When NSF conducts research or support projects that seek a level of transformational change within a team or wider organization, we apply our experience and expertise in the internationally recognizable current Good Manufacturing Practice (cGMP) expectations. We then run proven processes that we know work well or can be adapted to work well in any circumstances. In our industry, there is no substitute for a deep knowledge and broad experience in how to interpret and apply the cGMP expectations in practice at the workplace.

**However, can this alone be relied on to drive the type of changes that are often sorely needed?**

Why do projects that simply rely on cutting and pasting the regulations into a client’s pharmaceutical quality system rarely provide perpetual compliance to cGMP?

Why is it that many firms, who have documented and instructed on a comprehensive set of policies and procedures, still never achieve the level of business performance or risk management that the market expects? In other words, you may have the best set of policies, procedures and records, yet still not meet cGMP and still suffer unpredicted costs, supply chain issues and GMP non-conformance.

Kurt Lewin of the Massachusetts Institute of Technology was instrumental in changing the way we think about change management, and how we can ensure our teams and individuals are set up, encouraged and coached for success. His work in the 1930s and ‘40s led to a growing interest in how to engage individuals and large teams to work together in a way that allows the organization to be the best possible version of itself. This is achieved by:

- Improving a team’s ability to predict and confront problems rather than neglecting them, and to manage conflict collaboratively each time in a way that grows trust and cooperation within the team.
- Increasing the organizational skills in problem-solving through knowledge management and education.
- Engendering a spirit of improvement (without painful regret of the problems in the past).

Focusing on the long-term ability and collaboration of the team, while minimizing short termism or snap judgements, led to some startling improvements in industrial productivity during the 1950s and ‘60s, acting as a catalyst for the total quality movement. The big difference was that the focus was squarely on the most important aspect of any organization; its people and their ability to make the right decisions at the right time for the right reasons.

So, what does organizational development do for you in practice?

- It helps define a communication link that gives team members a reason for caring and for getting involved in change (see also NSF’s webinar on behavioral aspects of GMP – visit our resource library at [www.nsf.org/info/pblibrary](http://www.nsf.org/info/pblibrary)).
> It uses that engagement to break the stereotypes or assumptions that hold back a team from achieving more from its finite (and often shrinking) resources and budgets.

> It helps organizations define its values, so that ‘true north’ is maintained even when a storm is brewing.

Critically for us, it makes sure that the required changes to be made (whether during upsizing/downsizing, acquisitions/divestments, technology transfers or GMP remediation projects) are always rigorously defined using diverse perspectives and then executed flawlessly for the clear good of the organization. Without organizational development, changes planned can often be short lived, unloved and unsustainable. Of course, any change needing constant rework will add cost, creating mistrust and possibly impacting team confidence and momentum.

The key message is to make organizational development an important factor in plotting your team’s progress and in helping them take the collective foot off the brake and onto the accelerator!

**ABOUT THE AUTHOR**

John Johnson is passionate about helping organizations foresee and overcome the barriers to sustainable long-term growth. He brings 28 years’ experience across a range of companies in the pharmaceutical and healthcare industry. He has worked in small, medium and large pharma biotech companies across the product lifecycle for a wide range of dosage forms.

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