



# HOW GOOD ARE YOU...REALLY?

by Martin Lush

Martin Lush explains the crucial importance of setting Performance Measures and provides practical advice on how to implement them successfully.

A carpenter friend once offered some very sound advice. "Martin, always remember to measure twice and cut once". Roughly translated this means make sure you have accurate and reliable performance data before making important decisions! With your company facing a level of unparalleled change, the drive to improve every aspect of your business will be unrelenting. The need for making the right decisions at the right time has never been more important.

*'Effective decision making requires direct physical measures for operational feedback and improvement. Without these accurate and reliable measures you cannot make accurate and reliable decisions'.*

Historically, pharmaceutical companies have been very poor at measuring performance and acting on the data, partly because real and lasting continuous improvement has never been a priority. So do you measure twice and cut once? How accurate and reliable are your performance indicators and your decision making? Ask yourself the following questions:

- > Are your 'Key Performance Measures' designed and used by those close to the process?
- > Does everyone fully understand what your KPMs actually mean?
- > Do your KPMs accurately reflect true performance?
- > Are your performance measures clear, concise and unambiguous and not open to 'manipulation' and 'misinterpretation'?
- > Is your performance data collected, interpreted and acted upon quickly, within days. Not filed and forgotten?
- > Do you present the data in an interesting and understandable way to help and not hinder the reader?



- > Is performance data used to encourage and motivate rather than the opposite?
- > Does everyone have visibility of your KPMs, or is visibility restricted to the select few?

If you have answered 'Yes' to all of the above, congratulations. Your decisions are probably accurate and reliable! If you had a few 'No's then you should read on.

## QUALITY AND MANUFACTURING KEY PERFORMANCE MEASURES. THEIR PURPOSE:

- > To ensure that the requirements of internal and external customers have been met
- > To provide standards for establishing comparisons
- > To motivate the work force!
- > To quickly highlight quality and manufacturing problems and determine which areas require priority attention



- > To help you use your resources intelligently
- > To provide feedback for continuous improvement
- > To provide the QP and Senior Management with visibility of performance
- > To actually demonstrate to others, including regulators, that you are 'in control'

## DESIGNING AND USING ACCURATE AND RELIABLE KPMS: KEY STEPS

1. Select your measures with care
2. Get senior management 'Buy In'
3. Think long and hard about presentation
4. Think even harder about who is responsible for what
5. Have a mechanism in place to review, interpret and ACT on the data

### STEP ONE: SELECT YOUR MEASURES WITH CARE!

Remember that every measure must

- > Reflect true performance
- > Accurately and reliably represent the controllable aspects of the process
- > Be understood by those using them

It is very important to understand the needs of your readers. Senior and Middle management need to see performance data for the purpose of strategic oversight and planning they are not, however, the main audience. The most important readership are those who understand the process and who are able to quickly interpret and use the data for process improvement. There is one very important thing to remember when selecting any performance measure. Think very carefully about the behaviour each measure triggers. Let's take reducing the numbers of unplanned quality incidents (deviations) as an example. If the KPM forces plants to reduce the number of incidents, there is a risk that some incidents will go unreported. A more intelligent KPM would be one that measures the level of recurrent incidents:

- > Each measure must be designed to prevent 'manipulation' or 'misinterpretation'. All must be clear, concise and unambiguous
- > Measures must be compatible with any recognition and reward system
- > Measures must be timely. To add value, performance measures must be interpreted, communicated and acted upon quickly, within days not months. Before selecting any measure first ask: 'how will we use this information practically?' Our industry is good at collecting lots of data and information and then ignoring it!
- > Remember to keep measures up to date and relevant. Some companies, partly through habit, continue to use the same measures year after year, even though their business priorities have changed
- > Remember that less is more. Don't collect lots of data; concentrate on the 20% of measures that will provide 80% of the benefit. Do not get carried away!
- > When selecting the 20% that actually matter, you must involve the process owners and experts:
  - Process Operators and manufacturing personnel
  - Engineering and Validation specialist
  - QA and QC
  - Qualified Person

Involve them from day one and keep them involved, informed and engaged. They must own the measures, not 'management'.

When involving others be prepared for resistance and apathy. For many companies performance measures have a very bad reputation and many of your people will be very sceptical and distrusting of new ones. Have answers to the following questions beforehand:

- > Why do we need them...we have managed successfully without them?



- > How will the information be used?
- > How will this impact on pay and reward?
- > Will there be any additional responsibility?
- > What will happen if the data indicates 'poor performance'? Who will feel the 'pain'?
- > Will senior management see this data?
- > What happens if the regulators ask to see it?
- > How will the information be collected, communicated and acted upon?
- > Feedback. Who, how and when?

Never, ever use performance measures for political or other 'ulterior' motives.

## STEP TWO: GET SENIOR MANAGEMENT 'BUY IN'

Senior and middle management have been the traditional custodians of performance measures. **Historically such measures have been 'accountancy' based, too 'high level', understood only by the select few and often inappropriate.** If you're interested in real continuous business improvement we recommend the opposite. The 'local' process owners must own each measure and be responsible for using the data. After you've selected your KPMs make sure you convince your management of their benefit.

## STEP THREE: THINK LONG AND HARD ABOUT PRESENTATION

Remember, having generated the data and information you want people to actually read, understand and act on it. Winston Churchill once said "I can tell from the size of this document that you do not want me to read it".

- > Keep presentation of data simple and interesting
- > Ask the reader what they actually want

## STEP FOUR: THINK EVEN HARDER ABOUT WHO IS RESPONSIBLE FOR WHAT

Each measure must be 'owned' by someone. You must make someone responsible for collecting, interpreting, reporting and acting on the data. For example...

The Manufacturing Manager could be responsible for measures relating to:

- > Manufacturing output and efficiency. This includes operating processes and equipment within their validated/qualified ranges (this obviously includes change control!)
- > Good documentation practices and procedural compliance
- > Operator training and standards of GMP
- > Cleaning and sanitisation
- > Completion of Corrective and Preventative Actions relating to the Deviation Reporting and Audit programme

The Engineer could be responsible for measures relating to:

- > Planned preventative maintenance of equipment and plant fabric and utilities
- > Critical instrument calibration
- > Environmental control
- > Equipment performance

QA could be responsible for measures relating to:

- > The internal audit and self inspection programme
- > Deviation and CAPA system
- > Trending and interpretation of QC data (Micro and Chemical) probably with the assistance of their QC colleagues!

Without ownership, measures become meaningless.



## STEP FIVE: HAVE A MECHANISM IN PLACE TO REVIEW, REPORT, INTERPRET AND ACT ON THE DATA

Remember, the whole purpose of Key Performance Measures is to provide accurate and reliable data for accurate and reliable decision making. The data must be reviewed, interpreted and acted upon quickly by the local process owners. Remember:

- > Keep recording systems simple
- > The only way to discuss and interpret key performance measures is face to face
- > Meet on a regular basis, at least once every 2 weeks. The shorter the period between data collection and actual interpretation the better. The 'Plant Quality Meeting' is an ideal opportunity to review and act upon the data. This meeting should:
  - Be chaired by the Production Manager
  - Be attended by the 'responsible' QA representative, Plant Engineer and others. Each measure should be discussed:
    - 'Performance' assessed against agreed standards
    - Actions agreed and fully documented
    - A summary of performance fed back to
      - ◆ Senior Management
      - ◆ Qualified Person
      - ◆ Operators
- > It is also worthwhile having a system in place to allow for 'escalation of issues'. Remember, senior management do not like surprises.

## IN SUMMARY:

- > You and your company's future will be heavily influenced by the quality of your decision making
- > To make good quality decisions you need good quality performance data. You can't manage what you can't measure!
- > Measures must be owned by those close to the process
- > Select each with care
- > Make people responsible
- > Think long and hard about presentation and even harder about using the data for continuous improvement

As W. E. Deming once said:

***"You don't have to do any of this; survival is not compulsory!"***

## 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.

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