



Abstract:

There is very little doubt that a successful implementation of a Six Sigma program can benefit an organization. However, the probability and the level of success depend on several key factors including the overall strategy and approach, such as proper training and development of internal resources, and selection and appropriate utilization of outside resources. The strategy and approach include numerous vital considerations, including proper project selection, resource and management time requirements, relevant knowledge/experience, fair evaluation of results and cost/benefit analysis of the in- house vs. outsourcing options. We offer a handful of guidelines for making this crucial decision, taking into account unique issues and challenges in the Biopharma and Pharma industries. Both advantages and disadvantages of in- house and outsourcing options are provided along with critical success factors.

Based on a wild guess by a close associate of mine, there are well over 2,000 restaurants in the Manhattan area and its surrounding boroughs. Although I cannot validate the absolute accuracy of his count, I do trust it is in the ballpark, since he happens to be one of those guys who seem to know everything about everything in life (and more). His dream is to be on Jeopardy; if it ever happens, I already feel sorry for the other two contestants, who will undoubtedly be decimated on national TV. And, oh yes, he also happens to be a food- lover. There is definitely some credibility to his estimate.

There is a point to be made by this story (trust me!). Despite the overwhelming number of restaurants in the city-that-never-sleeps, there are only a dozen or so which I truly enjoy and actually look forward to visiting. I am certain that even if I try every single one of these 2,000 locations, the "can't-miss" list will be no longer than 50. So, assuming my buddy's figure is fairly accurate, what do I make of the other 1,950 establishments? Not much, I am afraid. Unfortunately, there are plenty of examples like this in life. Having spent many, many years in several universities (too embarrassing a number to

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admit), I have studied under approximately 100 professors. However, there are only three whom I regard as great teachers—individuals who have significantly influenced my life and whose lessons I actually remember.

Tragically, the example does not stop here. There are a plethora of Six Sigma experts out there. A simple search on Google on "six sigma consultant" yielded a whopping 70,000+ returns. Most of these folks, I am afraid, are mediocre at best.

So, as you consider or embark on a Six Sigma program, how do you select your competent and trust-worthy advisor(s)? With so many self-proclaimed experts, how do you find one who is right for you? Should you involve outsiders at all? How do you know if you can do this successfully only with your internal resources? As you ponder these fundamental questions, the following guidelines may be of interest.

Proper Training and Development of Internal Resources

The word "internal" should be emphasized here, since it is my strong belief that long term and/or ongoing dependence on external resources is not healthy—financially or strategically. Rather, the external help should be utilized on an as-needed basis for very specific reasons. We do not depend on our medical doctors to keep us healthy—rather, we best make use of them for regular check-ups and to help us quickly recover from an illness. A business organization utilizing external resources is no different. As a guideline, the rationale for external assistance can fall under two high-level categories. These are:

• Assistance in Training of Internal Resources

For on-going success of your Six Sigma program, it is crucial that internal knowledge and competence are first developed then continually retained. Your specific training needs depend on your existing capabilities and the level and timing of your targets. First, get an idea for the number of certified "master black belts," "black belts" and "green belts" currently in your organization. There are numerous ways out there to obtain these titles, so find out how, when and via which organization these individuals were certified. Next, consider the Six Sigma project experience of these individuals and the significance of the past results. As a basic rule of thumb, each black belt should deliver approximately \$1M in savings or in cost-avoidance each year. As another rule of thumb, the ratio of black belt to green belt should be between 1:3 and 1:6. One master black belt for each division or location with as many as 1,000 to 1,500 people is

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often sufficient. In deciding which individuals should be trained, consider the candidate's interest level, current position and background on basic statistical tools (or willingness to learn). These individuals should also possess the knowledge of the business (i.e., do not pick someone who just joined the company last week) as well as the respect from his/her peers (i.e., do not pick someone because you do not have any other plans for him/her). Lastly, resist the temptation to over-train. It is of no benefit to the organization to have everyone trained, unless the skills are put to use and bottom-line benefits are realized from early on.

- Assistance in Delivering Bottom-Line Results

In this role, you are asking the external resources to deliver specific results using Six Sigma and perhaps other tools and techniques. Prior to the selection of external resources, it is essential that you take the lead in defining the objectives and setting the success criteria. Having the consultants define their own scope of work can be a dangerous thing. Can you imagine getting in a cab and letting the driver decide on where you want to go? In this approach, clearly communicate your objectives and goals—the cab driver (external resources) can decide and/or advise you on specific routes to take, but you need have a clear picture of your goal and destination.

Resource and Management Time Requirements

You can tell a lot about a person by observing where he/she spends most of his/her time and money. You spend your time and money on the things you regard as important. This point (other than being a reminder that I should give my fiancée a call) has applicability in business as well. If you want to ensure a successful Six Sigma initiative, be sure to fall in love with the program. Allocate enough budget and resources to get it off the ground properly. If your organization already has a Six Sigma program (perhaps running for several years) that has hit a plateau, be the change agent to rejuvenate it and turn things around.

Perhaps your organization has had too many distractions in the past and never quite successfully implemented a Six Sigma program. These distractions, in the Biopharma and Pharma industries, can come in many flavors. Typical list of distractions for most FDA regulated organizations include:

- Customer complaints (written and verbal)—collection, analysis and closure;

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- CAPA—both externally (as a result of customer complaint, for example) and internally generated (as a result of non-conforming product, for example);
- Supplier quality problems and/or inadequate process capability;
- Potential major contract manufacturing decisions (especially important for many Biopharma companies at this point in time); and
- Compliance issues—perhaps an adverse FDA audit results and/or receipt of warning letters.

Avoid the common mistake of believing that the Six Sigma program is yet another thing to worry about in addition to the urgent items listed above. Instead, view Six Sigma initiative as a means to effectively resolve the above issues. For example, Six Sigma is not another separate effort on top of your ongoing attempt to improve your quality issues or to shorten a long turnaround time, etc. Rather, Six Sigma tools and techniques should be used as tools to help resolve your quality problems, shorten your lead time, etc.

Management also needs to devote some time on its own to learn the basics of Six Sigma. Management does not need to know how to perform DOE and ANOVA but, at a minimum, it

should be familiar with the key terms and be aware of the overall approach. There are many operational improvement tools and techniques available—however, understanding of Six Sigma's well-defined, consistently followed and established approach will prove exceptionally valuable.

If the management lacks either the knowledge or the experience of running Six Sigma programs, seek external help. In doing so, resist the temptation of letting the external resources taking control of your program. They are your helpers, but the client must take the ownership, set the direction and make the final key decisions. From a potential pool, seek out the ones with both Six Sigma and life science industry-specific knowledge/experience. During the initial screening, make sure that you will feel comfortable with your selection at a personal level. And most importantly, clearly communicate your expectations and demand bottom line results from early on.

Relevant Knowledge and Experience

There is no single, official Six Sigma training program or consistent requirements for green, black and master black belts. There are many organizations that certify people, but are not all the same. Make sure the consultants you are dealing with are certified with a reputable organization.

Avoid letting this be a training ground for your external resources. Certification may a good indication, but it is often

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insufficient. Being an expert means much more than just getting the required training and holding a certificate. It takes several years of applying various Six Sigma tools in real- life settings (specifically in life science industry) to be of true value. Remember one simple rule—any external resource you hire should be significantly better qualified in his/her specific area of expertise than your internally available capabilities.

Prior to making your final selection, insist on meeting the people who will actually be working with you and your team. This may not be an issue when you are dealing with independent contractors, but can be a major point when dealing with large consulting companies. Look for actual industry experience—avoid lifetime consultants. There is no suitable substitute for real-life experience. Although it is not impossible, it is very difficult for someone who lacks the actual experience to relate to the issues you may be facing. Someone who can recite a hundred cookbooks verbatim but has no real- life cooking experience is not a real chef, in my opinion.

Check your consultants' background. Check references and speak with previous clients. Ask about a specific FDA requirement during your initial screening. If ever in doubt, politely walk away—there are literally hundreds more who will be more than happy to do business with you. Some time and effort spent on the selection process will save you lots of headaches and easily hundreds of thousands of dollars (or perhaps millions) in the future.

Fair Evaluation of Results

If there is ever a doubt whether a program was a success or not, chances are that it wasn't. Success, when it comes to bottom line improvements, should not be an entirely subjective thing. A true Six Sigma success should transform the biggest doubters into enthusiastic believers.

Be sure to ask for and to check references. Have the former clients truly achieved success? How long did the relationship last? Any project lasting in excess of six to 12 months may indicate some potential issues ahead. Any good consultant should work him/herself out of a job. If the consultant you are dealing with seems more interested in finding ways to stick around longer, rather than helping you deliver results, then I am afraid you got the wrong person in there.

Ask very specific and pointed questions to judge their life science industry knowledge. Are they up-to-date on the latest biotech trends? How many other pharmaceutical clients have they

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had? Ask about one or two compliance issues they have solved (without compromising confidential agreements with other clients, of course). Have them provide case studies from other organizations that have faced similar situation/issues you are now attempting to resolve. Ask about their approaches, outcomes and the satisfaction of the clients. Ask for references and check them to make sure their clients share the same opinion.

Based on the external resources' previous experiences, what range of lead time reduction can you expect? Have they performed significant projects dealing with complaints and/or CAPA? What were the results? What did it take them to implement these improvements? What level of success can you expect in three months? With respect to quality, what tools and techniques do they have to identify sources of variability? Once identified, how do they reduce/eliminate the variability? How many companies have they worked with that were operating under consent decrees? What (if any) specific Six Sigma tools and techniques do they adopt to help with FDA audit process? What (if any) specific experiences do they have in migrating from clinical to commercial production? If a productivity gain was achieved, has the client been able to sustain it after the initial jump? Be sure to get a rough estimate of what the consultants can deliver. Make sure they are consistent with your own expectations and, most importantly, hold them accountable for delivering real bottom line results.

Cost/Benefit Analysis of In-House vs. Outsourcing

Consider the level of knowledge, experience, available resources and bottom line improvements gained in the past. If an organization has consistently achieved the highest levels of success on its own, there are no compelling reasons to involve external resources. If, on the other hand, there are disputes as to the effectiveness of your program or you currently

lack the knowledge/experience/resources, having the right external resources to fill in the gap can be a very smart move.

In choosing external help . . . shop around! With so many providers, the difference in cost can be mind-boggling. If you are used to dealing with hourly rates for outside help, expect to pay anywhere between \$100/hour (usually for an independent contractor who is getting desperate for work) and up to \$500/hour (for a well-established and well marketed consultancy or an individual regarded as one of leading experts). Keep in mind that

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more expensive consultants or better known organizations do not necessarily deliver better results.

With the right approach during negotiations, most consultants will be more than happy to tie their paychecks to performance and/or savings delivered. This can create a mutually beneficial relationship. It will minimize your risk and give competent yet lesser known consultancies/organizations an opportunity to prove its capabilities. If you are willing to go this route, clearly define the roles for the outside consultants and communicate your expectations both verbally and in writing.

Another option may be to have your selected external resources to work for a few weeks at a deep discount with the understanding that after the trial period, the rates will increase to a pre-defined level provided that you, as the client, decide to continue the relationship. Despite the long-awaited uptick in the economy, the supply still far outnumbers the demand with regards to Six Sigma consultants. Use this to your advantage and be selective.

The success of the program depends mostly on you. Seek external resources to compliment specific areas where you currently lack sufficient knowledge/ experience/resources. Most importantly, be demanding of both your internal and your carefully selected consultants. The journey is not an easy one, but the rewards can be quite satisfying.

For more information or to contact us, email us at info@tefen.com.

About Tefen

Tefen is a publicly traded, international operations consulting firm with seven offices in United States, Europe and Israel. The firm has over twenty years of experience in improving the overall operational effectiveness of Fortune 500 clients around the world. Tefen designs and implements solutions that enhance operational performance throughout an organization. The main areas of focus include operational excellence, manufacturing, quality, customer service, research and development, and supply chain management. All of Tefen's support programs are ISO 9001 and TCS (Total Customer Satisfaction) certified. Our hands-on approach has achieved success in delivering quantifiable and value-driven results. The company has remained profitable since its inception and currently employs over 250 professionals worldwide, 40 of whom are certified Six Sigma Black Belts.

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