



# KPIS AND THE HEAD OF CORPORATE QUALITY: KPIS ARE ESSENTIAL FOR A SUCCESSFUL PRODUCT RELEASE

by Martin Lush

## WHAT ARE YOUR VIEWS ON KPIS? ESSENTIAL OR A NECESSARY EVIL?

“They are absolutely essential, providing they are good! I remember during a regulatory inspection I was asked every QP’s most feared question:

*How do you know everything is in control before you release product?*

As I began to describe the KPIs I use, I realized that:

- > We were measuring the wrong things
- > The site and supply chain had expanded so rapidly many of the measures were outdated
- > Even though the business had changed, the measures had stayed the same
- > People had become KPI blind and collected numbers for the sake of it
- > Many of the measures drove the wrong behaviors
- > People didn’t link measures to improvement

So, for me when I think about KPIs, I visualize pilots sitting in the cockpit of their aircraft in front of their panel of instruments (key performance indicators) and came up with these criteria:

- > Measure only what matters to prevent KPI blindness
- > Less is more. I truly believe that the less you measure, the more you know
- > Measures are useless unless they are acted upon quickly. The time line from data collection to interpretation to review and action must be kept as short as possible



- > People must see what’s in it for them, otherwise they just focus on number crunching. Unless measures are owned, they are useless
- > Keep the KPI simple. If it’s complicated, people just end up ticking boxes”

## WHAT ARE ‘ARE WE IN CONTROL’ INDICATORS?

“When my CEO asks me if we’re in control, what he is really saying is ‘Is there anything I need to be worried about?’ The measures that address these concerns include:

- > Status of site regulatory and license compliance, including corporate audit information, like inspections complete, inspections due and inspection findings by category/region
- > Site risk status. I use a simple traffic light system based on data provided by each site’s risk register. I immediately know which sites are at greatest risk (red). If needed, I can drill down to the who, what, when and where



- > Status of regulatory submissions
- > Customer and client feedback, including customer complaints by category/region and adverse drug reactions (from Medical Affairs)
- > Critical quality incidents
- > Trouble indicators. I am a passionate advocate of leading indicators, rather than lagging. My regional QA heads are responsible for these and a simple traffic light system is used. Red means that we are moving towards a state of poor control, we're potentially heading for trouble and we need to act now"

## ABOUT THE AUTHOR



**Martin Lush** has over 30 years' experience in the pharmaceutical and healthcare industry. He has held senior management positions in QA, manufacturing, QC and supply chain auditing and has conducted audits and education programs for many hundreds of companies in over 25 countries.

## WHAT ARE YOUR STRATEGIC PLANNING MEASURES?

"My job is to help my sites prepare for what's coming. I also fulfill a vital role in helping my senior colleagues across the business understand:

- > They are ultimately responsible for quality
- > Measures are there to drive continuous improvement
- > Measures should never be used for anything else, especially politics
- > Measures must always drive the right behaviors
- > You can never rely on measures to tell the whole truth"

For more information, contact [pharmamail@nsf.org](mailto:pharmamail@nsf.org) or visit [www.nsfpharmabiotech.org](http://www.nsfpharmabiotech.org)

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