



WHAT WOULD STEVE JOBS TELL THE PHARMA BIOTECH INDUSTRY?

by Martin Lush

Whether or not you're a fan of the man and his products, two things are undeniable: He was successful and different, and his methods have merit. The title is just a metaphor to encourage our industry to radically change — not by reinventing the wheel, but by copying the success of others.

WHY MAINTAINING THE STATUS QUO IS NO LONGER GOOD ENOUGH

We live in an era of new everything — new science, new regulations, new presidents, new governments and new challenges. To prosper in this era of brutal disruption, we must think differently.

As Einstein said, "The definition of insanity is doing the same thing over and over again, but expecting different results."

To help us do things differently, let's imagine asking Jobs the question "**Based on your experience, successes and failures, what would you tell the pharma biotech industry?**" and then extrapolate some answers. Since he was a man who liked to get straight to the point, his list would likely be limited to five recommendations.

TOP FIVE RECOMMENDATIONS

1. SIMPLIFICATION IS SURVIVAL

Jobs was a complex man driven by a simple belief: Simplification is survival. For the pharma industry, this means drastically simplifying everything.

Your call to action:

- > Simplify documentation systems, particularly SOPs. For many companies, SOPs are out of control. They have become overly complex and impossible to follow. Instead of improving consistency, they increase the risk of errors



and mistakes. Instead of being written for the user, they have been written for the auditor or regulator. This must stop. If you want guidance on how to write a good SOP, just look at a recipe book! You'll see lots of pictures and simple diagrams! The answer to better documentation systems is in your kitchen!

- > Simplify batch manufacturing records (BMRs). Excessively detailed instructions, poorly designed documents and excessive check signatures (most of which are not required), all contribute to user overload, stress and mistakes. The purpose of the BMR is to provide essential guidance to the user, and provide an accurate and reliable history of events – the who, what, when and how. Unnecessary complexity slows everything down, dilutes accountability and increases risk.

2. NO, NO, NO AND NO: LESS IS MORE

Jobs believed success is determined by what you stop doing. He would be telling us, "Just focus on doing the basics exceptionally well, and forget the rest. If you try to do everything, you will fail."



Your call to action:

- > Tune up your change control system. If your change control system approves everything, it's dangerous. A good change control system works on the tried and tested principles of Pareto. A good system only approves the 20 percent of changes that provide 80 percent of the benefit — those vital few.
- > Hone your risk management skills. 'Less is more' requires good judgment. Whether your change control system approves or rejects planned changes, one thing remains constant: risk. To make the right decisions, you must have excellent risk management skills and competencies.
- > Remember, your success is determined by what you can unlearn.

3. HIRE PEOPLE WHO BREAK THE RULES

Steve Jobs challenged convention — and, on occasion, broke the rules. This recommendation will have many industry veterans running for the hills. Employing rule-breakers in an industry that prides itself on compliance seems counterintuitive. Think about it another way: Rule-breakers are simply those who keep pushing the boundaries. They keep challenging. They keep asking why and they never give up. History proves Jobs was right.

Your call to action:

- > Rethink your recruiting practices. If companies recruit the same types of employees, they get just that; the same decisions and the same outcomes, and, ultimately, maintenance of the status quo. But, in an era of brutal disruption, the status quo is no longer good enough. The pharma industry desperately needs people who think differently — more 'why?' people.
- > Allow rule-breakers to do what they do. Progress, in every walk of life, is usually made by rule-breakers; those who are always looking for a different way.
- > Don't just recruit people from the traditional sources, such as the pharma company next door — unless you want more of the same. Try attracting candidates from the automobile and microelectronics sectors. They have been practicing total quality management (TQM) for over 50 years!

- > If you want a lesson in how to manage quality, keep things simple and be laser focused on the end user. Hire people with backgrounds in fast-moving consumable goods. Instead of taking on graduates with traditional science degrees, recruit a few with degrees in philosophy — people who are trained to think differently.
- > Hire people who know how to think. The upside of falling prices for our medicines and rising manufacturing costs is that we all have to think differently. So, remember to hire based on two things; character and creative thinking ability.

4. BECOME OBSESSED WITH FINISHING AND FOLLOWING UP

Jobs was a details person. A recent survey conducted by Harvard Business Review found that a large percentage of changes and new initiatives fail because of poor implementation and follow-up. At NSF, we've found the same. For example, most deviation and CAPA (corrective and preventive action) systems have no effectiveness checks to make sure the corrective and preventive actions have been implemented correctly and are working. The same goes for many audit and self-inspection programmes.

Your call to action:

- > Become obsessed with disciplined execution, implementation and follow-up! The pharma industry is populated with very bright people who come up with lots of very bright ideas... that usually fail. The root cause? Poor (ill-disciplined) implementation. This is compounded by no follow-up to see what has worked and what hasn't. We just need to apply Deming's PDCA (plan – do – check [measure and follow up] – adjust) plan.

5. KEEP THE MAIN THING, THE MAIN THING... OR DIE

Jobs was obsessed with satisfying his customers, the end users of his products and services. From the minute you enter an Apple store for repairs or service to your Apple device, you are 'the main thing.'

When visiting companies, it's important to ask people – from the warehouse supervisor to the CEO – about



their products and patients. Do they really understand how their products work? Do they really understand every one of their products' key quality attributes? Crucially, do they really understand how their products improve patients' quality of life?

Those who put more focus on the monthly profit and loss (P&L) spreadsheet and forget patients usually go out of business. In contrast, companies who keep their patients at the centre of everything they do flourish.

Your call to action:

- > Conduct the 'patient test.' Ask everyone you meet about the products you make and the impact they have on your patients. Ensure that everyone is emotionally connected to the patient. If you don't, you're in trouble. Many companies put the 'patient first,' using posters and slogans that, in time, become meaningless words; invisible and soon forgotten. The most important job of leadership is to keep people motivated by giving them a reason to care about what they do beyond the P&L. This means constant reminders that the patient is at the centre of every decision — and this must be communicated not by using flashy posters or slogans, but through the actions of leadership.
- > Don't allow stress to eat away at your motivation. There is no shortage of quality, integrity and commitment in the people working in the pharma industry. However, the routine of working in a highly pressurised, 24/7 world can be dangerous. The hours consumed by emails and meetings, the obsession with measuring things that don't really matter and the pressure to hit manufacturing, testing and product release deadlines can cause our patients, 'the main thing,' to be forgotten.

ADAPTING BEST PRACTICES FROM BEYOND PHARMA

Apple is only one example of a company with a quality and customer focus that may be worth emulating. The pharma industry must get better at borrowing best practices from other industries, rather than reinventing the wheel. Many of the challenges and problems we face are not new. The answers are already out there. The solutions are waiting to be applied.

For example, the solutions generated by the aviation industry could guide us in human error reduction. IKEA's process for designing instructions for furniture assembly could be a model for writing user-friendly, error-free SOPs. Toyota's car assembly line could provide best-in-class practices for problem solving, deviation and CAPA. Amazon could be an example for using 'big data.'

For more useful resources including white papers, case studies, videos and webinars, visit NSF's resource library www.nsf.org/info/pblibrary.

ABOUT THE AUTHOR



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