

**HARMONIZING AND MERGING CHANGE MANAGEMENT AND DRUG
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ABSTRACT

Successful drug development requires an integrated approach. Over the past few decades, there have been considerable changes to the ways drug development has been conducted. To increase efficiency and to comply with the requirements of regulatory agencies,^[1] many companies have chosen to apply the Six Sigma method,^[2] implement new project management strategies,^[3] to avoid pitfalls and be more efficient, and follow the Quality by Design approach.^[4] However, the reality shows that it has been mainly large companies that have applied these improvement methods, which are costly in terms of both expenses and human resources and which pose enormous challenges for biotechnology and start-up firms. It should also be kept in mind that the Six Sigma and project management areas of expertise were not originally intended for drug development. Finally, many achievements have highlighted the scientific skills of those involved in drug development and project management. However, few articles or testimonials have mentioned (1) the challenge of implementing project and operational management in drug development; (2) the dependence of scientific and pharmaceutical discoveries on regulatory requirements, which have changed and become more stringent over time; or in particular, (3) the importance of the human element — of bridging gaps between people from very different fields (such as science, management, and government) in order to streamline the path to an effective drug launch as much as possible.

INTRODUCTION

As all stakeholders involved in drug development are constantly exposed to change, particularly as a result of technology and innovation, change becomes more perceptible. To maintain their competitive advantage, companies need to adopt sound change strategies. These are essential for both start-ups and multinational companies.

The authors of this article are senior executives who have been working in management and drug development respectively for over two decades. They have brought together their combined expertise to demonstrate that operational management and drug development can and should be merged.

This communication will briefly highlight this integrated approach, which should be recognized and adopted by start-up companies in particular, in order that they become as effective as possible, aiming to combine high performance with flexibility, empathy, and respect for human nature. Managing organizations and developments with rigour and political discernment enables people to be empowered and to provide the best

of themselves. Human resources must be safeguarded, as they form the heart and lungs of companies.

The way in which drugs are developed has changed significantly in recent decades, especially for start-up companies. In the past, large pharmaceutical companies conducted a great deal of basic research in their own facilities. While this still happens, much basic research and many new molecular entities also come out of universities and research centres. At first glance, this is a win-win situation, since it represents a profitable alliance between tenured or tenure-track professors and companies, where professors are chosen on the basis of their research interests, which correspond to the development focuses of the large pharmaceutical companies. Moreover, in terms of intellectual property (IP), this alliance undeniably brings added value. However, it has become more difficult to assess the potential of new drug delivery techniques, new pharmaceutical technologies, or new molecular entities, as the objectives of basic research may differ depending on whether they are viewed from academic or entrepreneurial perspectives.

For many people, the objective of academic research is research for its own sake, whereas for companies, research is intended to bring products to market. Barriers to raising funding (grants) have become increasingly difficult for academic research scientists to overcome. Given this situation, companies and academics have had to find ways to collaborate.

In recent years, several research centres and universities have been able to secure funding through collaborations with companies. However, the way these groups communicate has changed. For instance, academic and industry researchers may use different terminologies or measurements. In research on nanomolar activities, tiny molecules have become less and less soluble, making them increasingly difficult to formulate. In the early 1980s, drugs in Phase I clinical studies were very often administered intravenously, as the molecules were sufficiently soluble to enable relatively easy formulation of injectable products. The molecules were soluble and permeable enough (classes 1 and 2, according to the Biopharmaceutical Classification System, or BCS) that their physicochemical characteristics did not affect their reformulation into solid oral forms, allowing for similar results *in vivo*. However, a survey on new drug applications (NDAs) from 1995 to 2001,^[5] showed that almost 50% of NDAs were composed of BCS class 4 molecules (i.e., molecules with low solubility and low permeability). Comparative bioavailability studies at this time were feasible and did not lead to major unexpected results. Lipinski,^[6] indicated that, in a sample of 90,000 compounds screened at Pfizer in Groton, CT, since 1995, “35 to 40% of compounds have aqueous solubility less than 10 micromolar at pH 7”. These last two findings underscore the increasing importance of formulations that allow new chemical entities (NCEs) to be absorbed and to achieve good safety and efficacy profiles. The outcome has been that academics and professionals from industry do not share the same language; so to speak, a 10 micromolar solution is soluble for a chemist but not for a formulator. For this reason, it has become necessary to find a common language to meet common expectations. In this context, soft skills, interpersonal skills and methods for sharing information have become essential. Change management and emotional intelligence have then been promoted.

Change refers to the passage from one state to another and can be applied in very different areas and to varying degrees. Managing change is something we all do every day; we just don't always realize it. When change occurs, it can be worrisome and disruptive. That is why support is essential.

Most companies have forgotten the human side. Typically, companies recognize the need for change when communication is poor, when they lose money or efficiency, or when competitors come up with new offers or new capabilities. These are valid reasons for

implementing change, and companies generally take the human aspect into account in these situations.

Project teams often neglect the human aspects of change as they focus on the technical aspects of their solutions. They associate technical success with project success. Our mission is therefore to create convergent paths that combine change management and project management to achieve business objectives. A well-designed technology that no one uses creates no added value for an organization. A well-designed process that no one follows leads to no improvement in performance. Well-developed job roles that employees don't fulfill deliver no sustainable results. Change management allows people to adapt to change to ensure that the company's objectives are met. It is the bridge between solutions and results, and it is fundamentally about people. Our collective role is to transform change into positive results for our organizations.

A common myth is that change management addresses only the non-technical side of change. In fact, change management is about both achievement of financial goals, which are directly tied to the speed at which employees embrace change, and employees' ultimate use of and proficiency with new processes. People are the most important component of any organization — something we too often forget.

Organizations do not change per se: it is the employees who change, one person at a time. Individual change is essential to achieving organizational change. Change initiatives are successful when the fundamentals of leadership, project management, and change management are all in place. When these three elements are brought together, the likelihood that projects will achieve their objectives, be delivered on time, and provide a good return on investment increases significantly.

When the people affected by a project do not support or participate in the change, specific aspects of the change, including new processes, systems, or work roles, do not materialize. If these elements are not implemented, the project fails to achieve its goal. In short, the business objectives will not be met.

Data collected from 1,778 participants in Prosci's most recent study show that the success of a project — that is, whether it meets or exceeds its objectives — is directly related to the effectiveness of change management. This same correlation is found in research published in the business magazine *McKinsey Quarterly*.^[7]

When it comes to change, situations often get worse before they get better. How much worse and for how long both depend on how the human aspects of change are managed. Change projects with excellent change management are six times more likely to succeed than projects with poor change management.^[8]

Here are the five elements,^[9] required to implement change in ways that will increase the likelihood of success:

- **awareness** of the need for change
- **desire** to participate in and support the change
- **knowledge** regarding how to change
- **ability** to implement new skills and behaviours
- **reinforcement** to sustain the change

Managing change requires experience, ability, and above all, emotional intelligence. Emotional intelligence, a concept developed in 1990 by psychologists Peter Salovey and John Mayer, refers to the ability to recognize, understand, and control one's own emotions and to deal with those of others.^[10] This definition of emotional intelligence as a concept is incomplete; indeed, emotional intelligence is far more than a mere concept and is instrumental in building the deep connections that unite human beings.

Emotions are at the basis of all our decisions, even those that appear to be highly rational. How then can we manage a company without being aware of the place of emotions? Emotional intelligence is a skill that can be developed and improved, leading to increased compassion, caring, and even empathy.

Within organizations, communication is paramount at all levels. How do we communicate constructively with others? By using emotional intelligence, compassion, and empathy. These qualities make it possible to listen to others and not just hear them. Regardless of what you are doing — whether announcing news, giving an order, or making a presentation — you want to be listened to and not just heard. We hear words, but listening to another's message requires will and effort, which must be driven by interest and a feeling of being involved.

A concise analysis of the concept of emotional intelligence quickly brings us to the daily challenges encountered in all organizations. Change management is the art of helping people evolve on a new path, whether this involves new challenges, a change in corporate culture, a restructuring, or the need to leave the laboratory and conform to new political rules.

In this short communication, the authors have tried to demonstrate that change management and especially emotional intelligence should be integrated into almost every type of company in which people are concerned. In the drug development sector, this approach could be summarized as follows: the way a drug is developed should be the same for everyone and everywhere; it is the people involved in the drug development that will be key to making a difference. People are really the crux of the matter. A good technology developed or managed by disinterested people will not be successful, whereas weak technology development managed by people who are united around effective leadership, combining a balanced

ratio of emotional and intellectual intelligence, will nevertheless be able to produce remarkable results.

REFERENCES

1. Moore, Christine M. V. Acting Director Office, New Drug Quality Assessment (ONDQA/OPS/CDER). *Quality by Design – FDA Lessons Learned and Challenges for International Harmonization*. International Conference on Drug Development, 2012. (<https://www.fda.gov/media/85369/download>).
2. Carleysmith, S.W., Dufton, A. M., and Altria, K. D. Implementing Lean Sigma in pharmaceutical research and development: a review by practitioners. *R&D Management*, January 2009; 39(1): 95-106.
3. Pattanaik, Asima. *Complexity of Project Management in the Pharmaceutical Industry*. Paper presented at PMI® Global Congress EMEA, Dubai, United Arab Emirates. Newtown Square, PA: Project Management Institute, 2014.
4. Yu, L.X., Khan, M.A., Hoag, S.W., Raju, G.K., and Woodcock, J. Understanding Pharmaceutical Quality by Design. *AAPS J.*, 2014; 16(4): 771-83.
5. Mehul Mehta, Ph. D. (FDA). AAPS/FDA Workshop on Biopharmaceutics Classification System, September 2002.
6. Lipinski, C.A. Drug solubility: an issue here to stay? Capsugel Expert Meeting, Nashville, November 2005.
7. LaClair, Jennifer A., and Rao, Ravi P. Helping Employees Embrace Change, *McKinsey Quarterly*, November 2002; 4.
8. Prosci, *Why Change Management* [undated], <https://www.prosci.com/resources/articles/why-change-management>.
9. Hiatt, Jeffrey M. *ADKAR: A Model for Change in Business, Government, and Our Community*, Prosci Learning Center Publications, Loveland, Colorado, 2006; 2.
10. Salovey, Peter, and Mayer, John D. Emotional Intelligence, *Imagination, Cognition, and Personality*, 1990; 9(3): 185-211.