BY KIM RIBBINK

# Stepping Up to Challenges

For every idea and opinion, there are contrary points of view; this give and take is what feeds innovation, propels scientific thinking and discovery, and creates rounded, well-adjusted teams and companies. It's a perspective that Theresa Kane Musser embraces. She is a true advocate for teamwork, diversity of ideas, and volunteerism. These traits are what make her a smart, compassionate, and balanced leader and mentor.

"One of the keys to leading people is developing and sharing visions, getting people to see what the future might be, and then enabling them to figure out ways that they can make their goals happen," Ms. Kane Musser says.

It's that willingness to embrace diversity and share ideas that has encouraged Ms. Kane Musser to devote so much of her time to volunteerism — whether it's in the local community contributing to schools or with her long-term commitment to the Drug Information Association (DIA). (For more information on Ms. Kane Musser's role as president of the

# across the board

***Theresa Kane Musser*** believes life is multifaceted and that success and happiness come from a rewarding job, teamwork, voluntary pursuits, and devoting time to family.

THIS ROUNDED APPROACH TO WORK AND LIFE HAS MADE MS. KANE MUSSER A CONSIDERATE MANAGER, A THOUGHTFUL MENTOR, AND A DEDICATED PROFESSIONAL.

DIA and where the organization is headed, please turn to page 58.)

"I'm in a position where I can give back to others," she says. "But whatever I've done, I've always gotten back so much more. Volunteering and being involved in different organizations provides an opportunity to meet many different people and hear a diversity of ideas. These experiences have helped me realize that there's more than one side to things and that there are broader perspectives to consider when working on solutions."

That she cares about the opinions and ideas of others is strongly evident, and it is this quality that encourages others to open up and contribute to the successful outcome of the company, organization, or community group.

"Early in my working life, I learned the importance of making people feel wanted and motivated," Ms. Kane Musser says. "It's important to make people feel as though they are part of something big and that what they do on a day-to-day basis contributes to the goals or mission of the organization."

The DIA certainly understands and appreciates that trait, having named her DIA president for 2004-2005, as does her employer, Rigel Pharmaceuticals Inc., where her position as executive director of development operations involves managing cross-functional teams on many projects, problem solving, identifying constraints, and resolving conflicts. It also gives her an opportunity to mentor her young staff.

Rigel is a clinical-stage, drug-development company that discovers and develops novel, small-molecule drugs for the treatment of inflammatory diseases, cancer, and viral diseases. The company's research focuses on intracellular signaling pathways and related targets that are critical to disease mechanisms.

The company's lead product candidate, R788, completed Phase I clinical trials in 2005. It is a syk kinase inhibitor, which Rigel is developing for rheumatoid arthritis and for another autoimmune disease called idiopathic thrombocytopenic purpura (ITP).

"At Rigel, I have a small group of people who report to me, and they're all young, competent, intelligent people," she says. "I'm enjoying mentoring them and creating opportunities for them to learn more about project management, clinical operations, and regulatory document publishing."

She believes mentoring is one way to give back to the industry.

"The best way to repay the people who have mentored me in my career is to mentor others," she says.

Ms. Kane Musser believes the best management happens by walking around the different departments and having direct communication with the cross-functional development teams.

"I like the sense of being involved in all aspects of the process and being able to talk with all the different people who are involved in drug development," she says.

The value of that interaction was made clear to Ms. Kane Musser during her previous position at Genentech.

"A project manager, who previously had been in the lab several years earlier, told me that I was one of her role models because I would go into the lab to visit the scientists and speak with them," she says. "That feedback really made me feel as though I was making a difference."

## *A Learning Curve*

Drawn to physiology and how the body works, Ms. Kane Musser decided to study biology at college. Today, she finds she is able to use her chemistry and molecular biology background within development operations; more significant for her, however, is the process of learning and discovering.

"A university is a good place to realize that there's always something to learn, and one of the things that makes life fun and interesting is wanting to be in learning situations," she says. "For me, there is a constant quest for knowledge."

Ms. Kane Musser has not shied away from taking on jobs that are a means to an end and throwing herself into doing them well. She was the first member of her family to graduate from college, and paid her way by working at the campus coffee shop, which she eventually ended up managing.

She also worked as a supervisor in a laboratory while her husband completed his post-doctoral degree. It was, she says, an opportunity to put her biology background into practice and to further advance her skills in managing and supervising people.

Career success is not something that happens overnight, Ms. Kane Musser recognizes. After moving to the East coast in the early 1980s, Ms. Kane Musser had set her sights on working for what was then SmithKline Beecham because she was inspired by the innovation coming out of the company.

"I also was inspired by the company's social commitment to the Philadelphia area, and I was so eager to work for SmithKline that I took a temporary position just to get a foot in the door," she says.

Having garnered experience in clinical operations at a number of levels — as a clinical research assistant, as a scientist working on clinical-trial protocols, and as part of the worldwide clinical-investigation team — Ms. Kane Musser's goal was to become a project manager. She worked with her manager and took a lateral step into a job that would enhance her skills.

She attributes her success to persistence and learning what the job, any job, entails — management expectations, skill sets, and experience. This is a lesson that Ms. Kane Musser has taken with her throughout her career.

"Often, people believe that if they're not being promoted or moved to the next level, then they're not doing well," she says. "I've learned in my career that sometimes if one doesn't have all of the skills for a particular position it's best to take a lateral move. There's nothing wrong with this strategy; it allows one to develop the skills necessary to move up to the next level."

One of the most rewarding experiences in her job at SmithKline was an opportunity to work with an international team to conduct a Phase III study in congestive heart failure for fenoldopam, a drug that is now on the market to treat severe hypertension.

"Back in 1984-1985, conducting large international clinical trials was a fairly new concept," Ms. Kane Musser says. "We conducted the study in more than 10 countries and enrolled 1,000 patients, and back then a

## *Careful Progression*

**THERESA KANE MUSSER – RESUME**

**OCTOBER 2002 – PRESENT.** Executive Director, Development Operations, Rigel Pharmaceuticals Inc., South San Francisco, Calif.

**MAY 2001 – OCTOBER 2002.** Director, Clinical Business Operations, Genentech Inc., South San Francisco, Calif.

**MAY 2000 – MAY 2001.** Director, Clinical Operations, Genentech Inc., South San Francisco, Calif.

**JANUARY 1999 – MAY 2000.** Director, Commercial Operations Planning, Genentech Inc., South San Francisco, Calif.

**OCTOBER 1995 – JANUARY 1999.** Associate Director, Project Management, Genentech Inc., South San Francisco, Calif.

**JANUARY 1994 – OCTOBER 1995.** Clinical Project Manager, Genentech Inc., South San Francisco, Calif.

**AUGUST 1991 – JANUARY 1994.** Project Manager, Genentech Inc., South San Francisco, Calif.

**1989 – JULY 1991.** Project Manager, SmithKline Beecham Pharmaceuticals (now GlaxoSmithKline), Philadelphia

**1987 – 1989.** Associate Senior Investigator, Worldwide Clinical Investigation, SmithKline Beecham Pharmaceuticals, Philadelphia

**1984 – 1987.** Scientist/Senior Scientist, Worldwide Protocol & Forms Management, SmithKline Beecham Pharmaceuticals, Philadelphia

**1983 – 1984.** Clinical Research Associate, U.S. Medical Affairs, SmithKline Beecham Pharmaceuticals, Philadelphia

**1982 – 1983.** Clinical Monitoring Associate, Ayerst Laboratories, New York

**1978 – 1982.** Biologist/Animal Care Supervisor, American Health Foundation, Valhalla, N.Y.

**1977 – 1978.** Supervisor, International Research and Development, Mattawan, Mich.

**EDUCATION**

**1976.** B.A., Biology, University of California at Santa Cruz. Honors on Senior Thesis — Apical Dominance in Seliginella kraussiana

**ORGANIZATIONS**

**2004 – 2005.** President of Board of Directors, Drug Information Association (DIA), Horsham, Pa., an elected position

**2003 – 2004.** Chairperson of DIA Steering Committee of North America, an elected position that serves on the DIA Board of Directors

**2001 – 2003.** President of PTSA Board, Sequoia High School, Redwood City, Calif.

**1999 – 2003.** Faculty member for Advanced CRA Training Course sponsored by DIA

**1993 – 1998.** San Carlos Tennis Club. Served as President of a 17-member board and several other positions; the tennis club is a nonprofit community tennis association with more than 500 members in the San Francisco Bay area

**1998 – 1999.** Chair of DIA Project Management Special Interest Advisory Committee, Founding Member of SIAC in 1995

**1992.** Founded the Project Managers in Pharmaceuticals group in the San Francisco Bay area, which meets quarterly to discuss topics of interest

study of this size was considered huge. This was viewed as a major accomplishment."

The opportunity to work with people in Europe and the United States provided her with valuable insights into cultural differences — an experience that has stood her in good stead in her role with the DIA.

## *Making it Happen*

With sound experience under her belt, Ms. Kane Musser sought opportunities in California. In particular, she was drawn to Genentech because of its innovation, entrepreneurialism, and mission. There, she got the position of project manager.

Her experiences at Genentech were both exciting and rewarding. One drug Ms. Kane Musser worked on was Herceptin, the first humanized antibody approved for the treatment of HER2 positive metastatic breast cancer.

"Working on that drug was personal, as I had a good friend who died of breast cancer when she was 40," she says.

The thrill of working in a young biotech company and learning about the industry kept Ms. Kane Musser at Genentech for 11 years.

"I was always learning something, and I was always working and collaborating with great people," she says. "I learned a great deal about the industry and how biotech was different from big pharma. Although both have drug development in common, there are many differences in how proteins are investigated, as well as how proteins and biologics versus small molecules are manufactured."

Another appealing aspect to the company was its convivial and open environment, where employees were encouraged to speak to senior management.

"Genentech used to have Friday afternoon 'ho-hos,' where employees got together and chatted with one another," she says. "In those days, all of the managers went to those meetings because they viewed them as a way to foster a sense of community with the company and dispel any sense of hierarchy."

The pleasure of working in a close-knit environment led Ms. Kane Musser to move to Rigel after Genentech started to become a larger entity.

"I also wanted to work at a company where I could be instrumental in developing projects from the very beginning," she says. "My role at Rigel is very diverse; I'm involved in project management, clinical operations, as well as what's called development operations. Development operations is where I work with the consultants in QA and regulatory affairs. I enjoy being on the ground floor and helping to build a company."

Working in a small company requires job agility, and Ms. Kane Musser thoroughly enjoys the shift from one role to another.

"I can go from strategic thinking and planning to, within 15 minutes, being task oriented," she says.

Right now, her chief job at Rigel entails running and managing clinical trials.

"We have very aggressive timelines, and my job is to work with others to ensure we meet those timelines," she says. "One of the things I enjoy about Rigel is that as a company we execute extremely well. The people I work with are very competent, highly intelligent, and collaborative; it's a pleasure being part of that type of team dynamic."

## *A Holistic Perspective*

Throughout her career, Ms. Kane Musser

## *A Promise of Better Medicine*

**THERESA KANE MUSSER, EXECUTIVE DIRECTOR OF DEVELOPMENT OPERATIONS AT RIGEL PHARMACEUTICALS INC., BELIEVES PROFOUNDLY IN THE PROMISE OF MEDICINE AND FINDING NEW CURES TO ADVANCE HEALTHCARE.**

"Right now, until we understand and can do something about how diseases get started, we have to be able to treat diseases; and to that end, the life sciences have made huge differences to people's lives," she says.

But the potential to take those treatments a step further, through personalized medicine, is where Ms. Kane Musser believes the future lies.

"The concept of understanding what an individual's genetic makeup is, and how that individual might benefit from a drug or could possibly have an adverse reaction, is key," she says.

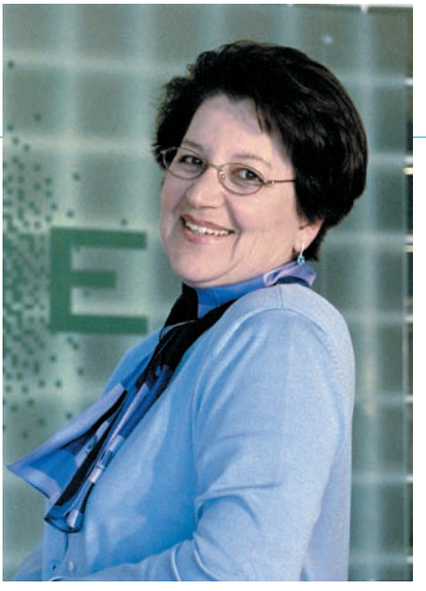
**THE DRUG HERCEPTIN, WHICH MS. KANE MUSSER WORKED ON DURING HER YEARS AT THE BIOTECHNOLOGY COMPANY GENENTECH, WAS THE START OF PERSONALIZED MEDICINE, SHE SAYS.**

"That drug is targeted to women who overexpress HER2; Herceptin is making a significant difference for women who have HER2 overexpressing breast cancer," she says. "Knowing how a person might respond to a drug is going to open up the ability to create more effective treatments."

**ANOTHER IMPORTANT ASPECT TO PHARMACOGENOMICS IS THE POTENTIAL TO IMPROVE SAFETY BY ENSURING PATIENTS WITH CERTAIN GENETIC MAKE UPS ARE NOT GIVEN A DRUG THAT COULD CAUSE THEM TO HAVE AN ADVERSE REACTION.**

"Pharmacogenomics is still in its infancy," she says. "It will be wonderful when patients can walk into their doctor's office with a rapid DNA test and their physicians can decide whether to prescribe a drug based on their genetic make up."

**GIVEN THE CURRENT ENVIRONMENT, WITH THE FINDINGS THAT DRUGS SUCH AS VIOXX CAUSED SERIOUS ADVERSE REACTIONS IN SOME PATIENTS, MS. KANE MUSSER BELIEVES PHARMACOVIGILANCE AND SAFETY WILL BE PARAMOUNT.**



"There is the potential to have even more stringent regulations in the wake of drug scares, and that may impact further the cost of drug development and the time it takes to get medicines to the market," she says. "These are issues that the industry has to deal with."

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## Working Toward the DIA Mission

For the past 25 years, Theresa Kane Musser, executive director of development operations at Rigel Pharmaceuticals Inc., has been volunteering her time to the Drug Information Association. She does so because she believes in the DIA's mission and the role it plays in the industry.

"The mission of the DIA is to be a neutral forum for sharing information that optimizes the process of drug development and life-cycle management," Ms. Kane Musser says. "As an international association of professionals working across pharmaceutical and biotech, we offer a unique environment because the organization's neutrality allows diverse perspectives to be shared at meetings or training sessions. The DIA enables professionals to share different views and get a perspective on best practices across multiple levels to improve health worldwide."

The DIA is a professional association of nearly 23,000 members worldwide who are involved in the discovery, development, regulation, surveillance, or marketing of pharmaceuticals or related products.

The organization is committed to the broad dissemination of information among its members, with continuously improved professional practice as the goal.

The DIA depends on volunteers, with people committing their time to give talks or put programs together.

"The annual DIA meeting is put together by volunteers; the session chairs are volunteers, the speakers are volunteers, and the role I play is to encourage that volunteerism," Ms. Kane Musser says.

At this year's meeting in Philadelphia, from June 18 to June 22, the DIA is expecting upward of 8,000 people to participate in more than 350 sessions covering 29 tracks.

"The annual meeting demonstrates the breadth and depth of multidisciplinary drug development," she says. "We're going to have more than 1,000 seasoned speakers; these are healthcare professionals who are leaders in academia, industry, regulatory, and other areas."

To facilitate the meetings, Ms. Kane Musser works with the board of directors to encourage people to get involved with the DIA and to look for new initiatives.

"At the Euro meeting, for example, we had what we called the patient initiative, where about 40 different patients who represented various patient groups in Europe came to the meeting and faciliated several sessions," she says. "This idea was put forth by a volunteer who felt strongly that we should involve patients because they are as much stakeholders in drug development as anyone else. So we approved the concept as a pilot program."

Ms. Kane Musser says during the years she has worked with the DIA, one of the biggest changes she has noticed is the use of technology and what that does to the efficiency of communications and how data are collected.

"With electronic data capture, patients can use handheld devices to input their diary data as well as information about how they're feeling by answering questions," she says. "This is pretty amazing considering that just 10 years ago everything was paper based. Today, there are so many ways that technology can be used to ensure greater safety of data and more timely information."

Another big change has been increased collaboration between pharma and biotech companies and regulators.

"Everybody is focused on the importance of bringing medicines to patients," Ms. Kane Musser says. "Today, there is more collaboration between the regulatory agencies and industry about how to improve drug development."

One of the most prominent changes has been greater patient awareness and involvement in drug development and clinical research, as well as a willingness by patients to take more responsibility for their own health, she says.

"The Internet has enabled patients to seek out information and become more knowledgeable," she says.

## Tackling the Hot Topics

The DIA's structure makes it possible to bring people together on contentious issues, to track the hot topics and to assess where members' interests lies, Ms. Kane Musser maintains.

For example, she cites a session from last year's annual conference titled, Transforming the Product Development Lifecycle: Where are the Opportunities and What Happens if We Don't Start Changing the Ways that Drugs are Developed? Ms. Kane Musser says it was a public policy plenary session that included experts from project management, clinical research, and regulatory affairs.

At the Euro meeting in Paris this year, a key issue that emerged was how to have a centralized approval process and still give credence to the local regulatory agencies.

"Europe has made a commitment to a centralized system, and yet local authorities also are responsible for the health and safety of the citizens in their countries," she says. "Everyone is committed to working in both systems, but there's a balance required with regard to meeting the needs of the local people within the more centralized approach."

At this year's meeting, DIA volunteers have put together a joint FDA and EMEA panel discussion addressing current and upcoming regulatory guidelines.

"Regulatory information is always of interest to people," Ms. Kane Musser says. "Even though the intent is to harmonize submissions through the ICH, there are still a lot of differences in regulatory guidelines between the United States and Europe. Holding a session that includes representatives from the FDA and EMEA on the panel can lead to a better understanding and possibly solutions about how to harmonize."

Other hot-button issues that are likely to be prominent at the meeting are pharmacovigilance, the new medicines legislation in Europe, and the FDA's Critical Path Initiative. The Critical Path Initiative is an effort to stimulate and facilitate a national effort to modernize the scientific process through which a potential human drug, biological product, or medical device is transformed from a discovery or "proof of concept" into a medical product.

The 2006 session also incorporates a landmark anniversary — the 100th year of the FDA.

"There will be a special plenary session with the FDA, the office of the commissioner, followed by a reception recognizing the 100th year of the FDA, which will be special," Ms. Kane Musser says.

*One of my jobs is to ensure the resources are aligned and obstacles are taken out of people's way, allowing them the opportunity to achieve their goals.*

People need to be given the opportunity to learn and they need to feel challenged. I get a lot of satisfaction out of being part of a team and working with others to make things happen.

has sought to work in an environment that has a strong connection with patients and the community. At Genentech, for example, she was drawn to a culture that drives home the need to treat patients with unmet medical needs.

"People are committed to that mission and the science is just so good there," she says. "During my time at Genentech, and probably still today, there was a quest to figure out how to achieve goals, and the company encouraged people to find new ways to innovate."

As executive director of development operations at Rigel, Ms. Kane Musser seeks to contribute to the larger goals of the organization, in much the same way.

One of her goals is to move one new product candidate for a significant indication into the clinic each year. Another goal is to establish strategic collaborations. To achieve both goals, she ensures that the people she manages share the company's vision.

"I believe that to be able to communicate a vision, one has to have a stake in being part of the mission," she says. "One of my jobs is to ensure the resources are aligned and obstacles are taken out of people's way, allowing them the opportunities to achieve their goals. People need to be given the opportunities to learn and they need to feel challenged. I get a lot of satisfaction out of being part of a team and working with others to make things happen."

It's that balanced and holistic approach to her job that enables Ms. Kane Musser to achieve so much and to celebrate the joy of work.

Balance also comes from the recognition that life must be equal parts work and external pursuits.

"One of the reasons I have volunteer roles outside of Rigel is that I've always believed my personal life is as important as my work life," she says. "I've been involved with my children's schools, both elementary and high schools, because I viewed this as not only as a way to get involved in the community, but also as a way of letting my children know that I believe education is important and that I'm willing to commit time to their schools."

A central part of her life is family — not just the nuclear family, but the extended family and the important role this plays in bringing perspective and roundedness to life.

It is for that reason that Ms. Kane Musser and her husband decided in the early 1990s to return to California and the Bay Area, where she grew up, to ensure that their children could have that larger family experience.

In addition, Ms. Kane Musser finds time for physical activities, such as tennis.

"Tennis is one of my favorite sports; I have a regular Thursday night commitment with friends," she says. "There's nothing better than getting together with people you feel comfortable with and enjoying good food and wine. It's a combination of the physical activity and spending time with friends and family that is important to me."

For a busy executive, who is equally committed to giving back to the life-sciences community and the larger community through volunteerism, taking on so many roles requires careful time management, a belief in what she does, and the support of her family and employers.

"It's always possible to make time for what's important and what you have a passion for," she says. "I'm extremely passionate about the mission and vision of the DIA. I've been involved with the organization for 25 years, and I believe what the DIA is doing is important so I'm willing to make the time. I was honored to run for president.

"At the same time, I have to acknowledge and recognize that I have the support of Rigel, as well as my family, to do this," she continues. "Without their support I couldn't be president of the DIA."

Whether on a professional level or the world at large, Ms. Kane Musser subscribes to a view of inclusion and open-mindedness.

On the world stage, she decries the failure to accept people's differences and show compassion for our fellow human beings.

"We need to recognize that what makes people and the world so interesting is that we're all individuals with differing views and perspectives; rather than viewing those differences as polarizing, we should seek to understand why we have different views and be accepting of that," she says.

Ms. Kane Musser believes people have the potential to make a difference by the way they interact with those they come into contact with and through volunteer work, even at the local level.

"Hopefully if enough people make a commitment — even at the community level — we can make a change in the world," she says.✦

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