CREATIVE. DYNAMIC.

Boehringer Ingelheim's Dr. Joanne Palmisano was actively involved in updating harmonized regulatory guidance as part of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use in two areas: clinical trials (E8) and pediatric drug development (E11).

DR. JOANNE PALMISANO

For Advancing Regulatory Affairs

Joanne Palmisano, M.D., VP, regulatory affairs, Boehringer Ingelheim, is revered as a strategic global regulatory leader with extensive pharmaceutical and biopharmaceutical expertise in small molecule and biologic drug development in multiple therapeutic areas. And as a baker. Her greatest passion — after science — is the culinary arts.

Her peers and colleagues know her better, however, for how she is shaping the future of both the industry and Boehringer Ingelheim (BI) as a company.

Serving as a member of the Human Pharma Medicine executive leadership team at BI, in addition to her VP of regulatory affairs duties, Dr. Palmisano is responsible for leading the regulatory affairs organization in the United States, including therapeutic area product development strategy, biosimilars, CMC RA, product labeling and labeling operations, promotion and advertising compliance, and regulatory operations. You could say she has a full plate.

She has a clinical development background in addition to expertise in regulatory affairs. Dr. Palmisano seeks to help her company consider the elements of innovative clinical trial designs and statistical approaches in areas of unmet medical need.

She has been actively involved in working with the FDA and international regulators on updating harmonized regulatory guidance as part of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) in two areas: Clinical Trials (E8) and Pediatric Drug Development (E11), which reflects her special interests in drug development in the pediatric population and complex innovative clinical trial designs.

Dr. Palmisano says working directly with diverse industry and regulatory authority colleagues — FDA, EMA, PMDA, HC, etc. — to author international regulatory guidelines for global drug development has been one of her most rewarding experiences.

As a member of key strategic committees in PhRMA and BIO, she is involved in directly engaging with regulators at the FDA on policy issues that are critical to all members of the biopharmaceutical industry in areas of drug development.

This active direct engagement allows member companies to ensure that they are working collaboratively with regulators to advance the tools that bring new medicines to patients sooner, which is one of the industry's biggest hurdles that needs urgent repair, she says.

"We need more collaboration through public-private partnerships to expedite how we develop new therapeutic options for unmet medical needs and to address the challenges of access to drugs and imbalances in care in our current healthcare system," Dr. Palmisano suggests.

Currently, Dr. Palmisano, along with other medicine and clinical development colleagues, is pursuing a patient-focused approach for BI's drug development programs. This includes innovative digital medicine approaches, such as virtual clinical trials and early incorporation of patient input into clinical trial designs.

Colleagues rely on her expertise, sound guidance, and leadership in pursuit of their own professional goals.

Outside of her day-to-day responsibilities at BI, Dr. Palmisano has been an active member of the Healthcare Businesswomen's Association-DIA Women's Leadership Project. She was a driving force in this leadership initiative to advance the careers of women in industry in medical roles, as well as those in regulatory, legal, and compliance positions. She helped to refine the project's goals, brought new thinking to the group of 40 executive volunteers, and consistently contributed to bring new value to the initiative.

I aim to be a force that drives innovation.

Over the years, she has been involved in the BI Women's Leadership Initiative, served as the lead sponsor for the company's Nurse Business Resource Group, and as a BI mentor in its corporate mentoring program. Dr. Palmisano also invests her personal time as an informal mentor to many of her colleagues. PV

Joanne Palmisano, M.D., FACP

TITLE: VP, Regulatory Affairs
COMPANY: Boehringer Ingelheim Pharmaceuticals Inc.
EDUCATION: MD, Columbia University, College of Physicians & Surgeons
FAMILY: Husband Russ; sons Robert and Michael — without their patience and support she would not have been able to advance her career
HOBBIES: Cooking; bread baking; swimming
AWARDS/HONORS: 2017 Fellow, Regulatory Affairs Professionals Society (FRAPS), in recognition of significant contributions and leadership in advancing the regulatory profession; Recipient of the 2014 We Work For Health Champion Award given by PhRMA annually to those individuals who have gone above and beyond, outside of their job description, as advocates for the biopharmaceutical industry; Wyeth 2008 and 2009 President's Team of the Year Award; Merck Move The Rock Award 2004
ASSOCIATIONS: DIA; HBA; RAPS; Board member, Community Culinary School of NW CT
PERSONAL BRAND: Come Hungry. Leave

SARAH DEMARE

For Being a Regulatory Guide

Sarah DeMare has never shied away from a challenge. As a product development champion at Facet Life Sciences, Sarah is a regulatory professional who uses her practical experience to guide small and emerging companies through regulatory pathways. Her in-depth understanding of current regulations and guidances, particularly in the chemistry, manufacturing, and controls arenas, helps her to build reliable, long-term, collaborative relationships with client project teams, as well as with regulatory agencies such as the FDA. Colleagues say she is an inspiring role model for any regulatory professional, and her knowledge, quality of work, and commitment to her clients are outstanding.

Sarah is a chemistry and manufacturing expert — her first industry job was as a process chemist at Parke Davis — who is well-versed in the potential development challenges and relevant development strategies faced by small teams. She thoroughly understands regulations and can translate them so that clients can adapt. She has a special talent of being able to track multiple moving parts for multiple projects, which has helped her to lead many companies to successful IND and NDA filings. She has a proven track record of bringing small pharmaceutical companies and the FDA together to advance therapies.

Sarah is comfortable wearing the hat of trusted advisor one minute and analyzing and forming interpretations of new regulations the next. She is a professional who understands the impact and importance of situational leadership.

"I am fortunate enough to have a job that allows me to wear a lot of different hats," she says. "So every morning when I wake up, I never know what new challenge will be waiting for me in my in-box."

Sarah is able to distill difficult concepts into basic key messages. She is adept at identifying problems — often before they arise — and finding win-win solutions. She thinks with the end in mind and works hard to save companies time and money by helping them to streamline development. She is a leader in the industry of PET radiopharmaceutical development as a CMC subject-matter expert, and she has helped more than a dozen companies achieve FDA approval.

Clients say Sarah goes above and beyond the call of duty, ensuring that upcoming submission timelines are met by proactively tracking the progress of the project, and she is willing to assist in many other areas as well.

Although she does not seek the spotlight, Sarah models leadership behavior that helps small teams achieve their goals. She believes anyone can be successful. It's not about how high up the ladder you climb; success comes with a feeling of a job well done. And she believes leadership is about seeing the potential in others that they may not see in themselves.

This could be why those she has worked with say she is such an inspiring role model. Her knowledge, quality of work, and commitment to her clients is outstanding. Her eagerness to simultaneously take on the role of teacher and student has led to a great deal of success throughout her career. This is also one of the many reasons why team members enjoy working with her.

If she had unlimited resources, Sarah would fund small businesses, so that they could bring their product to market as fast as possible.

I never shied away from a challenge.

"There are a lot of small companies out there with great products, but not a lot of money," she says. "Fundraising is challenging and can cause potentially promising products to be delayed, or even stopped simply because they could not raise the funds."

She has love for all things Disney; she plans Disney vacations for herself and others, her favorite app is Disney Emoji Blitz, and the person who most inspires her is Walt Disney. She says if she weren't committed to regulatory affairs, she would be a Disney Imagineer.

"Imagineering combines three things I'm good at: Disney, science, and math," she says. PV

ADAPTABLE. ORGANIZED.

Sarah DeMare is known for her ability to derive creative solutions for complex problems.

TRANSFORMATION IS: NECESSARY

Sarah DeMare

TITLE: Product Development Champion
COMPANY: Facet Life Sciences Inc.
EDUCATION: BS, Chemistry, Hope College; MS, Organic Chemistry, Penn State University
FAMILY: Husband; two sons
HOBBIES: Avid Disney lover, travel, reading
ASSOCIATIONS: Regulatory Affairs Professionals Society
SOCIAL MEDIA:
PERSONAL BRAND: If life gives you big ears, learn to fly