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R&D leadership in crisis

rebuilding innovation through people

Global Life Sciences Practice

Pharmaceutical Research & Development (R&D) organizations are in the midst of a leadership crisis. Shareholders question the sustainability of the billion dollar blockbuster pharmaceutical model and large cap pharmaceutical companies question their own commitment to internal R&D.

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Executive summary

Pharmaceutical Research & Development (R&D) organizations are in the midst of a leadership crisis. Shareholders question the sustainability of the billion dollar blockbuster pharmaceutical model and large cap pharmaceutical companies question their own commitment to internal R&D. In this research paper, we explore the thoughts and opinions of 150 senior R&D executives across a range of global pharmaceutical companies.

Startlingly, sixty percent of executives would be interested in moving out of R&D. These executives are inundated with multiple tasks and are unable to focus on creating productive innovation cultures. In an industry where innovation is intimately linked to value creation, companies with a de-motivated R&D leadership team are at greater risk of eroding shareholder value. Clearly, today's R&D organizations and

leadership teams are under tremendous pressure to deliver results, however, they must also develop a whole new innovation paradigm, which creates sustainable shareholder value.

We believe that difficult questions must be addressed around the current R&D leadership in place, as well as the profile of the next generation of leaders required to successfully drive this change. In this paper, we will explore these and other questions:

- How should R&D success be defined beyond the "blockbuster" model?
- What are the hallmarks of a successful R&D organization and culture?
How do we compare?
- How do we develop the R&D leaders of tomorrow?

Introduction

A business model in transition

Over the next six years the global pharmaceutical industry expects some US\$133bn worth of branded medicines to be eroded by generic competition in the USA alone. Companies have explored different avenues to mitigate this risk with varying degrees of success. Furthermore, the impact of shrinking public healthcare budgets and falling product approval rates will lead to further pressures and a faster adoption of generic brands. It is widely accepted that the classical pharmaceutical R&D model is under tremendous pressure and is unable to yield as many high-value, reimbursable products as it once did. Political, financial and regulatory changes have all raised the bar with regards to new product approval and reimbursement. As a sustainable pharmaceutical model is yet to be defined let alone operationalized, shareholders continue to demand more return on their investments.

end of the 'golden era' of the pharmaceutical industry, the drugs launched and marketed during this period were discovered and developed during the late 1970s and 1980s.

The commercial successes of the late 1990s led to an intense R&D focus on a few diseases and reduced investment in new disease areas, leaving this high-risk activity to academia and biotech companies. Instead, many companies focused on developing and launching 'me-too' products, to keep pace with competitors. However, a minority did continue to focus on areas of unmet medical need, which is the trend today. Soon governments realized they were paying premium prices for similar new drugs and increased the hurdles for reimbursement. Consequently, the cost of developing a new drug today has soared to over US\$1bn and for many companies their new product pipelines have dried-up and fewer new drugs have been approved by regulators (fig 2).

Pharmaceutical industry performance

At the beginning of this study, we analysed the performance of our sample (31 companies) over the last 20 years relative to other sectors (fig 1). The period between 1991 and 2001 marked a significant growth phase and the

Drug development is getting tougher and longer

Declining R&D output is due to many factors including tougher regulatory requirements, increased payer pressures and difficulties associated with building and sustaining creative and productive R&D organizations.

figure 1

Change in Enterprise Multiples (TEV / EBITDA) from 1991 to 2011

From the Heidrick & Struggles survey sample, S&P 500 and S&P 500 Healthcare Index.

Source: Capital IQ and Heidrick & Struggles analysis

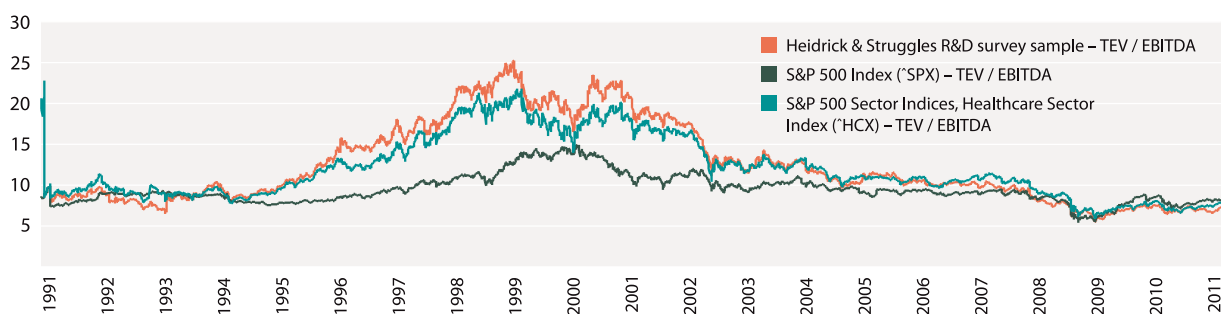
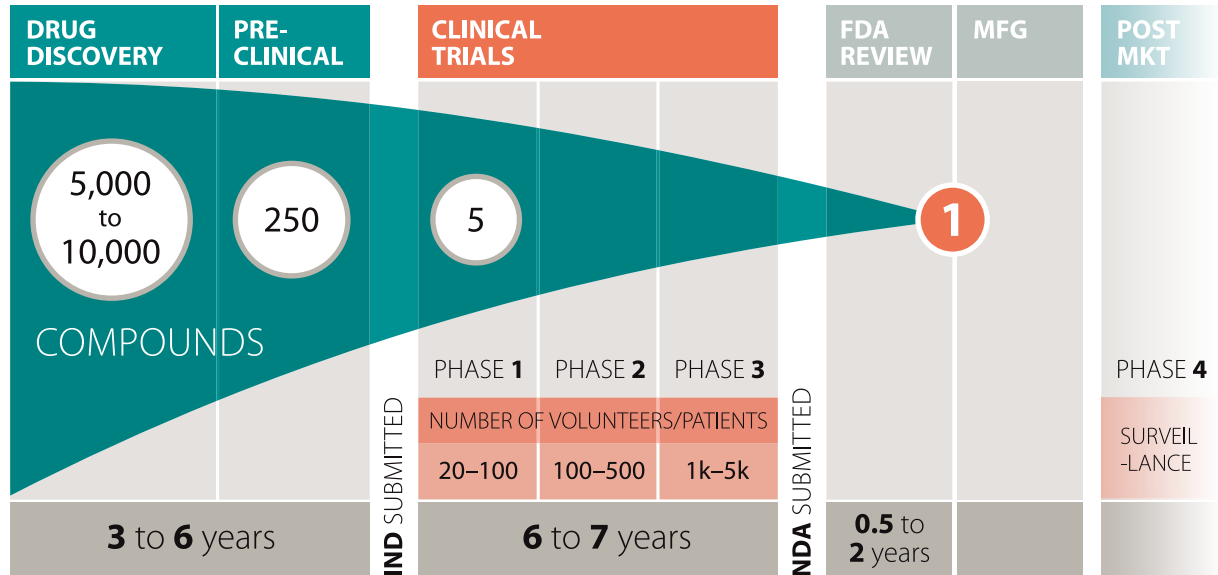


figure 2

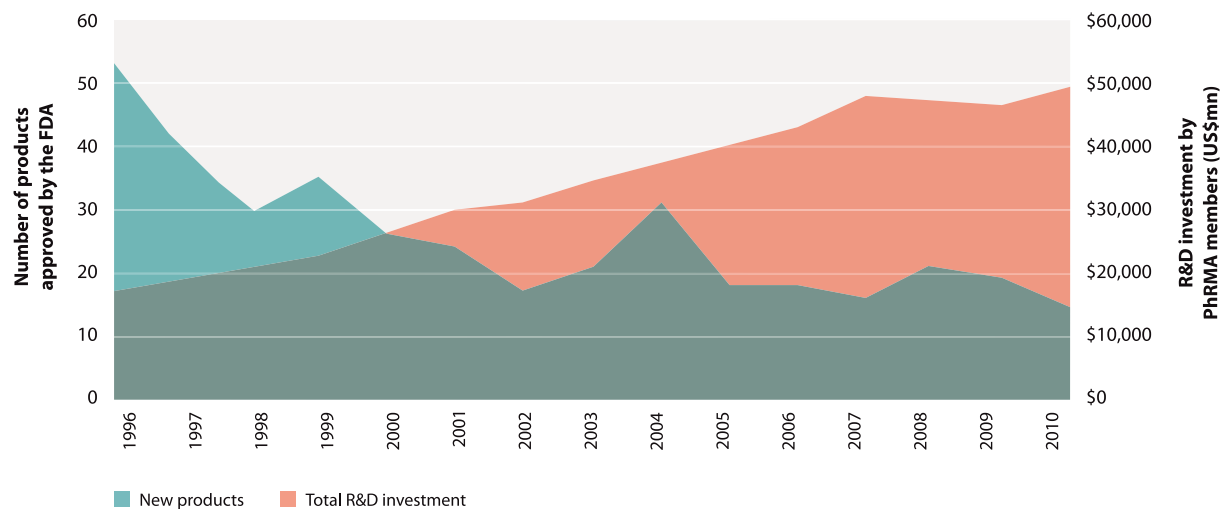
Phases of the R&D pipeline

Only one of every 10,000 potential medicines investigated makes it through the R&D pipeline and is approved for patient use by the Food and Drug Administration (FDA). The average time taken to develop a new drug is 15 years and costs more than US\$1bn. Source: PhRMA



The drug development process

Graph shows declining product approval despite increasing R&D investment. R&D investment figures only include company-financed R&D. Source: PhRMA member survey 2011 and Nature Drug Discovery¹



¹ Mullard, A, Nature Reviews Drug Discovery 10, 82-85 (February 2011)

Our findings

We believe that as the pharmaceutical industry explores different business models to create shareholder value, those who continue to focus on R&D innovation need to ensure they have R&D leadership teams, which are engaged and coordinated to deal with the complexity of this new competitive landscape. Although company strategy is usually set by boards and executive management teams, the execution of R&D strategy falls to senior leadership ranks. We believe and wanted to test whether struggling senior R&D leadership could be a key correlating factor with declining R&D output and ultimately shareholder value, as well as a significant barrier to changing the current paradigm. With this in mind, we surveyed 150 R&D executives across a range of 31 global pharmaceutical companies (*see fig 3 for a breakdown of the Heidrick & Struggles R&D survey sample*).

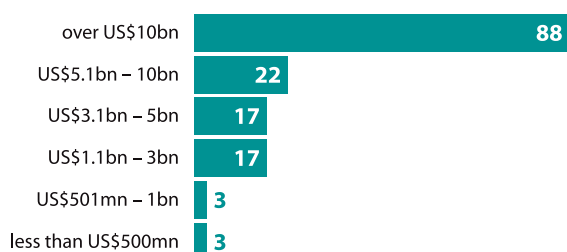
R&D investment is increasing

We expected more companies in our survey to have reduced their R&D investment, following the global economic crisis. In contrast, 43% of respondents stated that the global economic crisis had no impact on their organization's R&D budget in 2010, while 17% saw an increase in R&D expenditure (*fig 4*). This view is also shared by the US Pharmaceutical Manufacturers Association (PhRMA) and Burrill & Company, who found that America's biopharmaceutical research companies invested a record US\$67.4bn in 2010 in the research and development of new medicines and vaccines, an increase of US\$1.5bn from 2009.² However, we should acknowledge that a proportion of these increases may be due to industry consolidation, and we would not be surprised to see R&D budgets fall in the near term.

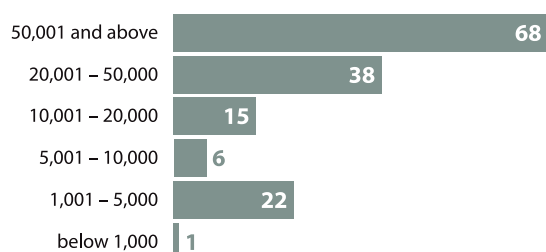
figure 3

Characteristics of companies participating in our survey

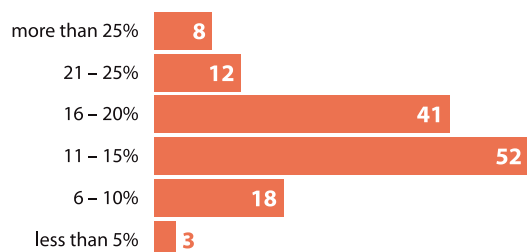
The majority of respondents were at the senior vice president to director level, from large cap pharmaceutical companies with market capitalisations over US\$10bn, located in Western Europe and North America. *Number of respondents from total of 150 survey sampled.*



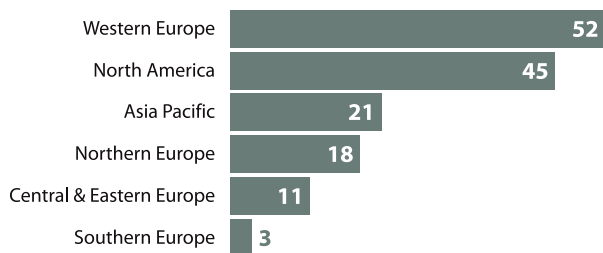
Respondents by global revenue in 2010



Respondents by number of employees



"How much did your company spend on R&D last year?"



"Where are you currently based?"

² www.phrma.org/media/releases/rd-investment-us-biopharmaceutical-companies-reached-record-levels-2010

figure 4

The impact of the Global Financial Crisis on 2010 R&D budgets

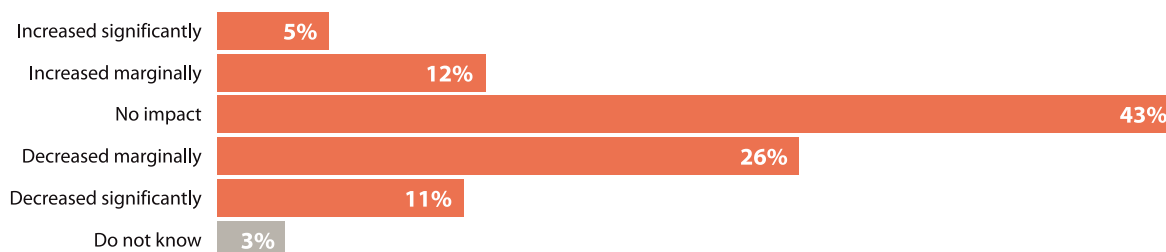
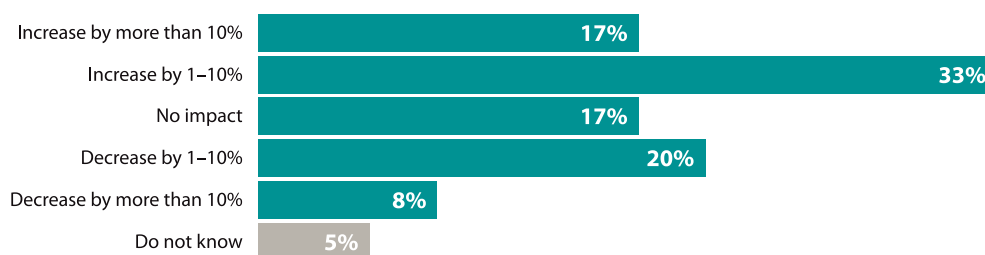


figure 5

Change expected in annual R&D expenditure in the next 2 years (2010 to 2012)



Furthermore, 50% of our survey respondents foresee an increase in their organization's annual R&D expenditure in the next two years (fig 5). In our opinion, the increase in R&D expenditure but decline in the number of new products approved is not sustainable (fig 2). Additionally, the continued availability of R&D funding is likely to present a barrier to changing the current R&D innovation model. Therefore, companies need to address tough questions in order to rebuild or recreate productive R&D organizations.

Organizational reasons for project failure

Beyond the obvious product candidate safety and performance issues, the three major reasons for R&D project failure cited in our survey include a lack of creativity and innovation, the absence of co-ordination between R&D and commercial teams, and the shortage of quality R&D talent (fig 6).

Lack of creativity and innovation

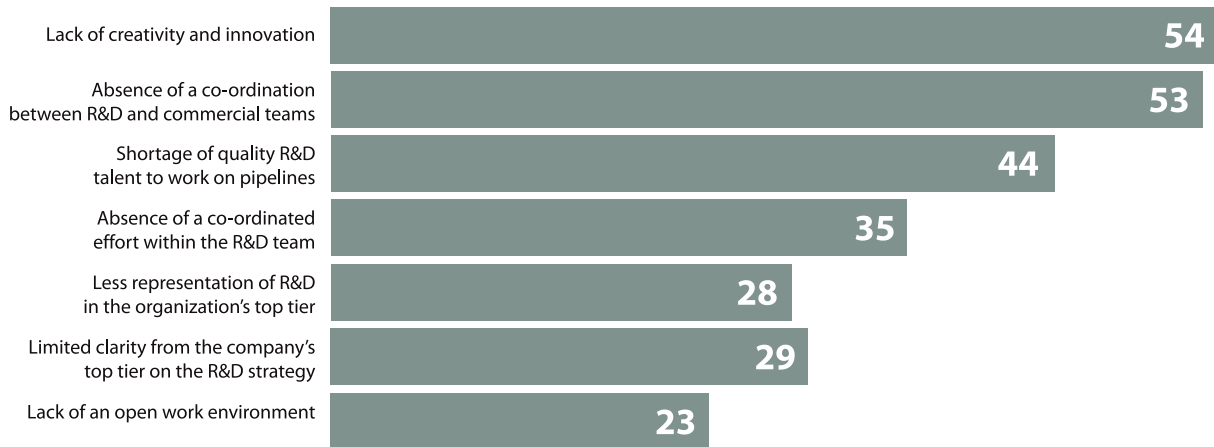
Value creation in the pharmaceutical sector depends on innovation more than any other industry. However, in our opinion, the pharmaceutical industry is mature and the structures, processes and systems in place prefer incremental over step change and more radical innovation.³ For example, the industry has focused on new indications for current molecules as well as making small incremental improvements to the pharmacodynamic and pharmacokinetic properties of a few small molecules to improve dosing regimes and reduce side-effects. The economic benefits of incremental innovation are clear and include: protection from competition; sustained market share; profitability; and dividend payments for shareholders. However, after most of the benefits of the blockbuster model have been reaped, we believe the industry requires leaders who can deal with ambiguity, anticipate and respond to environmental changes, and bring greater impact by going beyond incremental change.

³ Davila, T, Epstein, MJ, Shelton, R, *Making Innovation Work: How to Manage it, Measure it, and Profit from it*, (Prentice Hall, July 2005)

figure 6

Organizational reasons cited for R&D project failure

The graph indicates the number of responses per option, as respondents were allowed to choose more than one option.



“The really successful [R&D] people are slightly anarchistic and try to forge their own pathways...large cap pharma is too process-orientated with too much internal control... this overwhelms individual contribution...”

Former Global Head of R&D

Absence of coordination and collaboration

Alignment and collaboration at the managerial level is essential to ensure R&D clarity (sharing a mutual goal), unity (collaborating across work groups), and agility (adapting quickly to challenges and changes). Unity between R&D and commercial departments becomes even more important during an economic crisis or a time for step changes. For instance, emerging exploratory business units benefit from the revenue generated by exploitative units (e.g. mature product business units). Furthermore, commercial input at a very early stage in the R&D process is critical to ensure products in development are reimbursable and that clinical trials are designed to generate the right data to address future regulatory and reimbursement hurdles. Senior managers need to be able to balance their managerial attention adequately in order to remain flexible and efficient regarding potential opportunities within and beyond their environment.⁴

Shortage of quality R&D talent

The industry is demanding a new breed of R&D leader. For example, scientists who are exceptional ‘drug hunters’ and physicians who can predict and translate future reimbursement requirements into early phase II comparative studies and pivotal trails. These competencies are hard to find in today’s scientists and physicians.

Reasons for this shortfall include:

- Infrequent organizational support to develop the competencies required to create and lead tomorrow’s R&D business (fig 8).
- Decreased retention rates amongst experienced R&D leaders who have demonstrated tangible results across the whole drug development cycle, resulting in an absence of future leaders and role models for the industry. Several of these leaders have migrated to more entrepreneurial biotech environments.
- Financial pressure to cut costs. R&D outsourcing may reduce costs but if managed inappropriately, often results in the opposite effect. Thus creating more complexity and frustration resulting in higher staff attrition and loss of tacit knowledge from the organization.

⁴ Schmitt, A, Probst, G, Tushman, M, “M@n@gement in Times of Economic Crisis: Insights Into Organizational Ambidexterity”, *M@n@gement*, (13, no. 3 (2010): 128-150)

figure 7

The daily challenges faced by R&D leaders

The graph indicates the number of responses per option, as respondents were allowed to choose more than one option.



R&D leaders are losing focus

R&D leaders are inundated with multiple chores and do not have enough time to focus on their core task of developing and motivating creative drug development teams. The top three frustrations shared by R&D leaders in our survey include managing outsourcing, the lack of autonomy to allocate funds and the need to motivate R&D scientists to remain creative (fig 7).

Outsourcing

The pharma industry is embracing outsourcing with an eye on increased profitability, however, outsourced projects can be potentially difficult to manage and a significant source of frustration. For example, some medium-sized pharmaceutical businesses outsource the majority of their toxicology work, whilst this creates short-term cost savings; it can also create a knowledge gap within their own R&D organization, the impact of which some companies are now feeling (fig 7). Adequate technical competence as well as proper coordination and management are required to effectively utilize complicated and long-distance collaborative third-party relationships.

There are, however, a number of successful external new product development organizations. One such example is the Chorus Group, an autonomous division of Lilly Research Laboratories that started in 2002 as an innovative R&D pilot by Eli Lilly. Chorus Group was founded with the intent of transforming the existing drug development

process by designing and implementing a lean approach to generating clinical proof-of-concept (PoC) data as quickly and cost-effectively as possible through the utilization of a more flexible virtual development model. They deal with the complexity of vendor management by using a suite of in-house software tools to track the progress and impact of activities and opinions across multiple levels of the early stage development process.⁵ This can result in early go/no-go-decisions, which would then allow resources to be quickly allocated to higher potential development candidates.

Allocating funds

Drug development is time-consuming, risky and costly. Out of 5,000 to 10,000 tested compounds, only 250 enter preclinical testing, five enter human clinical trials, and one is approved by the Food and Drug Administration.⁶ A new medicine takes an average 10 to 15 years to develop and a cost of between US\$750mn and US\$1bn⁷. Unlike many other innovation driven industries, successful pharmaceutical R&D requires a much longer-term approach, which often leads to multiple challenges and hurdles over time. Consequently, organizations place many necessary restrictions on how funds are allocated in R&D, however, in our survey this created a significant source of frustration for leaders. Highlighting the need for companies to trust and empower cross-functional R&D leadership teams to make financial decisions quickly, and fundamentally improve the quality of interaction between R&D, commercial and corporate finance functions.

⁵ Bonabeau, E, Bodick, N, Armstrong, RW, 'A more rational approach to new-product development', *Harvard Business Review*, (2008 March, 86(3):96-102, 134)

⁶ www.phrma.org/news-media/related-resources/key-industry-factsabout-phrma

⁷ Includes the lost opportunity cost of not having developed another asset

Motivating teams to remain creative

A key frustration shared by many R&D leaders in our survey is the need to motivate scientists to remain creative (fig 7). Pay and promotion, whilst essential, are not enough on their own. Intrinsic rewards are essential, for example: the elation that comes when a new product is approved and fair recognition awarded for success, the clarity people gain when they understand how their contribution fits into the overall strategy and direction of the larger innovation organization; and the satisfaction subordinates feel when they are provided with challenging assignments and responsibility for an entire process or unit of work.

R&D career development

55% of our sample group felt that their organizations only occasionally supported them when it came to developing the competencies required to progress into senior R&D management positions (fig 8).

We believe this result represents an opportunity for organizations to reassess their R&D cultures, define which leadership, behavioral competencies and performance indicators are required at each level and re-examine the talent development processes in place to support the advancement of high-potential and high-performance individuals.

R&D leaders want to explore career opportunities in commercial functions (fig 9). Initially, we viewed this as a worrying trend, signalling that R&D executives perceive their commercial counterparts to possess key decision rights and more attractive career prospects. This further strengthened our view that the current pharmaceutical R&D people strategy is not supportive and aligned with the overall corporate strategy. However, one may argue that R&D leaders want to broaden their impact on their organizations by acquiring new skills and bridge the critical gaps between research, development and commercialisation.

Core leadership and behavioral competencies for leaders

Those who do pursue R&D careers require far more organizational support in acquiring and developing the competencies necessary to be successful in this new and uncertain R&D landscape. In addition to the relevant discovery, translational and clinical technical skills, the following leadership and management behavioral competencies are typically those critical for R&D success:

- **External awareness** – Recognizes trends and events outside the organization, and focuses on the financial, operational and human capital issues that affect performance.

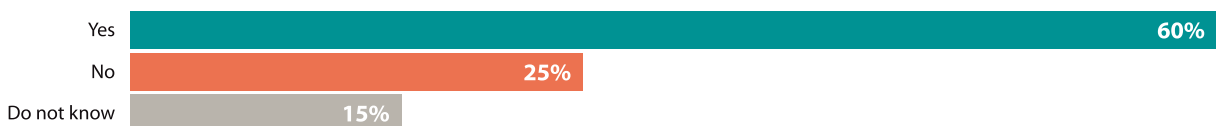
figure 8

How frequently does your organization support R&D leaders by helping them develop the competencies required to progress into senior R&D management positions?



figure 9

Would you be interested in moving out of R&D and into a commercial role in your organization?



- **Customer orientation** – Demonstrates knowledge and insights of internal and external customers and acts to fulfil their businesses needs and exceed their expectations.
- **Visionary leadership** – Creates and communicates a clear and compelling view for the future of the research and/or development organization.
- **Organizational buy-in** – Effectively builds commitment and excitement, winning support and resources for R&D initiatives at multiple levels both inside and outside the organization.
- **Relationship building** – Forms networks of positive business relationships that enhance personal and business success, essential for developing externalized R&D programmes.
- **Delegating and empowering** – Shares the responsibility for decision-making, ensuring the process is delegated to the lowest and optimal level of the organization; is “hands-on” when appropriate; and allows the people who share the responsibility to have the authority, support and resources they need to be successful.
- **Decisiveness** – Makes decisions in a proactive, timely way, essential when deciding which projects to promote or terminate.

These core competencies should be regularly reviewed, aligned with corporate strategies and optimized for different cultures and positions within R&D organizations (fig 10).

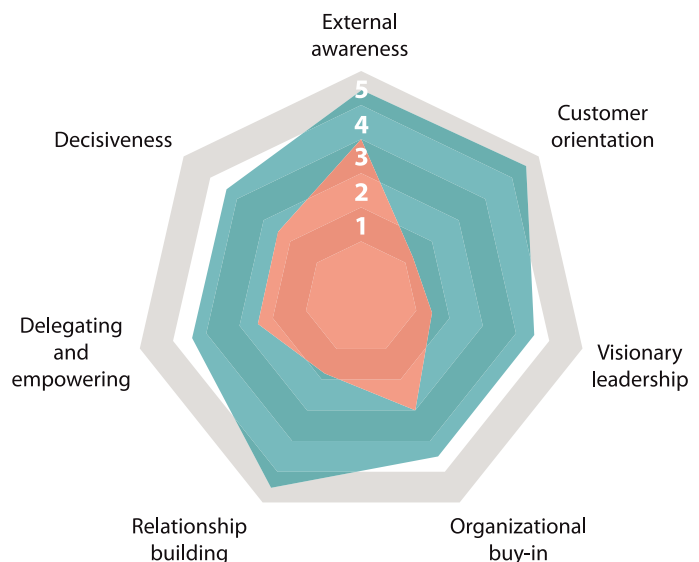
figure 10

An assessment of the core competencies for R&D leaders today and tomorrow

The scale ascends from 0 (low) to 5 (high), where 3 is equivalent to ‘competitive’ and 5 would be ‘market-leading’.

Source: Heidrick & Struggles research

- Today
- Tomorrow



Internal talent development

Companies need to focus on retaining and developing their R&D leaders of tomorrow, understanding that the number of R&D leaders, with the ‘ideal’ competency profile, is few and far between. An important hallmark of successful organizations is how they manage their leadership talent pipeline. Top organizations are adept at creating a talent strategy that aligns corporate priorities with stretching career goals and key performance indicators for their leaders. They create a workplace that supports the desires, needs and aspirations of their people and ensures clarity of career path and fairness of compensation and rewards. To ensure companies are developing and retaining the right R&D leadership, tough questions need to be addressed:

- How successful have we been at developing R&D leaders?
- How do our R&D leadership teams compare against the industry?
- What do our R&D leaders need to be successful in our organization today?
- How will these requirements change as our strategy evolves?

External talent acquisition

Organizations frequently hire talent externally from ‘successful companies’ with different business and innovation models in the belief that these individuals will replicate success in their own organizations. Recent research indicates that star employees appear to be heavily dependent on their former firms’ general and proprietary resources, organizational cultures, networks, and colleagues.⁸ However, there are exceptions, such as ‘stars’ that move with their teams and stars who switch to better firms. Female stars also perform better after changing jobs than their male counterparts do. Frequently, this approach works, however, sometimes the cultural fit between company and candidate is sub-optimal. Nevertheless, organizations can help mitigate the risk of senior executive failure by understanding the non-portable human capital factors that make their employees successful. Then integrate these insights into appropriate onboarding or accelerated transition programs to reduce the time it takes for an executive to adapt emotionally and intellectually to a new environment.

Therefore, key questions you should consider are:

- How successful are we at integrating new hires, ongoing career development and succession planning?
- Why are senior executives successful in our organization?
- Why do some senior executives fail in our organization?
- How can we mitigate the risk of senior executive failure?

Conclusion

There will always be a demand for innovative medicines. However, the cost of developing a single new drug is in excess of US\$1bn and new product approval rates are falling. Pharmaceutical R&D organizations are in the midst of a leadership crisis. Many scientists and physicians would consider leaving R&D and moving into commercial functions. Those that do remain are not always supported to acquire the skills and competencies required to be successful. Beyond uncertain career development prospects, R&D leaders are further frustrated by outsourcing, a lack of autonomy to allocate funds and the challenges of maintaining a motivated workforce. Critically, companies that fail to align R&D teams with colleagues in commercial functions will not succeed in this new environment.

The interventions required to address many of the issues raised in this study can only be achieved through thoughtful cultural change, internal leadership development and thoughtful external hiring. However, there are not enough R&D leaders in the industry with the right blend of skills to drive this level of change. Companies need to ensure their corporate objectives are underpinned by a rigorous R&D people strategy that balances internal development with external hiring and top team development. Furthermore, a thorough understanding of the non-portable human capital factors that enable people to be successful will enable companies to strengthen the power of their own employer brand and make the right external hiring choices. Clearly, the healthcare industry is in a state of flux and the only constant is the continual need for commercially astute and visionary R&D leaders to create innovation cultures capable of delivering long-term sustainable shareholder value. ■

⁸ Groysberg, B, *Chasing Stars: The Myth of Talent and the Portability of Performance*, (Princeton University Press, 2010)

Life Sciences Practice

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