## WHITE PAPER | PHARMA BIOTECH

## KPIS AND THE SITE DIRECTOR

KPIS SHOULD LOOK FORWARD AS WELL AS MEASURE RESULTS

### by Andy Barnett

Last week my site director attended a two-day conference on KPIs. He was hoping to gain insights to jump start process improvement at our facility. I caught up with him yesterday and asked him about the conference.

He said, "I got so tired of presenters telling me I need to pursue big data. Market analytics have their place – especially if your business lives or dies by online hits. But everything seemed so contrived, and a million miles removed from our day-to-day operations. Then, finally, a breath of fresh air! One guy got up and said, 'Think big, but start small.' His presentation was so different and I was instantly intrigued.

The guy said no one knows your business better than you. He made everything sound so simple. He said the biggest mistake most people make is that they only measure results. Results are important, but it is hard to drive down the road by looking in the rear view mirror. The key is to find leading indicators instead of lagging indicators."

## HOW DO YOU PINPOINT LEADING, VERSUS LAGGING, INDICATORS?

Being somewhat of a skeptic, I commented, "That's easier said then done" and my director agreed. We discussed a case study about a firm that was trying to reduce back orders. Slogans weren't helping and neither were goals. It just added frustration and disappointment when they fell short. Then the site started forecasting demand and built up an inventory in anticipation of demand. They really started to turn the corner when marketing agreed to give them 30 days advance notice of upcoming promotions. That gave them the lead time they needed to order raw materials and smooth out the production schedules.



# ARE THERE TOOLS FOR FINDING LEADING INDICATORS?

"Absolutely! One tool is to use 'lagged' trend charts. Plot various metrics that you suspect may influence the result. Then plot the result, but delay it by shifting the whole column down one or two rows in the spreadsheet. This is because there is usually a lag time between the input and the response. If the patterns on the charts start to align, now you have a leading indicator. It is a hit-or-miss technique, but when it hits, there is a nice payoff and you have a leading indicator.

Another technique looks for combinations of factors that trigger an adverse response. It is really difficult to find interactions. Some processes are plagued by interactions for years. No one can find them. Well, what you do is pair up two variables as inputs, and calculate the response, as in the example below.

Pressure	Temperature	
	Low	High
Low	2.4	2.3
High	2.1	3.6



The idea is collect data on two inputs. Lump each variable into high and low categories, and then create the matrix. What is the failure rate when pressure is low and temperature is low? What is the failure rate when pressure is high and temperature is low? And so forth. Calculate the scrap rates for each of these four combinations of pressure and temperature, and put the scrap rates into the matrix. Then compare the scrap rates. If one of the combinations stands out, you have an interaction. Then, the trick is to restrict one of the inputs so that you cannot repeat the combination that causes the spike in the response.

Finally you should have KPIs for the five 'P' metrics: Profit, Patient, Process, Product and Personnel. No more than three for each 'P'!"

## **ABOUT THE AUTHOR**



Andy Barnett has worked with clients in the pharmaceutical, medical device, biologic and biotechnology industries, for over 20 years, to develop quality

assurance and regulatory strategies for compliance with U.S. FDA regulations. His particular expertise includes providing statistical support for process development, process characterization and optimization; assisting with remediation activities, especially corrective actions and process improvement; and providing training in root cause, corrective actions and statistical methods for process improvement.

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