HEIDRICK & STRUGGLES



Leading cultural change in biopharmaceutical R&D

Life Sciences Practice

Why is cultural change so important for biopharmaceutical R&D?

The biopharmaceutical industry has achieved many breakthroughs that have greatly enhanced health care and extended life spans. For example, death rates from cardiovascular disease have declined by more than 30% in the past 15 years. Life expectancy for cancer patients has increased dramatically, with medicines and other new treatments accounting for more than 80% of those gains¹. For a range of complex diseases, long-held hopes for prevention, treatment, and cure are being realized through the efforts of biopharmaceutical research teams.

Despite these remarkable achievements, executives of biopharmaceutical companies are confronting an industry in transition – one that is characterized by both massive upheavals as well as significant opportunities.

Pressures from a wide range of sources are driving the need for biopharmcos to both reduce costs and produce a greater number of new drugs through more effective R&D processes. Factors such as the loss of patent protection for many profitable drugs, rising development costs, and payers' tougher stance toward reimbursement have made it necessary for R&D organizations to find new ways to remain cost effective and competitive by improving productivity and quality. Although recent years have seen a spike in new drug approvals in the US, many pipelines are not robust and returns per product are expected to trend downward². At the same time, increasing competition from developing countries is eroding the market share of many multi-national biopharmacos.³

Yet this challenging landscape also creates opportunities that biopharma R&D organizations should be prepared to capture. To help their company sustain a competitive advantage, R&D organizations need to become more innovative and adapt to new technologies. They will also need to embrace open innovation with other companies and academic institutions to co-create new medicines. For many R&D organizations, this creates the need to build new capabilities and collaborative skills as well as to develop a new mindset that promotes the sharing of ideas outside the organization.

In addition to arising from common pressures, these challenges and opportunities share a common response: cultural change. Simply put, biopharmacos will need to reinvent their R&D organizations to remain competitive. And this imperative gives rise to the greatest challenge – the need to implement cultural change in a large, diverse organization in which many people will resist new ways of working and new technologies. The need to address cultural change in the context of an increasingly globalized workforce creates a further level of complexity.

Leadership is the key ingredient to driving successful cultural change. Leaders both guide the organization through cultural change and serve as role models for the new ways of working. What principles should guide organizations in their efforts to shape cultural change? What types of capabilities must leaders possess to bring cultural change to R&D organizations? How can organizations bridge the gap between the skills their leaders possess today and the skills they will need going forward? In this paper, we delve into some of the answers.

http://www.fiercebiotech.com/slideshows/fda-approvals-2012 3 See "Global Pharmaceutical Industry and Market," at http://www.abpi.org.uk/industry-info/knowledge-hub/global-industry/ Pages/industry-market-.aspx

¹ See "Key Industry and PhRMA Facts," at http://phrma.org/news-media/ related-resources/key-industry-factsabout-phrma

² See "FDA Approvals of 2012," at

What are the challenges and opportunities?

What are the most significant challenges and opportunities for biopharmaceutical R&D companies in the evolving industry landscape? First and foremost, organizations must adapt to transformation and change in R&D. This will require new decisionmaking processes as well as enhanced capabilities for creativity and innovation. An organization's success in addressing each of these areas will be dependent on its leaders' abilities to foster the required changes in culture and mindsets.

Transformation and change in R&D

To some extent, the transformational challenges confronting biopharmaceutical R&D arises from its own success. Many companies have succeeded in building global R&D organizations, but this has created the challenges of facilitating collaboration among members of a diverse and geographically dispersed workforce and overcoming organizational inertia. Advances in the field of personalized medicine have also raised the bar for differentiation and increased costs at a time when payers are increasingly price sensitive.

The regulatory environment remains challenging, as riskmanagement measures and label restrictions will continue to be prerequisites for the approval of new drugs. Unless companies improve their selection of projects and make better decisions about which to advance, high levels of attrition in Phases II and III will continue to raise overall costs and reduce productivity.

Leading players have already taken steps to capture opportunities in this changing environment. Some biopharmacos have piloted ideas successfully by applying, for example, streamlined decision-making processes or innovative proof-of-concept strategies. Investments in quantitative sciences may yield big payoffs by enabling more-focused clinical trials – but this will require culture change, particularly in the development organization. And the commercial benefits of personalized medicine may yet outweigh the increased costs for the industry.

Decision-making processes

Decision-making processes in R&D organizations are often an obstacle to addressing both the challenges and opportunities arising from the industry's transformation. Risk avoidance has become a major problem in drug discovery, as executives seek to avoid a "false negative" finding that will result in a project's termination. Some project teams expend large budgets experimenting on many more pharmacology models than are required to provide confidence for moving to the development stage. What's more, several layers of committees often must approve key project decisions. The looming threat of organizational restructuring also impedes decision making - structural changes based on the latest design fad can distract, if not paralyze, project teams. On the other hand, competitive pressures can often cause organizations to unwisely accelerate decision making, forcing a riskier development strategy than might be ideal.

Creativity and innovation

Biopharmacos will need to achieve a new level of effectiveness in their development processes to build and sustain a competitive advantage in the transformed industry landscape. Reaching this higher bar will require a step-change in creativity and innovation within the R&D organization. The organization's innovation model is thus critically important.

Several organizational attributes can help to strengthen capabilities for creativity and innovation. To ensure fresh thinking, many successful organizations build a diverse workforce with respect to culture, ethnicity, academic background, and age, among other factors. Creating a global network of participants within and outside the organization can help to breakdown the orthodoxies that impede innovation within local networks. The organizational structure should be non-hierarchical and promote cross-disciplinary interactions. Both people and the development processes should be adaptable to new technologies and new ways of working. If applied skillfully, incentives and competitive pressure can also be constructive in driving innovation in the development process.

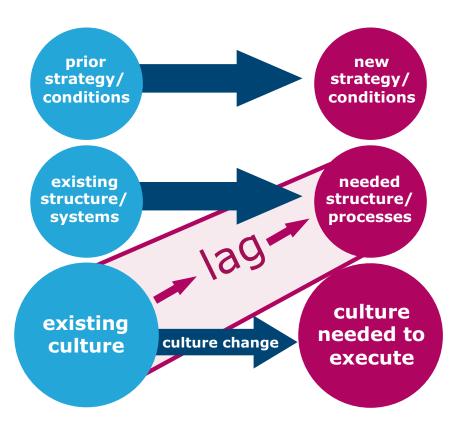


figure 1 Effective cultural change

New strategies that require organizational restructuring are most effective when the underlying culture is reshaped to align with and support the new focus.

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How to lead cultural change

To successfully address these challenges, R&D organizations must both drive effective cultural change and build the leadership capabilities required to make this happen.

Effective cultural change

Any organization is most effective when its strategy, structure, and culture are well aligned. An organization's strategy also needs to be agile enough to adapt to changing market conditions, customer needs, or regulatory pressure. New strategies, more often than not, require the organization to change its structure. Most leaders and organizations have experience implementing a new strategy and structure and are relatively adept at doing so. Unfortunately, very few focus effectively on reshaping the underlying culture so that it aligns with and supports the business's new focus and structure. As a result, the new strategy and structure fail to deliver the promised impact, causing frustration to build within the organization (*fig 1*).

Whether by design or default, all organizations have a culture. Shaping a culture by design is a complex challenge requiring a multifaceted approach that touches nearly every aspect of the organization. Over the past 35 years, we've identified four key principles that should guide and frame the task of culture change. The degree to which they are built into the process of culture change determines the degree to which the effort has the desired impact.

Purposeful leadership

Leaders think of their organizations as their shadows – people watch what their leaders do and emulate them. That means the leadership's focus and behavior is a critical factor in successful culture change. Leaders are role models for the change in all their actions, individually and collectively. Additionally, leaders tell the story of – and exemplify – the needed change in the context of the organization's aims and ambitions. Purpose, strategy, market plans, and culture must all be linked in the story.

Personal change

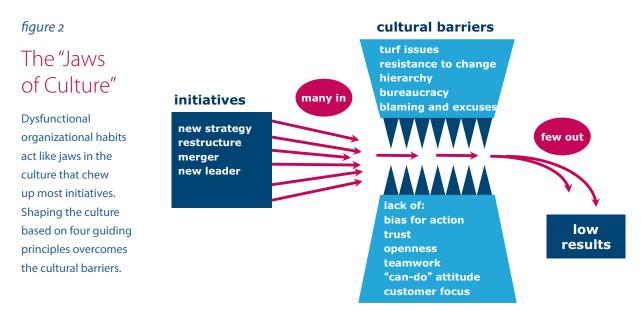
Culture, at its essence, is made of individual thinking, making it necessary for each person to embrace the new culture. From the leader through all levels of the organization, culture change requires a process of impactful insight and personal change.

Pace, momentum and engagement

Cultures typically resist making the changes they most need. In the absence of a conviction to achieve change – as manifest in building pace, momentum, and engagement – existing cultural habits end up overwhelming and limiting the desired change. Reshaping culture is not for the weak hearted – it requires a robust and sustained effort involving all employees.

Focused sustainability

Many factors impact an organization's culture. To sustain the changes, organizations align the key inputs with the desired change. This includes aligning institutional practices, systems, performance drivers, communications and capabilities needed to drive towards the desired culture. It is likely that changes to governance structures and decision making are also necessary. The organization aligns its approach to selecting, developing, paying, promoting, and terminating leaders and people with its new culture. The same is true for daily rituals such as meetings, team-based decision making, and measurement. Lastly, the organization examines customer/consumer and supplier/partner interfaces and, if necessary, adapts them to make the change real.



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These four principles have been essential to guiding the most successful efforts to reshape culture in which we've been involved. Without them, leaders see the "jaws" of culture devour their initiatives and find that good ideas fail to deliver the promised return (*fig 2*).

Leadership capabilities

What types of leaders are required to drive cultural change? The attributes of R&D organizations' leaders must fully reflect the characteristics that their organizations aspire to attain. These organizations need to be:

Agile

Innovation, openness to change (including personal change), and the ability to flex and adjust quickly are the cornerstones of the most effective R&D cultures.

Accountable and collaborative

Leaders have to show accountability for results across organizational boundaries and have a natural bias towards healthy collaboration. The organization needs to display these same qualities internally as well as with outside partners. Creating seamless collaboration with partners is critical to success.

Focused and commercial

Leaders need to create and represent new approaches to supporting projects that work, while quickly closing down those that don't. Too many unsuccessful projects are left to linger. Resource limitations mean both efficacy and commercial implications have to be discovered much earlier in the development process.

Patient focused

The historical focus on patients is a strength that must be maintained. New medicines and vaccines are about making people's lives better. This purposeful focus is reflected in behavior, partnership, and decision making at every touch point.

When leaders confidently, authentically, and sustainably demonstrate these capabilities – in both their behavior and the decisions they make – an R&D organization is much better positioned for success.

Today, R&D leaders possess cultural competencies in ethics, scientific excellence, long-term vision, objectivity, and patient orientation. Going forward, they must build cultural competencies that have not been their strengths historically. These include commercial skills, rigorous focus, creativity and innovation, conceptual thinking, coaching people and building their skills, accountability, natural collaboration, and personal agility. How can organizations bridge the gap? In many cases, organizations will need to acquire new talent. The selection process should include a "culture fit" analysis to ensure a high likelihood that new leaders will be aligned with the desired culture. Because no person will be a perfect match for a culture, on-boarding should include personal development to address the individual mindsets that may impede the desired change.

In addition to talent acquisition, organizations should also develop internal talent. Programs should be developed to provide training on new skills, systems, and policies, as well as specific training to instill the new mindset and culture.

For individuals, the focus should be on education that goes beyond skills and drives insight at the level of personal thinking habits. Each individual will need to become aware of and change long-held habits that are not consistent with the organization's new culture.

Organizations should also design training programs at the team level. The team is where people most often see culture in action. Any effort to reshape culture should be designed around teams as the fundamental work unit. Additionally, champions of the change must be trained and embedded in each of these teams to coach colleagues and monitor and lead the effort.

What's more, cultural change should emphasize improving coordination and collaboration between departments, especially with regard to the drug-discovery division and clinical-development function. The prevailing culture in R&D should encourage the efficient hand-over of assets from one team to another, without infighting and the pursuit of political agendas. Organizations may not be able to achieve seamless interaction between departments, but the principles we have discussed should help to reduce the friction that can impede performance.

Overall, efforts at the organizational level should be guided by the principle of "focused sustainability." All organizational policies, procedures, and programs must be reviewed and, as necessary, revised so that they support the change in culture and approach.

Getting started

Leading cultural change in R&D often requires significant investments in time and effort to put in place the right people, processes, and incentives to implement and sustain the transformation. As an initial "health check" to evaluate the effectiveness of their current capabilities, biopharma executives can consider the following questions:

- Does the organization see the senior R&D team as being aligned on mission, strategy, goals, and priorities?
- Do all senior team members "walk the talk" by living the values for which the organization stands?
- Have we created, communicated, and reinforced a set of core values throughout the organization?
- Do we hire people with attitudes and competencies that support our culture?
- Does our culture foster a willingness and eagerness among our people to lead and embrace change?
- How well do we as a company innovate beyond old solutions and, in an iterative process, rapidly learn from that innovation?

In many cases, answers to these questions will point to major improvement opportunities. An organization may find that it needs to rethink its approach to recruiting and developing leaders in order to make the desired cultural change a reality. Bringing new leaders into the organization is often essential to building capabilities and injecting fresh ideas that promote cultural change. This must be done carefully, however, to ensure that the new executives are well suited to leading cultural change.

Global Life Sciences Practice

60 YEARS IN LEADERSHIP

The global Life Sciences Practice encompasses medical devices, diagnostics, pharmaceuticals and biotechnology. Each of these business sectors is intellectual propertyintensive, with rigorous regulatory and reimbursement oversight.

Our clients operate in dual spheres – science and business – and we have shaped our leadership services around common challenges facing these segments. Industry specialists are located in all major markets worldwide, and possess first-hand knowledge of the criteria for effective leadership in the life sciences industry: innovation, a deep understanding of science and the ability to manage complex projects while maintaining a competitive edge.

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