

The Softer Side of R&D

An increasingly global environment for drug development is **CHANGING HOW TEAMS WORK TOGETHER**. Research and development leaders will need to hone their skills for managing people across cultures and across teams.

Just as the world of pharmaceutical research and development is changing, so too are the training and educational needs of professionals involved in R&D. The challenges faced by a global industry that increasingly partners with outside research teams require managers and leaders to have a whole new set of skills and competencies.

Industry experts say the technical competencies of drug development have to be combined with the softer skills of change management and leadership ability. R&D leaders will have to work in global teams to manage the output from their partners. This will require highly trained technical specialists who have strong interpersonal and communications skills.

Working in multicultural, multidisciplinary teams, experts say, makes leadership development even more critical since companies have to motivate a group of people to work together and be focused in the same direction as a dedicated resource to solving a problem.

Last year, Heidrick & Struggles and the Economist Intelligence Unit published a Global Talent Index that evaluated the current state of global talent. The survey found that very few companies across many industries have highly effective teams at the top.

“A true team works cooperatively, shares information immediately, knows how to communicate with each other, and knows how to solve problems as a group,” says Mike Laddin, president of LeaderPoint. “It’s up to the leader to build that team by providing clarity about what’s important and what needs to be accomplished and how progress is going to be measured.”

As the world in general, and drug development in particular, becomes more global, it will be important for managers to understand not just how to communicate and collaborate with people in the business sense but how to collaborate and communicate in a cultural sense as well, says Daniel Hiltz, Ph.D., director of global learning and development at Kendle.

“This is an important part of employee engagement, which is a big issue,” he says. “We know that employee engagement is tied to employee satisfaction and employee retention. We know this is a big issue in the United States and suspect this is probably the case in other countries as well.”

Terri Cooper, Ph.D., principal in the life-sciences practice of Deloitte, says the demand for highly qualified leaders in the research arena will only increase.

“Ultimately, one of the biggest challenges companies have right now is their ability to increase



New global leaders **MUST HAVE VERY SPECIFIC COMPETENCIES.**

Heidrick & Struggles

the productivity of clinical programs," she says. "Many of the large pharmaceutical companies are trying to expedite their clinical programs. Unless they can effectively manage external resources and can find highly trained individuals who can run their programs, they're not going to realize the productivity gains they're looking for."

The risks and the challenges that researchers face are large but these can be addressed by effective leadership, says Fred Hausheer, M.D., CEO of BioNumerik Pharmaceuticals.

"The strongest people who work in research — the ones who persevere — are the ones who are interested in solving development problems for the good of patients," Dr. Hausheer says. "The complexity of the problems is increasing very rapidly. We've had an explosion of technology that relates to the human genome and potential genes that can be targeted by drug therapies, by monoclonal antibodies, and by vaccines. The only way challenges of this magnitude can be solved is by leadership."

Such opportunities, he says, are creating a need and demand for those in research who can lead and who can develop future leaders.

"The best leaders are team builders, and they also develop more leaders,"

Dr. Hausheer says. "At the same time, they work on growing the people in the group to become better leaders."

Research organizations are looking at what their core competencies are, as well as what they need from an educational perspective to help people understand the softer side of leadership, such as change management and working effectively in teams, says Tim Bray, VP of global learning and development at Quintiles Transnational.

"The difference between someone who is good technically and someone who is an outstanding leader usually has to do with the softer leadership skills in terms of their ability to influence others and problem solve effectively with groups of people," he says.

Experts say, in general, the training and development of future R&D leaders is inconsistent and scattered. While many companies are putting in place learning opportunities, often missing is the recognition that leadership development is something that happens over time.

"I distinguish between training and development," Mr. Laddin says. "Training is an event. Development is a process that is often life long. Oftentimes as a Band Aid, we put in place a training event and hope people get it. People learn to lead by leading over time and by being placed in a variety of situations."

According to a recent ESI International survey conducted across 12 different industries, the skill gaps include critical thinking, strategic thinking, innovative or creative thinking, tactical thinking, and analytical thinking.

"Another gap identified was a lack of business acumen, being able to connect work, whatever it may be, to the larger picture and aligning with organization goals, strategies, and objectives," says Julie Zinn, executive director of project management and the business skills program at ESI International. "Another big skill gap was communication know how."

Working in **TEAMS**

Dr. Cooper says the outsourcing of clinical trial programs has changed the roles of many individuals within research and development.

"We are observing that the individuals who were accustomed to running study programs and managing their own internal CRAs are lacking the skills to manage an external CRO or other service provider," she says. "It is a challenge for individuals to manage these external partners. Quite often there seems to be a lack of trust and the contracts are not set up accordingly. So rather than actually realizing the benefits of outsourcing, what often happens is that there is a huge duplication of effort because the roles and the responsibilities



JEANMARIE MARKHAM Clinlogix

The burden for training those in research is falling to the community colleges and the universities, and maybe that is where it belongs in each community.

have not been clearly defined. As a result, the internal clinical development team will redo much of the work of the CRO."

From a training perspective, she says, there needs to be a great deal more instruction around contract negotiations, working in collaboration with external parties, and having people manage and report on the deliveries expected from an external party.

Alice Jackson, CEO and founder of Lifetree Clinical Research, says the ability to work in teams is critical.

"People have to work in teams, not just within their own companies but also with clients and third-party suppliers, such as labs, medical writers, and so on," she says. "Putting together a budget and negotiating with pharmaceutical companies are challenges."

Bev Hudson, VP and general manager of the research services group at Medpoint Communications, says managing a team requires a

high level of skills especially for complex project management.

“Most sponsors and CROs are looking for people who can execute projects with a high degree of expertise and be able to manage and lead teams in an environment that can change quickly,” she says.

Business success at the top (and further down the organization) DEPENDS ON THE LEADER PULLING EFFECTIVE TEAMS TOGETHER.

Heidrick & Struggles

Skills for *LEADERSHIP*

Researchers need to be able translate what happens in the clinic for senior management. They have to understand the technical details, as well as the language of business. They have to be able to help develop a business strategy and then be able to translate that to the objectives of the research organization.

“Managers often assume that as individuals progress in their careers, these types of skills

are automatically developed,” Ms. Zinn says. “We take thinking for granted. We take communicating for granted because we do those things all day long. These are soft skills, yes, but they are often the hardest things that we do. These skills can be developed if they are taught in a tangible ‘hard’ way. It’s important that we provide individuals with a structure and an approach to develop these skills.”

Research organizations are beginning to recognize the need to address these types of leadership skills.

Quintiles, for example, is working with CRAs to help them to be able to influence the physician or the staff to change something in the process to make sure that the study has quality outcomes.

“Frequently when I talk to line managers who manage clinical research associates, they will tell me the difference between an average CRA and a superior CRA is their ability to influence people to change something in the process to achieve better outcomes,” Mr. Bray says.

He says Quintiles is beginning to realize an impact from its program.

“While interpersonal skills are tough to measure, we do see some positive outcomes with our project managers,” he says. “What customers value about project managers is



MIKE LADDIN LeaderPoint

The leadership training that skilled technical professionals receive now is at best inconsistent and scattered.

their timeliness and accessibility, as well as their proactivity when issues arise. We see a strong correlation between engaged employees and loyal customers.”

Kendle breaks its training programs into two different groups. There is a series of clinical topics and a series of management and leadership topics.

On the clinical side, the company has curricula for project assistants, for various levels of CRAs and for project leaders, as well as additional programs for global megatrial project leaders.

The company also put in place a program, called Leadership 100, in May 2007 for senior level managers to help people at each stage of their leadership career.

“We have a series of events that are scheduled on a monthly basis,” Dr. Hiltz says. “The message is that leaders are people who drive change. We’re trying to make sure our leadership understands that it’s their role to make things change. Skills are related to a set of competencies and a set of behaviors that have been mapped and identified in academic settings. We believe that by identifying the behaviors around leadership, people can be taught to lead more effectively.”

For 2008, Dr. Hiltz says Kendle is developing a comprehensive measurement and evaluation strategy to assess the impact of the Leadership 100 program.

“Our orientation in 2008 is going to be based on action-learning concepts; there will

Essential Characteristics for a *GLOBAL LEADER*

The complexity, pace, and global platform of today’s business environment demands a special set of characteristics. Apart from heightened requirements in terms of background and experience, the leadership criteria have changed dramatically over the past 10 years. There is now no substitute for global leadership experience. But when looking at the global talent index and the concentration of talent across the globe, one key question emerges: how can one better assess the global leadership capabilities of the various talent pools?

FROM A SEARCH CONSULTANT’S POINT OF VIEW THESE ARE THE ESSENTIAL CHARACTERISTICS TO LOOK FOR IN THE NEW GLOBAL LEADER:

INTERNATIONAL LITERACY

- Operating in different geographic regions
- Understanding the cultural differences of employees and customers
- Dealing with ambiguity
- Enjoying diversity in a psychological sense

MANAGING PARADOXES

- Taking a helicopter-view and thinking strategically while keeping the focus on operational results
- Switching easily between different modes: from long-term thinking to short-term, and from cost saving to expansion and growth

Having the flexibility to handle these potential paradoxes is the key characteristic of future top executives.

Source: Heidrick & Struggles Global Talent Index, Chicago. For more information, visit heidrick.com.



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BEV HUDSON Medpoint Communications

With more complex and global clinical trials, there is a greater need to test and document whether the training was effective.

be specific deliverables that the teams within the Leadership 100 will be expected to deliver on," he says.

Ms. Zinn cautions, however, that before implementing any training, senior management has to align resources with job requirements and what needs to be accomplished.

"We recommend that some type of assessment occurs so managers can evaluate the current state of their workforce, as well as assess the competencies that are required to help an organization succeed," she says.

Distance **LEARNING**

The Internet and other alternatives to traditional classrooms have opened up a new world for training. Technologies such as Webcasts, Podcasts, and Web 2.0 social networking continue to shape how and when people want to receiving training.

"Global workforces and projects have sponsors as well as clinical service providers thinking about how to extend training to more peo-



JULIE ZINN ESI International

As companies begin partnering or outsourcing across the ocean, it's even more important to have effective communications skills.



DR. DANIEL HILTZ Kendle

We distinguish between management and leadership. The role of a leader is to create new processes and to make changes to existing processes to adapt to the evolving world of clinical research.

ple around the world for longer periods of time," Ms. Hudson says.

"We're in the midst of a culture change, moving from what was predominantly a face-to-face learning environment to a distance learning environment," Dr. Hiltz says. "We have found that classes that follow the principles of sound instructional design of adult learning theory adapt well to the virtual classroom environment and they are well liked."

Quintiles has a global learning management system that offers a combination of 650 technical courses available through either classroom instruction or e-learning and an additional 2,500 soft skills programs available through e-learning. Quintiles has found some success using Podcasting as a learning technique; this allows clinical team leaders to provide up-to-date information to all members of the team.

"We find that the clinical monitoring audience tends to be fairly young," Mr. Bray says. "Many grew up with video games and are part of the iPod generation. They want programs that are more flexible where they do not have to sit in front of a computer system."

Experts, however, caution that classroom training is still important, especially for developing soft skills.

"There are some skills that are better

learned in a face-to-face environment," Ms. Zinn says. "It's important that groups still go through a problem-solving process and see the way the group interacts. This is a good way to generate ideas and evaluate group dynamics."

Partnering for **TRAINING**

Pharmaceutical companies, says JeanMarie Markham, CEO and president of Clinlogix, no longer have formal in-house training programs.

"Training is left to the individual," she says. "People tend to look to organizations such as ACRP and other associations and professional organizations that provide training and education. There also are more universities that are entering into the field. Some of the training burden is starting to fall to the universities and community colleges, and maybe that is where it belongs."

Experts say graduate certificate programs — such as the one recently launched by Northwestern University in clinical research and regulatory administration — have value.

"There are more of these types of programs because clinical trials have become more complex," Ms. Hudson says. "These programs help move different professions forward, they identify best practices, and they emphasize safety.

More than 40% of Deloitte survey respondents BELIEVE THAT RECRUITING AND RETAINING TOP MANAGERS AND SCIENTISTS IS A KEY STRATEGY FOR SUCCESS.

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From a training perspective, there has to be more skill development around contract negotiations, working in collaboration with external parties, and managing and reporting the deliveries from external parties.



DR. TERRI COOPER Deloitte

Overall, they raise the bar. A mix of academic and on-the-job training is highly desired.”

Universities help bridge the academic world of research and the world of business so that companies get the latest and the best thinking to run their operations, Dr. Hiltz says.

Kendle, he says, has a collaboration with the University of Cincinnati.

“Every year, we sponsor two of our employees as scholarship participants in the university’s program, which is a master of science degree in pharmaceutical sciences with a drug development specialization,” he says.



ALICE JACKSON WITH WAYNE CROFT, Executive Director of Clinical Operations, at Lifetree Clinical Research

There has been very little education offered on an undergraduate or graduate level in pharmaceutical research. We end up training people on the job and that takes a lot of time, money, and effort.

“In addition to that, the university offers a certificate program in clinical research, and we have brought those classes in house so our employees can attend classes in our facility and get credit toward a University of Cincinnati clinical research certificate. We view this

as a great way to help ourselves and our employees.” ♦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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