Maximizing Speed to Market by EMPOWERING THE HUMAN ELEMENT

nder greater public scrutiny in an increasingly environmentally conscious world, Dow Chemical launched a new advertising campaign in 2008 to demystify the people behind the science of the products it developed. This award-winning campaign, called "the Human Element," featured stunning photos of people, rather than a detailed narrative of the many features and benefits of the company's products. Appealing to scientific minds, the campaign even introduced a new abbreviation for the Periodic Table of Elements to signify the importance of the people behind the chemistry working together: "Hu."

Today's pharmaceutical industry also is under public scrutiny, though for different reasons. Consider, first, that over the next year, according to EvaluatePharma, patents for drugs worth \$29 billion in annual sales will expire. Of those total sales, about 70% will be picked up by generics. By many accounts, the billion-dollar drugs will be unseated by generic drugs whose efficacy is every bit as strong but whose prices are significantly lower, an issue of exponential importance given changes resulting from the Affordable Care Act.

In addition to external challenges, pharma companies also must wrestle with internal constraints to accelerate the pace with which they bring new drugs to market. Cost-containment strategies — not to mention, the allocation of greater resources to marketing and advertising than product development — mean that companies need to explore creative paths to research and development; in many cases, larger pharmas will pursue strategic partnerships with smaller, more agile research organizations. If the company does not seek a strategic partnership, it still must identify opportunities to unleash the full, unfettered potential of the teams working to bring a new



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drug to market. Either way, at the heart of the opportunity are the people tasked with bringing it to fruition.

Identifying and Potentiating the Critical Factors for Success

Invoking the Dow Chemical ad, never before has an industry focus on "the human element" been more essential than it is for the pharmaceutical industry today. Central to all product development, be it in-house or with a strategic partner, exist teams composed of people who may or may not be predisposed to new ways of thinking and acting. The key to accelerating innovative thinking and product development lies in establishing a new frame-



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work for breakthrough performance that removes real and imagined barriers so the teams can work to their fullest, most creative potential.

Creating a Breakthrough Mindset

Real breakthrough performance starts with getting teams to work together effectively by identifying assumptions, unhooking themselves from those deeply held beliefs, and creating a new and shared vision forward. Individuals always will bring past experiences and personal biases — both good and bad — to current projects. These experiences actually can limit performance if subjectivity and predisposed opinions of the team or the process take on greater impor-



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tance than a shared vision of possible achievement.

Establish Trust and Potent Relationships

The relationship the team forms is the foundation for the results it produces, so trust is critical. We believe trust to a large extent is predicated on each party paying attention to and honoring their commitments and concerns. While each party may have different intermediate goals they are producing, each party must share the same end goal and understand each other's boundaries. After these background drivers are surfaced and addressed, the next most critical step is to agree upon the end state — and the structure to get there.

Ensure Strong, Decisive and Inspirational Leadership

Leadership is vital to any organization, and its importance is amplified when there is a critical business imperative such as accelerating a clinical trial to deliver breakthrough products. To produce a breakthrough, all team members must consider themselves to be "inspirational" leaders, "breathing life" into the product. The job of team leaders, who do not accept business as usual thinking and behavior, is to ensure that each team member brings his or her best to the project.

Align on the Desired Outcomes

As part of this important fundamental step, our methodology includes a time investment in coaching teams to identify and internalize the possibilities of partnership — that is, what partnership and teamwork look like for each team member (each, with his or her own "way of doing things"). What does the future look like for this trial? Who can they be together, and what possibilities can they envision? What difference will this drug make in patients' lives? This step is so critical, though it sounds so easy, because it means checking an individual and functional mentality at the door.

Provide Disciplined Project Management

Next, the team is tasked to create structures for how it will work together. This includes frequency of meetings, the process for communicating progress to all involved constituencies, and clear operating principles for how people will work together. Every person on the team is accountable for keeping commitments, for accountability and reliability, and for communicating early if a promise cannot be delivered. In essence, this step is designed to underscore the importance of integrity to the process in order to keep the team working to its fullest potential. Three important steps comprise disciplined project management:

1. Agreement on governance and decision rights.

The team must align on project governance. That is, who will make key decisions and at what points in the process? Who needs to be consulted regarding which decisions. How will these responsibilities be communicated to the team, and back to the respective organizations, so there are no gray areas? Clarity at the beginning of the working relationship is critical to avoid downstream finger-pointing, which slows the process and damages the relationship.

2. Cultivate a shared focus.

It is important to recognize that people who work on these types of projects bring with them a set of experiences that tell them exactly how all the different functional areas should operate, as well as what's possible and what's impossible. Some on the team may believe, for example, that a certain functional area "always works too slowly" and can "never make decisions" or "will never take big risks." These types of predetermined views of capabilities represent the greatest limiting factor to breakthrough performance, which is why we place such an emphasis on the initial relationshipbuilding process. Creativity cannot thrive in an environment riddled with interpretation and mythology that may no longer be applicable. That's why it's imperative to put these preconceptions to the test at the beginning of the project, and then deconstruct them to cultivate a shared culture focused on breakthrough performance.

3. Engage key stakeholders to gain buy in and alignment to the team's goal.

After the kick-off meeting, the cross-functional team must begin to create a plan to engage all key stakeholders so everyone is clear the project goals and timelines. This step is vital to mobilizing the "human element" and critical to the project's success. Managing the essential constituencies is vital for the project's success. We believe that people produce results correlated to what they see as possible. If they are naturally inspired by and engaged with the project vision, plan, targets and goals, the success of the project is on track. Inevitably, there are some team members who are not engaged or who have concerns about the project goals. Ensuring these stakeholders' concerns are heard is a necessary part of the process; it cannot be brushed under the rug. If someone can authentically listen to another's concerns, they naturally begin to engage with the team's commitment.

The Art of the Science

Regardless of the brilliant science that sits behind a new and potentially breakthrough drug, the most critical element to accelerating the clinical trial process is the human one. It is important to diagnose and treat the root causes of the problem, not just the symptoms, so that healthier teams result. The more confidently and effectively that teams work together, the higher the probability that the clinical trial will be successful and that the pharmaceutical company can move forward to regulatory approval and product launch. It's not an ephemeral concept that once outlined in a strategic plan, can be cast aside as the teams return to "business as usual."

With numerous case studies to support this path to breakthrough performance, we know that the people working on these initiatives must bring the same rigor they apply to science to the manner in which they work with one another. It is a discipline — and for some a new experience — but a proven and repeatable discipline that once mastered, can transform a pharmaceutical company so it can bring products to market faster and thus, positively enhance its bottom line.

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