Insight Technology
Statistical Guidance
http://www.fb2c.com From: Mark Shal

My Goal
I aim to reduce healthcare costs through improved R/D and manufacturability.
If you are a large international medical device/pharma company involved in combination products, I can save you a lot of frustration, time and money. I can take the lead, and apply my skills and expertise to mitigate risks in your combination product design, realization, and post-market surveillance. This is something I have done several times over the past 16 years. Additionally, if you are fast growing, and innovative, you will face unstructured opportunities where I can creatively contribute in reducing variability (stem-cell, cell programming, phage display, third generation combination products, small implantable electromagnetic devices; but also a Bayesian approach to preclinical activities that expands the design space, and speeds up NDA and PMA's).

My process consists in identifying gaps, and organizing resources to bridge them. Doing so, I save you time and money, and improve product quality, and patient health through application of sound scientific techniques. The present paper is emphasizing the application of these techniques to packaging, and labeling of drug delivery devices in which I have 16 years of experience.

My background
My entire education, and career has been focused on Quality Management. It includes:

- A Ph. D. in statistics, and teaching graduate courses in business statistics at Cal. State Northridge
- Consulting with my students and realizing successful implementation requires a better understanding of hidden driving forces underlying the organizational structure
- Joining Edwards Deming, learning about organizational change, and leading CI in large organizations such as Chevron, PBS, and American Medical Response
- Leading Curlin Medical's QA/RA, and CMO's including implementing CI throughout the supply chain - suppliers attestations about my performance is available at http://fb2c.com/Insights.html
- Founding Insight Technology to help clients with their CI Processes.

I have already posted an example in design improvement for an implantable endovascular device, and an example of post-market improvement for an implantable orthopedic device http://fb2c.com/Insights.html

This paper focuses on examples related to sterile packaging of disposable devices and their transfers, and expansion.

Changing CMO
In 2006, Curlin Medical acquired the assets of a third company. This company's disposables were packaged by an overly pricy subcontractor. Additionally, this subcontractor was carrying a heavy inventory. My goal was to reduce pricing, and improve lead time, and inventory.

As an intermediary step, I negotiated a discount with the company owner. The costs were still higher than what Curlin was paying for packaging of similar disposable devices. As a secondary step, I qualified the packaging system at the contract manufacturer we were using for other Curlin devices, and moved the packaging there. I had an established long-term relationship with them, so the transfer was achieved in a timely manner, in compliance with QSR, and without any hick-ups. It included IQ/OQ/PQ, and Validation for sterility, integrity, and shelf-life. It resulted in considerable saving, less transportation cost, lower inventory, and better lead time.

As most challenges in any transformation are organizational, the following example emphasizes the chain of past commitments, and their underlying currents I needed to gain awareness of, and harness. This is achieved through recognition of strengths and weaknesses of past commitments, and building of a consensus around compelling new goals. Technical skills, although necessary to unearth the evidence, are not sufficient to successfully renegotiate historic commitments. Below is a labeling related example illustrating the point:

Changing Labeling

When Curlin Medical acquired the above mentioned company, this company was purchasing a disposable elastomeric pump from a Korean supplier. After importing the pumps, they were repackaging and relabeling them with their own name, and trademark. I saw an opportunity to achieve the same goal at a lower cost/lead time, by asking the Korean manufacturer to label the product to my specifications at the point of origin. This involved 1) convincing our Buffalo based management - Exec. VP, head of medical devices - that this is a worthwhile project, and can be achieved in compliance; 2) designing the new label; 3) obtaining regulatory clearance; 4) renegotiating the agreement with the Korean manufacturer so they do the labeling to Curlin name. The results were substantial savings in cost and lead time.

All of the above examples were across multiple locations, and countries. Below is another packaging related example:

Qualifying off-shore CMO's

At Curlin, in addition to QA/RA, I had responsibilities for the supply chain. We were located in Huntington Beach, CA, and initially manufactured, and packaged our disposables at a driving distance in Santa Ana CA. As we grew, and sought to increase capacity, and reduce costs, I identified a potential supplier in Mexico, and was able to transfer manufacturing, and packaging. This of course required me to supervise the quality of production in Mexico. Soon after that, to accommodate additional growth, I identified a second source in Thailand, and started a second off-shore manufacturing, and packaging. I also had to help them through the process of becoming FDA compliant, and establish, and validate their capability of producing Curlin products (Audits, IQ/OQ/PQ, training, etc.). Additionally, I had to work with a number of suppliers of critical components on the East Coast, and of accessories in China. In all cases I needed to demonstrate QSR/ISO compliance to regulatory bodies, and customers at the time of their respective audits.