September 11, 2013

Imagine... a Process-Centered Pharma

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Last month was the 50th anniversary of Martin Luther King Jr.'s famous "I have a dream" speech, and this month is the 42nd anniversary of John Lennon's "Imagine" bringing images of utopia to the world.

They motivated me to ask why pharma can't seem to get itself a better business model and what that might be.

We already know all too well the blockbuster paradigm: invent, produce, market, and genericize. Yes, it has worked beautifully and kept us all employed for decades, but is it sustainable? Will it serve the needs of 60 percent of the world's population? Will it allow the industry to innovate, not just in the drugs it introduces, but also in the way it develops and makes them? Can it move the industry beyond its current quality-by-analysis approach marked by inadequate manufacturing and quality systems that slow efficiency, limit the market's potential, and are at the root of many of today's quality failures?

In developed nations, the old model is propped up by the overall healthcare system, high drug prices, and acquisitions that often fail to yield adequate ROI. Isn't it time for an easier, more ambitious plan? I imagine a new world where economies of scale are the norm. Production of key APIs or finished drugs takes place in fewer facilities. Current and innovative technologies and methods are applied to pharma manufacturing (APIs and their formulations).

In this new world, drug dosage would no longer shackle drug companies to old-fashioned mom-and-pop approaches to API manufacturing, formulation, quality, and distribution. Pharma's entire business model would be based on everything from how much an API is needed to plans for production, formulation, supply chain management, and every detail, down to the purchase of raw materials, solvents, excipients, and packaging materials. The process would determine the technologies and the improvements and would allow output to be adapted simply and rapidly to address changing business needs.

At this point, the industry continues to focus on regulation. Companies often fear that improvements would change the product profile from what regulators previously approved. In addition, they don't see any ROI for process innovation or improvement, given the low production volume of APIs or formulated drugs involved at each site.

Most of what is discussed at conferences today focuses on how to meet regulations, rather than how to create excellent and improvable processes that exceed minimal regulatory requirements. As a result, many within the industry have forgotten how to apply the fundamentals of science and

engineering. We read more about risk management, FMEAs, and fishbone diagrams, for instance. Some of us might recall that this was common practice in the 1970s.

Consolidation is the key to the alternate model, but it provokes fear. People fear loss of their livelihood, but they don't realize that consolidation would increase jobs as the market expands, and it would raise the level of skills required.

Having fewer manufacturing sites would produce the economies of scale that would allow us to have the best manufacturing technologies. Moving from regulation centricity to process centricity would make it easy for companies to comply with and even exceed regulatory requirements. Costs would be lowered, redundant quality testing would be minimized, and profits would rise. The savings could exceed $200 billion per year. In addition, pharma could add 1.4 billion or more customers to its demand base. This would be a laudable accomplishment.

This might seem radical, but major changes are usually worth the effort. Landing on the moon was radical, but we did it.

Change is painful. The establishment usually complains and clings stubbornly to what it knows. Just consider the reaction of technicians, phlebotomists, and others in healthcare to new, automated processes that allow blood testing and some basic diagnoses to be completed much faster and at a lower cost. The Wall Street Journal recently looked at one company innovating in this area.

Pharma manufacturing and development are ripe for game-changing innovations and improvements like this. Will we seize opportunities or continue to fight them out of fear? Can we allow ourselves to imagine? "You may say I'm a dreamer, but I'm not the only one."