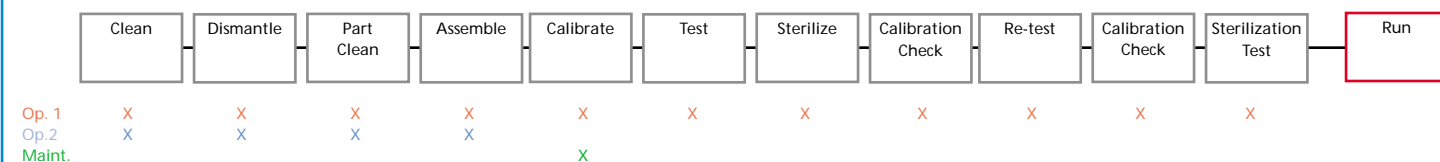


## Set-up Reduction in Biotech: When Every Minute Counts

By Gérard Massai, Senior Management Consultant

Macro Process Map 1



**T**he biotech companies that create the drugs to treat everything from cancer to weight loss have a different relationship with delivery than most manufacturers. For the small appliance maker or the engine builder, delivering a product to market late represents a missed opportunity, a probable loss on the balance sheet.

For a pharmaceutical company, a late product can mean lost lives. Reputations have been won and lost around the delivery issue and, as with most businesses in the medical field, reputations directly relate to the bottom line.

So, when we began work in the summer of 2001 with a pharmaceutical company that needed to increase capacity and ensure delivery, we knew we were dealing with a bottom-line issue. This company's new drug was on the verge of being approved in a huge market and – in order to prepare for the probability that was still not a certainty – leadership knew they had to increase capacity without spending capital.

We launched a LeanSigma® initiative in October, with leadership joining teams as we mapped the entire value chain, looking for the greatest opportunities to increase capacity. Soon, a set of bioreactors leapt off the walls where we had hung our huge maps.

As you can imagine, a biotechnology plant is a challenge for change agents, where hygiene and the risk of contamination put a new emphasis on materials handling and careful action is more important than fast action. Working with bioreactors only adds a level of difficulty. Most bioreactors – which are like large, complex ovens – work 24 hours a day, seven days a week. They are only shut down for cleaning after long intervals, which vary depending on the process. Dismantling, cleaning and calibration of each machine is a careful, time consuming task that, at this company, took more than two weeks. Our first goal: a set-up reduction event to slash cleaning and recalibration time in half.

With such a long cycle time in the cleaning

process, we knew we couldn't employ the usual kaizen methodology of observation, improvement and testing. We broke the project into two weeks: an investigation and preparation week in December and implementation in February. In many ways, this looked like a business-process kaizen as we created a macro process flow, then detailed each step and classified the opportunities.

As you can see in Figure 1, there was some redundancy to be eliminated. We also needed to collect all necessary tools to a central point, create a spare parts list and define the role of each operator. Most importantly, we needed to formalize standard operations for each of the two operators, which we plotted in large format using Microsoft Project software.

At the end of phase one, we discovered that we had slashed bioreactor downtime not by 50 percent, but 70 percent – to just four days. Standard operations were in one file instead of three and total operator time had been reduced by 53 percent.

In the weeks between phases, team members built a tools trolley, refined the spare parts list and updated the standard operating procedures.

When phase two was completed in February, we were certain that the bioreactor could be shut down, completely cleaned and put back on line in just 2.5 days. The team is currently completing the entire process in 3.5 days and concentrating on training.

The company leaders will be able to replicate the team's set-up reduction work to other bioreactors in their plant. They predict annual estimated savings at more than \$2 million.

The best part is this: when the company's drug was approved for use in the new market, all the press releases confidently included two important words, "Available immediately." ■

