Background
A leading medical equipment company selected us to manufacture their Class II diabetes product. The federal government designates Class II medical devices as those devices which have a moderate to high risk to the patient and or user. More than 40 percent of medical devices fall under this category. They require the utmost reliability as any mistakes or issues in the design or manufacturing process could put patients at risk.

Establishing compliant manufacturing processes for medical devices can take years due to the stringent performance, reliability and safety specifications involved. Additionally, any modification to those processes requires revalidation, documentation and resubmission to regulatory committees, a time-consuming and costly process that can cause delays.

Given the high stakes of a patient’s well-being and the need for precise planning and forecasting, medical device manufacturing is an ideal candidate for simulation technologies that use software-based environments to optimize processes. One such technique, discrete event simulation (DES), models the operation of a real-world system as a sequence of discrete events. It allows us to safely and accurately model, simulate and analyze the necessary relevant assembly, testing and shipping processes.

DES accelerates time-to-market and reduces costs significantly by enabling us to:
- Design an efficient flow of people and materials
- Predict yields more accurately
- Reduce inventory
- Increase throughput

Challenge
As the healthcare industry adapted to the pressing needs of the global pandemic, medical professionals also had to continue addressing other critical healthcare demands. We needed to help our customer accelerate and optimize the development of a Class II diabetes product to ensure speed, quality and reliability during the first quarter of 2020.

Solution
To optimize the manufacturing of the diabetes product, we used DES to create a digital twin of the factory floor.
With this virtual representation of our complex production system, we tested how it would perform under various scenarios and gained insights on optimization tactics.

First, we imported representations of the production assets, like equipment, layout and staff, into the DES software to mimic the physical production process. We also analyzed how equipment in the environment related to other equipment, people, materials and other objects. This provided a baseline for the process flow.

With the process flow in place, we then loaded relevant data and assigned them to the appropriate asset, creating a digital twin of our factory operations. This enabled us to simulate processes without expending equipment or materials, iterating hundreds of thousands of “what-if” scenarios. When the tests were completed, our business and engineering staff worked with our simulation experts to review the output for further optimization. We focused on several key dimensions, including:

- Improving yields
- Utilizing carts to remove bottlenecks for value-added processes
- Evaluating the master schedule to increase delivery from 5.5 million to 8.1 million units per quarter
- Optimizing work order sizes to deplete material in the given unit

Results

Without simulation this testing process would have taken at least three months longer. But our DES tool allowed us to complete our optimization analysis in only three weeks, enabling our customer to get the product to market faster. This saved our customer time – and money. It also tested the process to ensure it would yield a reliable product, a critical success factor for Class II medical devices.

Using our simulation expertise to optimize production processes, we helped our customer achieve significant ROI. For example, using more carts to transport material and work-in-progress products around the factory for value-added processes introduced greater process efficiency. Without performing simulation, we would not have identified carts as a solution to unblock potential bottlenecks.

Major efficiency gains included:

- **70%** increase in station output by optimizing work order sizes
- **47%** more units produced per quarter
- **15-21%** higher value-added process utilization through cart availability optimization

We’ve been recognized by The Manufacturing Leadership Council for our application of simulation and digital twin technology.