into the cloud. Data will then be made available to systems and reports. Visualization tools will be configured to pull data directly from the cloud, making it easier to analyze and show information. Finally, data will be provided to build and run models, and predicted output from the models will be stored in the cloud for further comparison."

The Tauber team identified, mapped and integrated critical data points, and created visualization templates. In addition, the Tauber team created visualizations using a similar method to create a real-time operations dashboard to provide information to managers to make faster and more effective decisions.

"To develop the PCMM/SDC focus area, the current state of PCMM data flow was analyzed, with a focus on benefits of coupling PCMM and SDC," said Lobaza. "The Tauber team conducted interviews with experts to understand specific use cases. One was selected: bringing manufacturing and raw material data together to understand the relationship between these data sets, and using this knowledge to fine tune equipment settings to optimize manufacturing. After identifying critical data points and sources, the Tauber team created visuals, pulling data through SDC.

"For the operations dashboard, a similar approach was taken. First, the Tauber team interviewed stakeholders to identify important data and necessary visualizations. Next, the source of the data was located, and finally visuals were created with an automatic

From left to right: Paul Stuart, Vice President, Katherine Lobaza, Pradeep Gopalsamy, Jessica Sigurdson, Operations Support Engineer, Robert Noack, Director of Clinical Manufacturing

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connection to the source system. The pain points in the current state—that reports are static, time-consuming to create, and shared primarily in presentations—are solved by this dashboard, which replaces traditional reports with a template that automatically updates and can be viewed by individuals to make decisions quickly and effectively."

Recommendations for expanding the visualizations and making improvements in other areas of the informatics strategy were also provided so that Pfizer can continue to advance in informatics after the Tauber team project concluded.

"Developing these focus areas helped the Tauber team recognize other opportunities for improvement," said Lobaza. "Recommendations include creating automatic and direct uploads to SDC, validating data collection, and minimizing data manipulation within Spotfire software.

"In addition, other areas of the informatics strategy can be explored, helping Pfizer continue to improve in informatics after the Tauber project has completed. Advancing in informatics will move Pfizer forward: making decisions faster and based on more complete information, shortening development timelines, and taking advantage of advanced technologies."

Benefits from the PCMM visualizations include reducing time spent gathering information and creating visuals from weeks to minutes. In addition, the knowledge gained from PCMM visualizations will lead to increased process understanding, helping to limit development runs. Cutting one development run could save over $800,000 in active pharmaceutical ingredient costs alone, and would free the equipment for other purposes, resulting in better equipment utilization.

In the end, however, the real benefit is to the patients who will receive treatments that Pfizer will be able to develop faster and more effectively.

Pfizer Project Team

Students
Pradeep Gopalsamy–Master of Supply Chain Management

Katherine Lobaza–EGL (BSE/MSE Mechanical Engineering)

Project Sponsors
Vijay Bulusu–Director, Informatics and Innovation

Qing Chang–Senior Manager, External Supply

Robert Noack–Director, Drug Product Supply

Jessica Sigurdson–Support Engineer, Drug Product Supply

Matthew St. Louis–Director, Data Science and Analysis

Faculty Advisors
Jun Li–Assistant Professor of Technology and Operations, Ross School of Business

Henry Wang–Professor of Chemical Engineering, College of Engineering

About Tauber Team Projects

The 2016 Tauber Team Projects resulted in $460 million in savings according to sponsoring company calculations, an average of $14.4 million per project over 3 years.

Each two to three person Tauber Team consists of graduate engineering, MBA, and/or MSCM 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!* 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.