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JOE FICALORA, SBTI's President of Global Services, shares how Lean Six Sigma tools can transform a pharmaceutical company's business on multiple fronts and improve the organization from top line to bottom line

Future Pharmaceuticals **How does a Lean Six Sigma deployment affect a pharmaceutical company?**

Joe Ficalora A Lean Six Sigma deployment affects a pharmaceutical company in many ways. First of all, the deployment itself is not static, because the company's executives make the decisions in terms of how it will be deployed and how significantly it will be integrated as a business initiative. The fundamentals of a deployment are very valuable to any company, whether you're talking about pharmaceuticals or any other industry. Companies are looking to get their products and services out to customers and receive appropriate compensation in a way that they hit the bottom line. A Lean Six Sigma deployment can affect everything from the top line all the way down to the bottom line, so there's a fairly significant financial aspect of a good Lean Six Sigma deployment, and especially so in a pharmaceutical company.

FP **What impact could Lean Six Sigma have on the operations department?**

JF Lean Six Sigma originated in operations and manufacturing companies. So, specifically, the Lean portion of Lean Six Sigma will improve the efficiency of operations. To stop taking unnecessary steps, doing unnecessary processing and instead removing waste in an operations environment is critical to having an efficient and effective manufacturing or service delivery setup. In Lean Six Sigma, our impact on operations is enormous. A Lean Six Sigma deployment will have tremendous impact on the speed at which product flows, the use of resources, space, human resources in terms of the number of people, and the hours utilized to produce and deliver pharmaceutical products and services. Overall, the effectiveness of each operation improves dramatically with the Six Sigma tools, which focus on removal of defects.

FP **How can Lean Six Sigma affect domestic and international supply chains?**

JF Lean Six Sigma can have a critical effect on supply chains. If you look at today's pharmaceutical environment, increasingly, the supply chains no longer just cross local borders within a country, they actually cross international borders. So, any modern pharmaceutical manufacturing operation will be getting from both suppliers and customers a tremendous amount of product flow and materials flow across countries.

To make these transitions, each step has to have proper regulatory approval. Having the proper speed and efficiency there is critical to the overall efficiency of the manufactured product. Lean Six Sigma helps remove barriers at these interfaces and optimizes the entire system of the supply chain, as opposed to just your local manufacturing or servicing area. Having the same language and the same tools across the supply chain promotes cooperation and coordination in a way that previously hasn't been seen. This is especially important when you're starting to compete in new ways, and in today's market, companies have to change their business models sometimes as often as quarterly to keep up with the competition that's showing up worldwide. Having the same language in place across your supply chain makes changing the business model or even changing the business that much more effective when you have achieved it.

FP **How can Lean Six Sigma be applied to the back office, in terms of invoicing and accounts receivable?**

JF After many deployments that we've done, we've found that there's as much money, opportunity, savings, and resource opportunities within the back office operations as there are within the operations themselves. In a heavily regulated environment like pharmaceuticals, there is a tremendous amount of paperwork, there is information that has to flow, and there is a need to get the right information to the right people at the right time. Doing that is no different than getting the right supplies and components to the right manufacturing center at the right time. So, it applies tremendously to the back office operations, specifically to invoicing defects: missing information or incorrect information will slow an invoicing process or accounts receivable immensely. To make that more effective and efficient, the focus on identification, measurement, analysis, and finally the removal of defects, as well as setting controls in place, has a huge impact on the back office operations.

FP **Could Lean Six Sigma be an asset for companies' human resource departments and hiring practices?**

JF Lean Six Sigma could absolutely be an asset to these areas. When you look at a hiring process function within human resources, your goal is to get the best candidates to the right positions. You also need to make sure that the candidates have an overall positive experience, because you're no longer competing with just internal situations, you're competing with other companies that are also trying to get the best talent, and you need to leave them with a professional impression. Having a smoothly run hiring process that leaves the right information with the candidate, and ensures the right handoffs are made as that individual interviews across several different people creates a sense of balance and timing. When Lean Six Sigma is applied to any process, it makes it more smoothly run and erases any glitches or defects.

FP **How does Lean Six Sigma impact research and development?**

JF With research and development, we normally use something a little bit different: it's called 'Design for Six Sigma'. Unlike in operations or business processes, where you have an existing process and you're trying to improve it and remove problems from that process, with research and development there's just one major process, which is new product development.

New product development is the most complex business process any company has, because it's the most leveraged business process. It's important to remember the company stakeholders — both shareholders and those who have their internal reputation on the line when a new drug is launched. By this point, you've poured millions and millions of dollars into research and development efforts, so it has to be perfect when you launch. You can't afford missteps; you cannot afford surprises.

"WHEN LEAN SIX SIGMA IS APPLIED TO ANY PROCESS, **IT MAKES IT MORE SMOOTHLY RUN AND ERASES ANY GLITCHES OR DEFECTS.**"

We always say the goal of research is to create surprises, and the goal of development is to remove them.

When you finally launch a new product, you want it to be something that your supply chain is ready for, which means you need to have Lean Six Sigma deployed in your supply chain. With Lean Six Sigma deployed, you know the capabilities of each supply process, and you can have the process designed so that the needs of the end users are being met. You also need to meet the needs everyone else downstream: the doctors, the distributors, the distribution centers, and others. In all of that, the greatest leverage you have is in the design decisions and the design process. So, the tools there are a little different because the focus is on getting the right value into the design of product and design of process as you create and launch new pharmaceutical products.

FP How does Quality By Design compare to Design for Six Sigma?

JF Quality By Design (QBD) has been promoted by the Food and Drug Administration, and it has a tremendous amount of things in common with Design for Six Sigma (DFSS). DFSS pre-dates QBD by at least five years. They've got a lot of commonalities, and the goal is fundamentally the same, which is to make certain that there are no surprises. To do that, they also use statistics and statistical tools like design of experiments, model building, having the right critical-to-quality metrics, and they have a focus on the end-user requirements and meeting those predictably.

There is also a focus on process quality. Understanding how you reach your endpoint and understanding the key independent variables within formulations and process designs affects the outcome of the critical-to-quality results. Certain tools, such as process tools and statistical tools, focus on finding the sources of variation and reducing or eliminating those variations. Finally, within the now-confines of what variation you will allow, having the right statistical process controls is one of the key tools at the end of the process. Those are the similarities between QBD and DFSS.

When we look at the DFSS that we've deployed and compared it to QBD, we find some fundamental differences. With regard to the first aspect, we call that 'voice of the customer', and it's not clear to us that QBD has a rigorous approach and a focused set of tools to properly analyze the voices of customers, identify their needs, prioritize them, and then validate the needs before designing. Within DFSS, we have a much greater focus on voice of the customer.

The second difference is that we have in DFSS what we call 'voice of the business': an understanding of the product lifecycle and what the investment is likely to be. We tend to say that there are three questions which must be answered, and I don't see these being answered in completeness within QBD. Those three questions are: is it real? Can we win? Is it worth it? 'Is it real' means: how large is the opportunity? Most businesses ask themselves this already, but there are tools around how to define and delineate this piece. 'Can we win' asks: what are the competing alternatives? How is what will be developed under this particular group of projects better than any of the alternatives? Lastly, is it worth it? What is required to make this new product a reality?

Most pharmaceutical companies rely on a blockbuster drug or result every few years to make their revenues and to grow. DFSS spends more time on the product portfolio side, helping to identify which projects are going to have the greatest chance of success, and, through data and analysis, stopping the ones that aren't going to have success, earlier. Therefore, you make a maximum usage of your available scientists and development people.

FP What effects could these methodologies have on a pharmaceutical company?

JF Looking at the big picture, you can have tremendous growth and a much more robust product development portfolio by using DFSS than you would otherwise. You can lead the marketplace by launching product services that far better meet the demands and needs of your customers, be they the end users of the drug, the doctors, or the pharmacists. On the operations side, you want to make certain that once you have that blockbuster chemical drug formulation, that you can recreate it with consistency, efficiency, and in the best manner possible, including distribution and invoicing, and making sure that your accounts receivable is doing the best it can. From top line to bottom line, by using Lean Six Sigma tools and DFSS tools, you can have a better company with much happier people, because everybody likes to work at a company that's growing. **FP**

JOE FICALORA President of Global Services, Sigma Breakthrough Technologies, Inc. Mr. Ficalora is certified as a Black Belt and Master Black Belt. He has consulted clients in the pharmaceutical, medical devices, beverage, health care, food packaging, electronics, metal, glass and plastics manufacturing industries. He has mentored, designed and taught workshops to Executives, Champions, Master Black Belts, Black Belts, and Green Belts in Design for Six Sigma, Six Sigma in Manufacturing, and Transactional Business projects worldwide. Mr. Ficalora is a top-rated and sought after instructor and speaker and is the developer and designer of number-one-rated Master Black Belt program in the country.