



MANAGING CHANGE

THERE IS NO TIME LIKE THE PRESENT...

by Jim Morris

Organizational change can take on many guises. Most changes are planned and orchestrated by company management (such as a plant expansion, an updated MRP system or a new incentive program). However, some of the most impactful changes are nearly impossible to predict. Tectonic shifts such as Brexit leave lasting changes that play out over a long time. Changes can also result from a public health crisis (such as Heparin contamination and counterfeit Avastin). Adapting an operation to meet new regulatory requirements can be extremely demanding and costly, as with the work underway to implement serialization and the European Medicines Verification Organisation repositories. And unfortunately, some changes may result from a problem of our own making. For instance, a regulatory warning letter is usually preceded by a series of poor GMP inspections that point to reoccurring and often avoidable issues. Resolution of these issues will undoubtedly require significant changes to company quality systems and, in many cases, even larger changes to the company quality culture.

In all of these situations, change, regardless of its origins, always spells opportunity. What results is often an opportunity to improve what you do and what your company does. However, there are differences in the execution that will ultimately have an impact on how well a company, plant site or unit operation embraces change. Let's examine three types of change and considerations for navigating each type.

CHANGE TO WORK

Planned changes of small or major design (such as a new method, new equipment or IT system) will typically be met with resistance. Company and personnel habits are strongly embedded, and it takes a lot of planning to overcome existing ways of doing business. Installing new manufacturing equipment or a new MRP system requires careful planning to ensure that personnel are competent in their environment before the system goes live. One of the most prevalent weaknesses in



plant operations is a failure to gradually bring people on board with something different. As the adage goes, failing to plan is planning to fail. The operative word for any change to work is to PLAN to make the change in a way that involves the users early in the change process.

CHANGE IN BEHAVIORS

Eliciting a change in behavior is truly the most challenging type of change to manage.

Examples of other behavioral-focused initiatives may include fostering a more safety-conscious culture across a plant network and developing a more positive donor experience among blood collection sites.

The driver could be a commitment made as a result of a serious problem (regulatory warning letter, product recall) or it could be a forward-thinking leader seeking to embed new behaviors that will help the company succeed in its mission. Consider leader initiatives such as Pfizer's CEO Ian Read promoting an "own it" philosophy across the company or ex-Alcoa CEO Paul O'Neill's focus on a safety-minded culture which dramatically improved operational performance and company valuation during his tenure as CEO¹. At NSF we have been asked to establish programs to create a more open and "speak up" quality culture across functional groups within multi-national organizations.



Regardless of the driver for change, companies seeking to embed a new behavior among all personnel need to carefully consider the following factors:

1. **The plan must come first.** A change that is only driven from the top is doomed to fail, whereas changes that enlist the buy-in from a broad cross-section of employees have the greatest chance of success. For instance, a biologics manufacturer seeking to foster a “speak up” culture across the organization leveraged first-line supervisor training sessions to cascade key messages and obtain broad-based feedback from employees. A large cross-section of employees were reached in this deployment and an appreciation for the behavioral changes expected was gained.

For a change to be successful, it must be taken on board by a critical threshold of like-minded people.

2. **Senior leadership must embrace the change and walk the talk.** There must be complete buy-in by the executive team for real behavior change to take place. If senior leaders express support for a change, but their actions do not, the initiative will not stand a chance of getting traction. For instance, if managers cancel safety meetings or put quality metric reviews last on a meeting agenda, they are indirectly communicating their lack of support. In contrast, if a safety meeting is never cancelled and quality metrics are first on the agenda, the message is clearly reinforced.

Senior leadership must be authentic in their expression of support.

3. **New habits must be reinforced.** A new habit is introduced through constant, visible reinforcement. The flavor of the month comes about when there is a lack of reinforcement and we move onto the next initiative. It is better to focus on getting a single initiative right than expecting employees to tackle multiple large-scale initiatives successfully. Does implementing a new MRP system, on top of the roll-out of a new LIMS system, while rolling out a cultural change initiative sound familiar?

Beware of the risk of initiative overload in a company or plant site. Recognize the value of a constantly reinforced simple message. It will ripple throughout the organization.

4. **Success must be measured.** Change programs require the identification of indicators to measure impact and success. At NSF we work hard with each client interested in a change initiative to consider the measures needed to determine the impact of the program. Positive shifts in quality trend data is one approach or anecdotal measures of employee engagement may provide useful input. Measurement criteria must be part of an initiative and defined early in the change process.

If we don't measure it, we cannot gauge success.

UNEXPECTED CHANGES

Often change comes about as a result of a surprise “gift” that lands on our doorstep. Experienced managers will recognize the opportunity and embrace it. For instance, I have used an example of a plant that was cited for cross-contamination risk of two highly sensitizing drug substances. This risk was escalated to the regulatory agency and resulted in a partial plant shutdown, remediation of the site quality systems and ultimately a series of regulatory agency re-inspections to confirm the cross-contamination risk had been eliminated. Twelve months later I must have looked twelve years older.

The salient message learned throughout the experience was the focus of the plant on one thing – the



investigation report into the root cause of the cross-contamination. The depth of that report and resulting CAPAs saved the day (and the plant).

By focusing on the primary issue and not losing sight of its importance, the plant staff worked through a partial plant closure and began to make the changes to improve long-needed quality system improvements at the site. It was also critical to engage outside support – not only across the company plant network but external consultancy support. The “gift” wrapped in the unpleasantness of regulatory action, was the opportunity to make timely and lasting improvements to the site quality systems.

CONCLUSION

What is common in the above situations is the need to be tenaciously focused on the thing that you are seeking to change. Change is met with skepticism and resistance. People need to travel the journey from denial to commitment as quickly as possible and gain an appreciation for why the change matters. When change sponsors paint a picture of the future (what good looks like) and a critical threshold of people embrace the change, only then will that change begin to take shape and become embedded in the new way of working.

<p>Denial</p> <p>No way, this is not my problem.</p>	<p>Commitment</p> <p>I am on board.</p>
<p>Resistance</p> <p>I don't have the time on top of everything else I am doing. This won't work.</p>	<p>Exploration</p> <p>I get it. Am beginning to understand. My peers are recognizing this is important.</p>

Get more valuable guidance on changing GMP behaviors by applying our B = MATh model in the white paper *Changing Your Quality Culture and Improving GMP Behaviors: What Works and What Doesn't* available in our resource library, www.nsf.org/info/pblibrary.

ABOUT THE AUTHOR



Jim Morris has over 25 years of pharmaceutical management experience in both plant operations and corporate offices, working with Pfizer, Cilag AG and Mass Biologics in the U.S. and Europe. He has held positions as Deputy Director QA/QC and Regulatory Affairs while at Mass Biologics, Director of QA/QC for the Biologics business unit of Cilag AG and a number of quality assurance and manufacturing roles with Pfizer over a 16-year timeframe, culminating as the head of Quality Assurance for Pfizer in Latina, Italy.

For more information, contact pharmamail@nsf.org or visit www.nsfpharmabiotech.org

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NSF INTERNATIONAL | PHARMA BIOTECH

The Georgian House, 22/24 West End, Kirkbymoorside, York, UK YO62 6AF
T +44 (0) 1751 432 999 | **E** pharmamail@nsf.org

2001 Pennsylvania Avenue NW, Suite 950, Washington, DC 20006 USA
T +1 (202) 822 1850 | **E** USpharma@nsf.org

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