

# Journal

2016, Issue 35

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## How Do You Really Know What's Happening Out There?

*– Using KPIs in Quality Risk Management*



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# welcome

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## Measure Twice, Cut Once

A few months ago I sat around a boardroom table with the leadership team of a large biotech company. The mood was sombre. They had just received a costly warning letter, which had come as a shock. Up to this point, all of their KPIs and performance measures (they had 57) looked reasonably good. I then told them the truth. Their measures were inaccurate, driving the wrong behaviors and creating an illusion of being in control. Their KPIs were wrong. FDA was right. **The focus of this edition of the Journal is making sure your KPIs work for you, not the other way around.** My old woodwork teacher used to say 'measure twice, cut once.' To make good decisions, you must have good KPIs. To find out how, just read on and spread the word!

Martin Lush



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Martin Lush,  
President, NSF Health  
Sciences Pharma  
Biotech Consulting

In this series of articles, we provide perspectives on how various job roles value and utilize KPIs, based on actual interviews as well as our overall experience working with clients.

## KPIs and the Head of Corporate Quality:

### KPIs Are Essential for a Successful Product Release

#### 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 The site and supply chain had expanded so rapidly many of the measures were outdated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"

#### 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"



by Martin Lush,  
President, NSF  
Health Sciences  
Pharma Biotech  
Consulting

## KPIs and the Regulator:



by Rachel Carmichael,  
Executive Director, NSF Health Sciences Pharma Biotech Consulting

### I'm Looking for Quality Metrics, Management Review and Continual Improvement

Interviewing an ex-MHRA inspector on the importance of KPIs provides us with some interesting insights.

“Generally, I will ask to see the metrics that are used to confirm the performance of the quality system and then I will watch the blood drain from the faces of those present.

Then we will waste the next few minutes explaining that it is a requirement to have management review, that they need to be able to demonstrate continual improvement and that this is, and has been, an inspectable part of their processes since 2013 when EU GMP chapter 1 section 1.6 was updated.”

*There should be periodic management review, with the involvement of senior management, of the operation of the Pharmaceutical Quality System to identify opportunities for continual improvement of products, processes and the system itself.*

#### So what sets apart the company that uses KPIs well from those that appear to be driving in the dark with no headlights on?

“If it is a good company and confident that it has identified appropriate performance metrics with appropriate actions coming from the management reviews, then there is no drama in letting a regulator see the metrics. Equally it is important for regulators to remember that just because a company blocks

visibility of information it does not actually mean that the information will be poor. But it does mean wasting the regulator's time and it leads to a feeling of discomfort with regard to their knowledge and understanding of the requirements of EU GMP and the requirements for disclosure.

Vital to an inspector would be the overall picture of performance. There may be areas of weaknesses but if actions can be seen as being allocated and delivered as a result of the identified weaknesses, then that is a demonstration of a well-managed company.”

#### In your experience, how would you react to indicators that are either good or show room for improvement?

“The inspection of the management review and the associated metrics should not constitute a large proportion of an inspection – probably no more than 15 to 20 minutes – which would include a quick look at the procedure and then a review of the output of the meetings over a year or so to make sure meetings are being held at the time points committed to and delivering the review dictated in the procedure.

If there are indicators which are showing weaknesses, it will influence the focus points of the inspection, though ‘good performance’ will also require verification during inspection.

A management review and quality metrics which fail to identify weaknesses are a waste of everyone's time and indicate a lack of management oversight of the quality system.”

#### Is there anything that is out of scope or irrelevant to the regulatory inspector?

“As a regulator, I'm not particularly interested in the productivity metrics. My focus needs to be on the quality metrics such as documentation ‘right first time’, overdue quality actions or repetition of deviations. I will try and ignore the metrics that are focused on speed of change over or time for line clearance or equipment utilization. One company I inspected attributed a cost to every



## KPIs and the Regulator:

activity including the cost of writing, reviewing and approving the deviations. Although it is essential that companies are well managed and understand the impact of non-compliance, having such a driver can encourage people to cut corners and not report events.”

### What are the typical non-conformances identified when inspecting the management review process and KPIs?

“The inspection of the management review and the KPIs related to it tends to have a limited number of outcomes. The typical deficiencies include:

- > No management review takes place or is late
- > The review does not cover the full site operations
- > The KPIs the company chose do not include sufficient focus on the quality management system
- > The KPIs chosen have the potential to drive the wrong behavior. For example, a measurement of the number of deviations is likely to lead to a lack of reporting or reclassification of events so that they are no longer captured within the deviation system
- > The review process lacked actions for improvement
- > The review is ineffective since it has not identified the issues that the inspectors have, during the course of the inspection, found on the site”

### If there were only three key measures that you'd see as insightful, what would they be?

“The metrics that you want to see depend on the type of site that you are in. If it is a sterile or low bioburden formulation, then the performance of the environmental monitoring and the performance of the water system will be key. If the results demonstrate a completely perfect output, then I would be worried about the accuracy of the data and I would spend more time in the microbiology laboratory.

My personal metric of choice throughout my time inspecting with the MHRA was a review of

the number of procedures past due for review and what percentage of the overall procedures this represents. A quality unit that is in control will be on top of the review process, there will not be a significant number of procedures past due date and the ones that are past due will be a matter of months, not years. If the company is failing to manage the operation and if there are insufficient staff, then this aspect of the operation is the one which seems to be a good indicator of the state of control.

I would be looking at the performance of the deviation system and the complaints system (perhaps in tandem with the CAPA system when possible). However, we can't have a discussion about KPIs without mentioning the fact that the U.S. FDA is seriously looking at a standardized set of metrics as part of its vision for the future announced last summer. The metrics would be the same for each site, enabling the regulator to identify supposedly good and poor sites and increasing operational flexibility. The first set of proposals indicated that the four core metrics that the FDA will require are:

- > Lot acceptance rate
- > Product quality complaint rate
- > Invalidated out of specification rate
- > Product quality reviews on time

Optional metrics cover senior management engagement, CAPA effectiveness and process capability/performance. Those with good performance could be rewarded through less frequent inspections or less time on site. The vision is one report per product and one report per source of API, generated by the sites and electronically submitted. Facilities would have to register and the quality unit at each site would be expected to develop the report. Overseas sites would be encouraged (but presumably not required) to report. The metrics proposed are the logical conclusion of the regulated environment. There has been quite a robust response from many aspects of industry, and a company would be naïve not to take these metrics into consideration at the current time.”

## KPIs and the Site Director:



by Andy Barnett,  
Director, Quality  
Systems, NSF  
Health Sciences  
Pharma Biotech  
Consulting

### KPIs Should Look Forward as well as Measure Results

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 than 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'!"

## KPIs and the Production Director:

# Select Fewer, More Significant KPIs and Set Goals for Your Metrics

by Andy Barnett



### What are your concerns about KPIs?

“As Production Director, I can’t possibly oversee the performance of every process, every day, across every production unit even though I am responsible for delivering cost-effective, safe, efficacious drugs according to cGMP and of course without missing any delivery dates.

The things I care about the most, and need visible indications for, are:

- > Review of historical performance
- > Indicators of future performance
- > Performance of processes, equipment, plant, utilities, staff and how they all contribute to ‘right first time’ and ‘on time in full’”

### What KPIs would you recommend?

“One thing we can probably all agree on is that when it comes to metrics and KPIs none of us can agree. I did a cursory Google search and found one article that talked about the 75 essential KPIs. Another article talked about the 28 metrics that actually matter. Add in dashboards and you have literally hundreds of metrics and charts. What we end up with is tons of data but no insights. For these reasons, I think it would be a mistake to give you a list of the KPIs I would recommend. Instead, I’ll focus on how you decide what is important.”

### How do you decide what is important?

“It’s critical to focus on the vital few. If you are buried in metrics and KPIs, the chances

are none will get the attention they deserve. A major fast food chain struggled to adopt a competitor’s proven system, which had over 100 metrics. After much frustration, it abandoned the attempt and switched to FACT. Four metrics: Fast, Accurate, Clean and (right) Temperature. Of course, performance of the unit soared.

As management we play a key role in selecting the vital few. Even if you end up selecting 50 KPIs, you can cascade them down in your organization so that no department is responsible for more than three or four. Your organization simply cannot fix everything at once. Once a year, review all the metrics and prioritize. Select a subset of KPIs that need improvement. Processes that are stable may not need attention. Lower priority items can be deferred. No one can fix everything at once, so make a justifiable selection and nail them first.”

### Isn’t it common, though, that organizations can react on a hair trigger, causing confusion, increasing complexity and acting as ‘busy fools’?

“To avoid this, set goals for the metrics you select. Is the target reasonable and achievable? When monitoring the performance over time, when should I take action? This is not a trivial question. One company reacts when they get two points in a row above the average. Imagine flipping a coin and getting two heads in a row. It happens all the time. We all have too many irons in the fire to worry about false alarms. As managers, we should understand that everything has variation, and the last thing we want to do is exhaust our employees by demanding investigations to explain ‘common cause’ variation.”

1. Understand the process
2. Select the vital few
3. Set goals that are reasonable and achievable
4. Include triggers or signals for adverse trends
5. Select metrics that are actionable
6. Move from reaction to prevention

## KPIs and Employees:

# Involve Us Upfront and Let Us Help Define Relevant Measures



by John Johnson,  
Executive Director, NSF  
Health Sciences  
Pharma Biotech  
Consulting

So, what about the use of KPIs from the perspective of the employees, the people who are directly involved in the manufacturing, testing and support services that fill the supply chain with pharma products?

What is their perspective? Do they read KPIs? Do they need them? What do KPIs actually mean to them?

We intercepted a production operator at a client's premises and asked her these key questions.

### Are the KPIs posted round the shop floor useful to you and your job?

The operator laughed as she explained how the answer would have been quite different a year ago, "In the past, we had KPIs plastered all round the walls and they looked like wallpaper. No one explained them to us, they didn't get changed very much and we all just walked past them," she said. "We ignored them as they looked like management babble and we took the view that if management needed us to change something important, they would speak to us. I don't know how many hours people put into preparing them, but it made no difference at all to the way we performed our jobs."

### So what changed?

"For years, nothing! But one day they were all taken down and we spent a morning with the supervisor discussing how we were losing contracts to competitors who could do more with less, performed changeovers faster than us and made fewer reworks or reinspections. We were all really unhappy about that as we didn't want to be second best and it could affect our long-term futures if we didn't make our best a little better.

I love this job and didn't want to change as I live locally and the firm had been the best employer in this region for years. We talked about how we could help the company improve the costs associated with 'not-right first time,' and how we could boost output simply by understanding waste and error and at the same time avoid frustrating waiting periods or reinspections (everyone hated those jobs).

We talked about how we could manage the unit better and make it more fun. The supervisor introduced daily huddles with each line team, everyone got a say, everyone was told the same message face to face and any issues were brought to the surface. At first there was a lot of opinion, but we quickly realized we needed more facts."



### What facts did the line teams need?

"Simple things at first. Information like notification of any new steps in SOPs, 'watch outs,' introductions to new team members,



## KPIs and Employees:

discussions on expected output, actions needed to avoid stoppages and such like. Most stoppages were related to poor quality product so we knew that if the line was set up well and run smoothly, the product quality would improve and we would get fewer rejects and better yields.”

### How did this make a difference?

“At first the team huddles felt odd and clunky but as we established for ourselves what was important, we started to model ourselves on a Formula One pit stop team; everyone being clear on what was needed, when and why; and we looked out for each other. The metrics took care of themselves really. We got better and the metrics improved without us needing to fiddle them. It felt good!”

### What switches the team off?

“We just don’t have time for anything irrelevant and we have a low tolerance for management babble! We didn’t allow any metric to enter our huddles unless we agreed it was useful and we agreed we could act on it. Once it was accepted though, we ran with it. A couple of times, management wanted to measure something else but we just countered it with something more insightful, fought our corner and showed how much more useful our measure was. We were taking control of our own performance and we wouldn’t be distracted from our job – making quality products on time and to budget.”

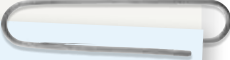
### So what were your three most insightful measures?

“We knew that quality was paramount but a quality product not available on the shelves or too expensive wouldn’t even be ordered and we needed contracts to pay our wages. So

we knew the metrics had to be balanced into quality, service and cost measures and we chose three measures for each and made each one important.

In terms of quality, we measured the team’s ability to complete the batch records without errors and omissions, the reject rate and our 5S housekeeping scores (each of these were within our so-called sphere of influence).

Of course we also measured output per shift, reasons for stoppages and schedule adherence, but what drove better figures in those areas was generally the team’s accuracy of set-up, speed of response when something went wrong and our ability to do the right thing, follow procedures and avoid the need for GMP deviations. Prevention is quicker than a cure and we used the team huddles to avoid false starts, mistakes and poor communication. The metrics looked after themselves after that.”



“If you always do what you always did, you’ll always get what you always got.”  
Henry Ford

### So in conclusion, as long as what you measure is relevant and you can influence it, you are happy?

“Absolutely, just don’t get in our way and distract us with fancy charts that look like wallpaper – keeping it simple and local has made all the difference to us.”

For a final word on KPIs from the perspective of a site quality head, please see the case study on the back page.

For more information on any of the topics raised in our KPI articles please contact us:

Europe – T +44 (0)1751 432999 | E [pharmamail@nsf.org](mailto:pharmamail@nsf.org)

USA – T +1 202-822-1850 | E [USpharma@nsf.org](mailto:USpharma@nsf.org)

Or visit our website at [www.nsfhealthsciences.org](http://www.nsfhealthsciences.org)



# Remediation of Pharma Quality Systems – It's All About the People



by Maxine Fritz,  
Executive Vice  
President, NSF  
Health Sciences  
Pharma Biotech  
Consulting

## **Much of NSF Pharma Biotech Consulting's work involves helping companies remediate flawed quality systems.**

This is usually done as a result of threatened or actual enforcement action by regulatory agencies. In these circumstances, companies are desperate and willing to do 'whatever it takes' without a full understanding of what that means. While expansive in concept, 'whatever it takes,' for many, means simply deploying internal and external resources to design and document a new quality management system. This is a significant commitment by management in resources, but unless the cause (how did this happen?) is also considered, the effort is doomed to fail.

## **In our experience, one of the answers to 'How did this happen?' is almost universally organizational quality culture.**

Most companies are surprised by this answer and find it difficult to imagine. Most companies will tell you and truly believe that they are committed to quality; and in fact most companies make the pursuit of quality part of their corporate mission statements. However, failing to address organizational culture as a root cause during the remediation initiative will foretell an unsuccessful outcome. We often meet senior leaders of pharmaceutical firms who are willing to invest in quality systems and processes, but we find that they do not understand that there is an underlying issue in the organizational culture and the change that is necessary to support quality initiatives. Unfortunately, without a true culture of quality built into the DNA of your organization, most quality improvement projects will fail. Worse still, such a failure could lead to even more aggressive and difficult regulatory enforcement action.

We possess the experience, skills and methodology needed to help a company design and document a world-class quality system. We also learned very early that this methodology

must address the imperative of organizational cultural alignment and this is the most difficult part of a remediation project. Many individuals are drawn to the healthcare industry by altruistic desires to help people. Consequently, healthcare companies are bewildered and aghast at the suggestion that their cultures may not support quality principles. After all, what healthcare company doesn't want to produce high-quality products? It is no wonder that a company would challenge a consultant's suggestion that attention to the corporate culture is necessary.

One aspect of the NSF process is to encourage a self-assessment by company management of its policies and practices that influence employee behaviors. While most companies have stated values supportive of quality objectives – the easy part – it is management's compliance with them that is determinative in influencing employee behaviors. Does management override the quality assurance unit's decision to withhold product release? Does management cut funding of the quality function before, or to a greater extent than, others? Does management recognize and reward quality achievements as it does financial ones? Does management effectively balance its capital needs and initiatives with its commitment to quality? An integral element of the NSF methodology addresses management's responsibility to 'walk the talk' and model the company's quality values. Among other things, we encourage the most senior executive managers to have at least one performance element related to quality. Our goal is that each member of the company's senior executive management team has as intimate a knowledge of the state of the company's quality system as he or she does its financial condition.

During a remediation project, NSF consultants are on site working collaboratively with the company to create a new system, coaching and mentoring throughout the project. Organizational values and principles, as well as an effective means to communicate them, are established by the top of the organization.

Does your company have a communication plan? Does the company communicate collaboration, openness and transparency? Does the communication plan clearly define process ownership and who owns the process? During the planning process, we can be effective in counteracting the negative impacts of organizational culture through open

collaboration and communication. Recognizing that an antagonistic corporate culture can have its greatest negative impact at this point, our overall approach is designed to address cultural issues early in the process. This enables the company to operate in a quality-supportive coaching and mentoring environment, assuring ultimate success.

#### NSF Health Sciences quality system remediation experts:

##### **Martin Lush**

President

Over 35 years' experience in operations, QA, troubleshooting and due diligence. Now committed to helping clients do better with less.

##### **Maxine Fritz**

Executive Vice President

A former US FDA investigator and industry expert with over 25 years of pharma, biologics and biotech quality systems, compliance and regulatory experience specializing in strategic pragmatic solutions to customer needs.

##### **George Toscano**

Vice President of Quality Systems

Over 16 years' experience with a proven record in providing clients with strategies for the implementation and remediation of quality systems to comply with FDA regulations.

##### **John Johnson**

Executive Director

Expert at GMP remediation and passionate about education, continuous improvement tools and mentoring of senior managers.

##### **Rachel Carmichael**

Executive Director

Over 20 years' experience of pharmaceutical manufacture, control and quality management including nearly 11 years as a GMDP Inspector for the MHRA.

##### **Rocco Duran**

Executive Director

Over 33 years' experience in pharma production, technical services and quality. A passionate leader who champions pragmatic approaches in quality.

##### **Peter Gough**

Executive Director

40 years' experience in pharmaceutical law, manufacturing, QC and quality systems.

##### **Mike Halliday**

Vice President

With his unique training style and over 30 years' experience, Mike is responsible for our world-class QP and IRCA education programs.

##### **Nicholas Markel**

Executive Director

25 years' experience in biopharmaceuticals and 15 years' experience providing general and strategic consultation to domestic and foreign clients in the biotech, biologic and pharmaceutical industries.

##### **Jim Morris**

Executive Director

Over 25 years' pharmaceutical management experience in both plant operations and corporate offices.

##### **Jesse Ahrendt**

Executive Director

Quality assurance and manufacturing improvement innovation leader who optimizes organizational resources to exceed business quality goals.

##### **Marinka Tellier**

Director

9 years' experience in pharmaceuticals and biologics. Areas of expertise include regulatory affairs, clinical trials and FDA submissions.

##### **Andrew Papas**

Vice President of Regulatory Affairs

26 years' experience in the industry, providing leadership and guidance on global regulatory affairs, quality and drug development programs.

##### **Shritin Shah**

Executive Director

Over 25 years' experience in regulated industries with a successful record of helping companies address regulatory compliance with USFDA, DEA and NRC.

# Regulatory Update



by Pete Gough,  
Executive  
Director, NSF  
Health Sciences  
Pharma Biotech  
Consulting

## EU News

### Clinical Trials Regulation

The implementation of the new Clinical Trials Regulation 536/2014 is delayed until 2018. When it was published in May 2014 it stated that it would become effective six months after the new EMA Web portal for clinical trial submissions goes live but not earlier than 28 May 2016.

In December 2015 the EMA stated that the EU clinical trials regulation will come into effect by October 2018 at the latest. This was endorsed by the EMA Management Board, taking into account the timeframe for the implementation of the EU clinical trial portal and database. The board stressed that this is a maximum timeframe and that all possible efforts must be made to shorten it and bring the regulation into operation as soon as possible.

### 'Safety Features' Delegated Regulation 2016/161

The final delegated regulation on how to implement the safety features requirements of the Falsified Medicines Directive 2011/62/EU was published in the Official Journal on 9 February 2016. This means that for most of the EU Member States the date for implementing the FMD requirements is 9 February 2019. Belgium, Greece and Italy have six extra years to implement the provisions as they already have similar national requirements so they are given the extra time to transition. In practice, it is expected that they will attempt to meet the 2019 deadline so that their systems harmonize with the rest of the EU.

The requirements in the final version of the regulation are the same as those in the August 2015 draft version, as detailed in Issue 33 of our Journal.

The big question remains, can this hugely complex implementation be completed within the three-year timeframe laid down in the legislation?

### PhEur Changes Monograph for WFI

The PhEur has adopted a revised monograph for water for injection (WFI) which allows the water to be generated by processes such as reverse osmosis in addition to distillation. The revised monograph (0169) will be published in PhEur Supplement 9.1 and will become effective in April 2017.

This change should be in alignment with what is expected to be in the revised Annex 1, which is currently being prepared by a joint EMA PIC/S working group led by MHRA Expert Inspector Andrew Hopkins.

## ICH News

### ICH Q3D Elemental Impurities

In late 2015 an Implementation working group published a series of eight training modules to support the implementation of Q3D. The eight modules, which can be downloaded from the ICH website, are:

0. Overview
1. Developing Acceptable Levels for Other Routes of Administration
2. Justification for Exceeding a PDE
3. Developing Acceptable Levels for EI not in Q3D
4. Considerations for Large Volume Parenterals
5. Risk Assessment
6. Controls on Elemental Impurities
7. Calculations Options

## UK News

### Transitional IMP QPs

The MHRA is publishing the process which current transitional IMP QPs will need to follow to maintain their QP status before the new CT regulation comes into effect. This will involve the completion of a new application form, which will have to be sent to the MHRA. It is



possible that some applicants will be called for an interview with the MHRA. There will be no charge for this re-assessment process. If successful, the transitional IMP QP will be given a certificate of eligibility by the MHRA.

## MHRA Blog

The MHRA continues to publish useful information on its blog ([www.mhrainspectorate.blog.gov.uk](http://www.mhrainspectorate.blog.gov.uk)). In January 2016 it published the first part of a blog on refrigerated medicinal products and in March one titled 'GDP: 3 steps to assure supply chain integrity.'

## US News

### Robert M. Califf Confirmed as FDA's New Commissioner

The U.S. Senate voted 89-4 on February 24, 2016 to confirm Robert M. Califf, M.D. as the commissioner of the Food and Drug Administration, ending a five-month confirmation process. Despite the delay, he received widespread support from both Republicans and Democrats. He was sworn in on February 25.

Dr. Califf, a globally recognized medical leader in cardiology, is a former Duke University researcher and had recently served as the FDA's deputy commissioner of medical products and tobacco. His extensive experience in clinical research, having worked with many large pharmaceutical companies, and his public health experience sets him apart from recent FDA commissioners. He intends to bring a patient-based focus to the FDA.

### New Inspection Protocol Project (NIPP)

The NIPP is an FDA-driven, internal analysis and modernization of inspection protocols to explicitly address manufacturing quality. The inspection includes analyzable observations that will enable FDA to assess the state of quality in the inspected facility. This project started in the spring of 2014 and should be

fully implemented by the end of 2016. The aim is to improve consistency and provide an objective basis for assessing a quality culture. Currently this project is separate from the quality metrics initiative, but may eventually be combined with quality metrics information.

Phase 1 of the project was completed in late 2015 and phase 2, which extends the trial to a much larger number of inspections, started at the beginning of 2016. The FDA intends to eventually share some aspects of the new protocols with industry.

#### The project has three sub-groups:

- > Pre-approval inspections (PAIs)
- > Surveillance inspections (routine GMP inspections)
- > For cause inspections

For routine GMP inspections, it will add additional elements relating to quality culture to the existing six-system approach.

The new protocols have what are called 'ratable elements' that will have to be covered during the inspection. The FDA investigator will assign a numeric score to each element covered during the inspection. The scores will be aggregated for each system that is evaluated. The protocol sets basic performance levels and has several additional levels above and below this basic level. Investigators' scores will be added to a library that will hopefully over time drive greater consistency.

These new protocols will not change the existing inspection outcome classifications of No or Official or Voluntary Action Indicated (NAI, OAI or VAI) but will supplement them with more details on the state of the facility.

### Draft FDA Guidance on Data Integrity

On April 15, 2016 the FDA published a draft guidance for industry entitled Data Integrity and Compliance with cGMP. This draft guidance is intended to clarify the role of data integrity in current Good Manufacturing Practice (cGMP) for drugs, as required in 21 CFR Parts 210, 211 and 212.



by Andrew Papas, Vice President of Regulatory Affairs, NSF Health Sciences Pharma Biotech Consulting



John Johnson, NSF Health Sciences Pharma Biotech Consulting Executive Director, responds to questions from the **Ask John** series.

# Expert Corner

John Johnson recently received a particularly thought-provoking and highly challenging question.

**A former colleague caught up with me and sighed, “We upgraded the SOPs like the regulator wanted, but it hasn’t worked out well at all”. The pain and confusion was etched across his face – he had tried to do the ‘right thing’ but to no avail. So he asked “What should I have done differently?”**

Satisfying your shareholders’ expectations, satisfying the legal and cGMP expectations of the international regulatory bodies and staying on the right side of your Board of Directors is a basic requirement of staying in business.

But, often we see the **law of unintended consequences** raise its ugly head. What do I mean by this? Let’s say you identified a need to improve something in the workplace; possibly a process, SOP, laboratory method or system. You planned out what to do and you trained the staff and implemented the change. Yet some time later you noticed:

- > No one is following the new process, SOP, method or system
- > People are working around it
- > It isn’t working; it’s clunky, unwieldy, unpopular and hard to follow
- > **It has caused more variation and more waste than it sought to prevent**

So what went wrong?

Why has this change, put in with the best intentions, been so disruptive or difficult to comply with? After all:

- > You did what you thought was right
- > You worked at the desk long into the night
- > You were so busy that it took heroics to make the change

- > You did exactly what you thought the regulators wanted, so why are you now experiencing so much angst and heartburn, recriminations and rework?

From our research and case studies, this ‘doom loop’ is remarkably common, yet relatively easy to avoid given:

- > A staunch commitment to intimate involvement of the user in all proposed changes
- > A discipline to drive simplification into all operations; stripping out what is not needed, removing distractions and underscoring critical steps
- > An obsessive commitment to employee education, not just on-the-job training
- > A deep understanding of the science and compliance requirements associated with your technology or product; leading to effective risk-based decision making

This issue’s Expert Corner describes a fabulously successful GMP remediation program that appeared at first to be impossibly daunting, expensive and unattainable. The company had received a range of critical and major GMP deficiencies from the UK regulatory body, MHRA, and was facing a referral to MHRA’s Inspection Action Group. Manufacturing had to be suspended pending a risk assessment of the non-compliances; evaluating the effect of the non-compliances in terms of risks of misbranding and adulteration of the products. Shifts were cancelled, the supply chain was suspended and an urgent remediation program begun.

The obvious things were done immediately:

- > Acknowledgement of the issues with the Agency
- > Evaluation of the error chain that led to the non-compliances
- > SOP changes, batch manufacturing record and log book upgrades

- > Timely and thorough correspondence with the Agency

NSF was asked to participate in leading this activity, advising on what to do to avoid false starts, wasted effort and reworked documents. With our involvement, the company made a critical decision that was estimated to reduce the time in IAG referral by six months and to allow the company to get back into production three months earlier. These were ‘must haves’ not just for the performance of the business, but for its **survival**.

We worked with the company to:

- > Look critically at the staff behaviors that led to the critical and major non-compliances
- > Assess how those behaviors relied on the motivation, ability, simplicity of method, triggers/cues and basic habits of staff performing their daily work
- > Assess how those behaviors could be altered to ensure the right decisions are made at the right time by the right people without relying on the ‘senior few’
- > Underpin the remediation program with a series of measured, targeted interventions in:
  - ◆ Leadership and management development training
  - ◆ Behavioral GMP
  - ◆ Human error reduction and focus on preventing recurring variation/deviation
  - ◆ Risk identification, evaluation and action-centered programs to mitigate risk
  - ◆ Compliance and technology-based training so that staff understand the ‘know why’ not just the ‘know how’

We mapped the whole range of expectations from the U.S. CFRs, the EU GMP Vol. IV guide, ICH guidelines and using a deep knowledge of the FDA Quality Systems Inspection Technique, we:

- > Fixed the true root causes and addressed the behaviors that led to the non-compliances
- > Fixed the issues in a way that was error-proofed, sustainable and economic to the business
- > Identified other, previously unknown critical risks so the site could face future inspections with more confidence and therefore reduced risk of business discontinuity, recalls and poor yields/outputs
- > Helped grow successors and partners to the senior few, spreading the workload and sharing the responsibility for maintaining perpetual inspection readiness
- > Mapped the GMP expectations against our education syllabus and selected key interventions which would give the biggest (and longest) ‘bang for the buck’

The key message here is:

- > Educating your staff (beyond the typical training events) promotes less complexity throughout the documentation system, drives flawless execution of key steps and grows your staff’s contribution to the long-term health of your organization
- > So don’t even think of making a change without thinking education, not simply training!

Please visit the NSF YouTube channel ([www.youtube.com/user/NSFInternational](http://www.youtube.com/user/NSFInternational)) and find the Pharma playlist for additional resources like our videos and webinars on:

- > **How to Jumpstart Your Pharma Business by Simplifying Processes**
- > **The Art and Science of Simplification – How to Win Your War on Complexity**
- > **Remediation the Right Way**



## Lab Insights – NSF Erdmann Analytics Extends Laboratory Space

NSF Erdmann Analytics, located in Germany, serves as a leading laboratory for food producers and traders, and as a strategic location for Central Europe. As an accredited laboratory, NSF Erdmann Analytics provides routine testing of products as well as flexible, custom services through state-of-the-art laboratory equipment and skilled, continuously trained expert staff.

The wet chemistry department at our NSF Erdmann Analytics lab recently expanded with a move to a new building. The wet chemistry department has a newly equipped laboratory with more than 700 m<sup>2</sup> of space, 40 percent more than the previous location. By restructuring and creating new space, many workflows can be optimized.



Other laboratory equipment is also being updated and reconstructed to allow the expansion of our services in the field of water analysis (mineral and mineral water and beverage quality).

Three employees have taken on new roles in the lab expansion:



**Gerd Untiedt:**  
Customer Relationship  
Manager

Gerd Untiedt takes over as Customer Relationship Manager and is responsible for acquisition, customer care, sample logistics, results, test report generation and transmission as well as our in-house laboratory software (LabEx).



**Sascha Kaltenbach:**  
Technical Lab Manager, Food

Sascha Kaltenbach is Technical Lab Manager for all areas of food testing. Sascha is the main contact for all issues concerning food and is responsible for the development of our analyses and the scope of our analysis methods. He works closely with our global laboratory network.



**Andreas Hartmann:**  
Technical Lab Manager, Health  
Sciences

Dr. Andreas Hartmann takes over the role of Technical Lab Manager for the Health Sciences Division, including the sectors pharma biotech, cosmetics and water analysis. He is responsible for the construction and expansion of analysis services according to customer-specific requirements and needs.





## Acquisition of NSF AuthenTechnologies® Adds DNA Authentication and Supply Chain Verification Services

NSF International recently acquired AuthenTechnologies®, the first and only FDA compliant, ISO/IEC 17025-accredited provider of innovative genetic technologies to improve the authenticity, safety and quality of natural products. Now known as NSF AuthenTechnologies®, the newest addition to our Health Sciences Division delivers high-quality, efficient and effective solutions based on cutting-edge science to solve identity challenges across a wide range of products and industries, including agriculture, food, dietary supplements, cosmetics, beverages, and herbs and spices.

No other laboratory in the world is capable of providing this type of advanced DNA-based identity testing and authentication technology, which has been brought together under one roof with NSF International's chemical analysis and other testing, auditing and certification programs.

NSF AuthenTechnologies® tests utilize a proprietary method called Target Specific DNA Sequencing™ (TSDS™), which integrates the most leading-edge processes and equipment available today, including next-generation sequencing. Our methods have been developed and validated by an experienced team of scientists to provide the most accurate and reliable identification of species and detection of unexpected contaminants, even those that are morphologically or chemically indistinguishable.

Our authentication services are compliant with the U.S. FDA's cGMP requirements for 100 percent identity testing, for virtually any species

of plant, algae, fungus, animal or bacteria and can be used to replace other traditionally used methods, including TLC, HPLC, HPTLC, FTIR and NIR.

NSF AuthenTechnologies® also offers unique contaminant and GMO testing services including:

- > **Clean Screen™:**  
Screens for the 10 most common plant allergens and fillers, including soy, wheat and tree nuts
- > **GMO Species Screen™:**  
Screens for the 10 most common GMO species
- > **GMO Event Screen™:**  
Screens for the 10 most common GMO transgenic events

Our services can be used to authenticate and detect contaminants and GMO species and transgenic events in a wide range of natural materials and products, across the entire supply chain from seed to shelf.



For more details, please visit the NSF AuthenTechnologies® website at [www.authentechnologies.com](http://www.authentechnologies.com)

## NSF Welcomes Kim Trautman as Senior Vice President, Medical Device International Regulatory Compliance



NSF Health Sciences would like to welcome Kim Trautman to our family. Kim joined our colleagues in the NSF International Medical Devices group, part of the global NSF Health Sciences Division, in late January 2016.

Kim is an expert in medical device quality systems and international regulatory affairs, and brings over 30 years of U.S. FDA experience to her new role as Senior Vice President of Medical Device International Regulatory Compliance. In this position, she will leverage her experience to expand international regulatory affairs and compliance services for NSF medical device clients. This includes expanding

current U.S. and European medical device training services internationally, and spearheading the development of an independent, third-party regulatory certification program.

At the U.S. Food and Drug Administration, Kim served as the Associate Director for International Affairs in the Office of the Center Director at the Center for Devices and Radiological Health (CDRH). In that position, she led the CDRH's international efforts and initiatives, which included coordinating the center's medical device single audit program, the harmonization by doing initiatives, bilateral and multilateral programs, exchanges with foreign regulators and many other international activities.

She was responsible for writing the current U.S. FDA Medical Device Quality System regulation and preamble published in 1996. She also developed and implemented the extensive quality system regulation roll out and training programs, and led continuing

harmonization efforts with ISO 13485, which includes the most recent version of ISO 13485 which will be published later in 2016.

Kim served on the International Medical Device Regulators Forum (IMDRF) Management Committee and chaired the IMDRF Medical Device Single Audit Program Working Group. She was the chairperson for the Global Harmonization Task Force (GHTF) Study Group 3 from 1996 to 2005, and has been a member of GHTF since 1993. She is a U.S. delegate for ISO/TC210, Quality Management and Corresponding General Aspect of Medical Devices Working Group 1 and is the U.S. TAG co-chair for Working Group 1, the authoring group for ISO 13485. She is also a representative to the U.S. TAG to ISO/TC176, Quality Management and Quality Assurance, the authoring group for the ISO 9000 series of standards. She was also a member of the FDA Combination Products GMP Working Group.

Check Kim's New ISO 13485: 2016 Training Courses:  
[www.nsf.org/info/md-training](http://www.nsf.org/info/md-training)



## NSF Kirkbymoorside Office Celebrates 30 Year Anniversary

2016 is a very special year for the Kirkbymoorside office of NSF, celebrating 30 years of patient protection. On April 30, the journey (so far!) was celebrated and the people who have played such an important part in the office's continued success were acknowledged at the York Marriott Hotel, UK. Over £700 was also raised on the evening for Macmillan Cancer Support.

Here are some photos from the evening.



Martin Lush



Mike Halliday and David Begg



30 Years of Patient Protection



**Die richtigen Leute. La bonne solution. La prima volta.**

*Over the decades, NSF Pharma Biotech Consulting (initially as David Begg Associates) has built a strong reputation as a leading provider of pharmaceutical education and consulting in Europe.*

Numerous pharmaceutical and biotechnology manufacturing sites across Europe are valuing the fact that we are able to bring our education programs not just to leadership teams but also to shop floor operators and warehouse staff. Our 2012 addition of native-speaking Italian, French and German

subject experts expanded this capability. We are constantly adding subject experts to our team, and our highly skilled and enthusiastic French, German and Italian-speaking consultants have extensive experience in European and U.S. Good Manufacturing Practices (GMP) requirements.

Contact NSF Pharma Biotech Consulting to discuss how we can help you to improve your business so that it meets the economic, service-oriented and GMP compliance expectations of the future.



30 Years of Patient Protection



## NSF International Promotes Dr. James Scull to Vice President, Pharmaceutical Development

Congratulations to Dr. James Scull on his promotion to Vice President, Pharmaceutical Development in NSF's Health Sciences Division.

In this newly created role, Dr. Scull will lead the strategic development, growth and expansion for pharmaceutical and medical device testing throughout the NSF Health Sciences network of laboratories worldwide. He will work with leadership at each facility to develop centers of excellence that will provide a testing continuum throughout the product development lifecycle. He will also be tasked with the development and enhancement of client relationships to drive revenue and promote the NSF brand, both locally and worldwide. He will continue to report directly to the Vice President of NSF's Global Health Sciences.

Since NSF's acquisition of Pharmalytica Services in 2011, Dr. Scull has held the position of General Manager at NSF Health Sciences' Bristol Laboratory in Connecticut. Prior to joining NSF, he held positions as Executive Director and Managing Member of Pharmalytica Services from 2004 to 2011, Outsourcing Manager at Purdue Pharma from 2000 to 2004 and various roles culminating in the position of Research Scientist at the DuPont Pharmaceuticals Company from 1987 to 2000.

Dr. Scull holds a Ph.D. in analytical chemistry from Villanova University and a B.S. in chemistry from Widener University of Pennsylvania.

## Our People Define Our Organization, Join Our Experts

A key characteristic of a high-performing team is that it has an obsessive curiosity about the future – How can we improve, how can we grow, how can we serve our customers better, how can we anticipate customer trends and put in place the infrastructure to meet those future needs? It doesn't matter if your team is associated with football, banking, service industries or pharmaceutical manufacturing; being sure recruitment is timely and focused on creating a better future is key to creating an agenda for long-term, sustainable growth.

Our clients rate our associates as outstanding because:

- > They are seasoned professionals who have walked in your shoes
- > They quickly assess problems, engage with colleagues and create sustainable solutions to multifaceted issues with empathy, diplomacy and action-centered leadership
- > They are recognized as industry experts in their field

### Does this sound like you?

If it does, please get in touch with John Johnson at [johnjohnson@nsf.org](mailto:johnjohnson@nsf.org) as we are looking to add some talented people to our UK and European associate team and John would be glad to explain our vision and immediate needs.

In future editions of the Journal, John will profile some of our current associates but in the meantime if you are interested in discussing this opportunity please don't hesitate to contact him via email or phone at **+ (0)1751 432 999**.



From left to right: Deborah Cuming, John Johnson, Pete Gough and Martin Lush



The right people. The right solution. The first time.™

## Is Looking for an Associate Director

We are looking for an Associate Director of Pharma Biotech Consulting to join our busy Kirkbymoorside office in the UK. This position provides an exciting opportunity to grow into a senior leadership and management position within the company.

### Associate Director – The Role

The Associate Director is a high profile, professional role within our NSF Health Sciences Division. With much of NSF Health Sciences' work deriving from repeat business, customer management, satisfaction and relationships are key. The Associate Director's initial focus will be to work closely with our Client Liaison Manager to support key client projects in on-site training and certification programs. The successful applicant will take a share of key client management while developing new clients to ensure first-class customer satisfaction. The Associate Director will personally contribute to business revenue and performance, taking an increasing role in training course design and delivery.

### Associate Director – The Person

The successful applicant will have a minimum of a bachelor's degree in science and will most likely be a Qualified Person with experience in the pharma industry, preferably covering dosage forms and quality assurance. A passion for excellent customer service and for delivering training and education are musts. NSF Health Sciences is looking for a committed individual with high integrity and a focus on patient protection and making a positive difference.

Contact Mike Halliday at [mikehalliday@nsf.org](mailto:mikehalliday@nsf.org) if you have what it takes to succeed in this position.

# Forthcoming Courses

What's planned for June 2016 – February 2017



## Modern Process Validation

June 7-9, 2016

Manchester, UK

Course Fee: £1950 plus VAT

## Investigational Medicinal Products

June 13-16, 2016

York, UK

Course Fee: £2680 plus VAT

## Risk-Based Decision Making in Sterile Products Manufacture

June 20-22, 2016

Manchester, UK

Course Fee: £1950 plus VAT

## How to Simplify Your Change Control System to make it Fast and Efficient

June 30 – July 1, 2016

Manchester, UK

Course Fee: £1500 plus VAT

## The Role & Professional Duties of the Qualified Person

July 25-28, 2016

York, UK

Course Fee: £2680 plus VAT

## Active Pharmaceutical Ingredients

September 12-16, 2016

Newcastle upon Tyne, UK

Course Fee: £2880 plus VAT

## Human Error Prevention

September 14-16, 2016

Manchester, UK

Course Fee: £1950 plus VAT

## Pharmaceutical GMP Audits and Self-Inspections

(An IRCA Certified Pharmaceutical QMS Auditor/Lead Auditor Course)

September 19-23, 2016

York, UK

Course Fee: £2810 plus VAT

## Risk-Based Decision Making for Quality Professionals and QPs

September 27-28, 2016

Manchester, UK

Course Fee: £1500 plus VAT

## A – Z of Sterile Products Manufacture

October 3-6, 2016

Amsterdam, The Netherlands

Course Fee: £2600 plus VAT

## Pharmaceutical Legislation Update: Continuing Professional Development for Qualified Persons & Technical Personnel

October 4, 2016

Manchester, UK

Course Fee: £750 plus VAT



*Early Bird or Multiple Delegate discounts apply to some of our courses. Please visit our website, [www.nsf.org](http://www.nsf.org) for full details.*

For more information, email [pharmacourses@nsf.org](mailto:pharmacourses@nsf.org) or visit [www.nsf.org/info/pharma-training](http://www.nsf.org/info/pharma-training)

Course details are correct at the time of printing and are published in good faith. NSF reserves the right to make any changes which may become necessary.



The right people. The right solution. The first time.™

### Statistics for Ongoing Process Verification – Analysing and Trending Data

October 11-12, 2016

Manchester, UK

Course Fee: £1500 plus VAT

### Pharmaceutical Law and Administration

October 17-21, 2016

York, UK

Course Fee: £3395 plus VAT

### Free QP Seminar for Prospective QPs and Sponsors

October 18, 2016

York, UK

Course Fee: FREE

### Pharmaceutical Legislation Update: Continuing Professional Development for Qualified Persons & Technical Personnel

October 18, 2016

Milan, Italy

Course Fee: €625 AFI members plus VAT  
€690 Non AFI members plus VAT

### Pharmaceutical GMP Audits and Self-Inspections

(An IRCA Certified Pharmaceutical QMS Auditor/Lead Auditor Course)



October 31 – November 4, 2016

Amsterdam, The Netherlands

Course Fee: £2810 plus VAT

### Medicinal Chemistry & Therapeutics

November 14-18, 2016

York, UK

Course Fee: £3395 plus VAT

### Pharmaceutical GMP

November 21-24, 2016

Amsterdam, The Netherlands

Course Fee: £2240 plus VAT

### Formulation and Processing

January 16-20, 2017

York, UK

Course Fee: £3395 plus VAT

### GMP for Biological and Biotechnology Products

February 28 – March 3, 2017

Manchester, UK

Course Fee: £2300 plus VAT

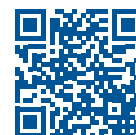


30 Years of Patient Protection

2016 marks our 30<sup>th</sup> year in the business of providing training to the pharmaceutical industry. We're proud to be part of NSF, with all the benefits we can bring to our customers through the expertise and professionalism of our colleagues across the globe.

Although you may be more familiar with one of our former names, our values and commitment remain the same.

A full, up-to-date course listing is available online. Book your place at [www.nsf.org/info/pharma-training](http://www.nsf.org/info/pharma-training)



# A Final Word on KPIs – A Case Study From a Site Quality Head

by Martin Lush, President, NSF Health Sciences Pharma Biotech Consulting

## The Problem

A contract manufacturer producing a range of sterile and non-sterile products for some 108 clients had struggled with their KPIs for some time. These were some of their pain points:

- > 80 percent of indicators were lagging, 20 percent leading
- > All measures had been introduced by the site leadership team with no involvement of process owners
- > Many of their 47 KPIs were confusing, and difficult to understand and interpret
- > Although KPI reports were on time, they were reported to senior leadership and rarely shared with process owners in manufacturing

The site quality head was concerned that the measures were no longer fit for use.

## How Was The Problem Tackled?

### Step 1: Recalibration of Site Leadership Team

Leadership had mixed views of KPIs. Many did not distinguish between leading and lagging, and none focused on behavior first, measure second. We emphasized that:

- > They were all collectively responsible for business performance and for the KPI system, not just the site quality head
- > Their existing KPIs, with a focus on lagging indicators, were making their reactionary firefighting culture worse
- > That the existing measures were driving the wrong behaviors and exposing their business to risk

### Step 2: Engagement of The Process Owners

Our workshop involved team leaders, supervisors, operators and subject matter experts from manufacturing, planning, procurement, engineering, QA and QC based on their process knowledge and frustration with the current KPI system.

### Step 3: Focus on Systems and Behaviors

We started by focusing on what was in it for them: fewer, more accurate measures that waste less time and make their life easier. They then generated a process flow map listing all manufacturing equipment, plants, utilities and systems. We helped identify the desired behavior and outcomes (business benefits) (first three columns in the table in step 4).

### Step 4: Identify Measures That Drive the Right Behavior and Outcome

We described what drives behaviors (for details on this step, view our webinar on Changing Behaviors in the Workplace, [www.nsf.org/info/pbwebinars](http://www.nsf.org/info/pbwebinars)).

| System                | Desired Behavior                 | Outcome required        | Leading Indicators  |
|-----------------------|----------------------------------|-------------------------|---|
| Deviation & CAPA      | Better root cause investigations | Fewer repeat deviations | > Time interval between incident and investigation<br>> Numbers of repeat incidents |
| Equipment & utilities | Timely review of performance     | Fewer breakdowns        | > Review of equipment logs<br>> Daily plant inspections                             |
| SOPs                  | Better compliance                | Fewer errors & mistakes | > 7th grade Flesch-Kincaid readability score  |

### Step 5: Agree on Measures and Review Every Two Weeks

Responsibilities were allocated for data collection, interpretation and reporting using a simple traffic light system, and **RED** and **AMBER** performance measures were reviewed every two weeks in face-to-face meetings:

- > **RED:** Failure to achieve desired performance
- > **AMBER:** Process 'in control' but improvement required
- > **GREEN:** Optimal performance achieved

## The Solution and Results

The site quality head called in NSF to design and facilitate a customized three-day workshop to remedy the situation, which generated this return on investment:

- > **Reduction in cost of goods creating savings in excess of \$3.7 million in 9 months**
- > **Levels of 'work in progress' reduced by 11 percent, generating savings of \$475K**
- > **Repeat deviations reduced by 35 percent**
- > **Equipment breakdown reduced by 18 percent**
- > **Plant utilization improved by 14 percent, allowing 36 additional batches to be manufactured**

If you would like more information or examples of other performance measures, email [martinlush@nsf.org](mailto:martinlush@nsf.org)



#### Europe:

The Georgian House, 22-24 West End, Kirkbymoorside, York, UK, YO62 6AF  
T +44 (0)1751 432999 F +44 (0)1751 432450 E [pharmamail@nsf.org](mailto:pharmamail@nsf.org)

#### USA:

2001 Pennsylvania Ave, NW, Suite 950, Washington DC 20006, USA  
T +1 202-822-1850 F +1 202-822-1859 E [USpharma@nsf.org](mailto:USpharma@nsf.org)

[www.nsf.org](http://www.nsf.org)

