DR. LISA JENKINS

Guiding the Regulatory Process

DRIVEN TO INNOVATE BY GROWTH

If Dr. Lisa Jenkins could time travel, she would use that opportunity to listen to the world's great thinkers speak: Aristotle, Jesus Christ, the U.S. founding fathers, JFK, and Martin Luther King Jr., for example. Being a strong leader and change maker herself, it makes sense she would want to hear firsthand what the historical big guns had to say. According to peers and co-workers, Dr. Jenkins can hold her own in that regard; she is an inspiring leader in the regulatory sciences world who is respected and followed by peers and customers. In her 15 years in the industry, she has never encountered a challenge she didn't embrace and there is no project too big or too difficult for her.

Dr. Jenkins serves as VP of regulatory strategy and content development at Virtual Regulatory Solutions, and her extensive range of experiences is far beyond most in her age group. She has been a strategic program leader for more than 80 products with more than 20 NDA/BLA submissions. She is a nationally recognized leader within the Drug Information Association (DIA) and has an array of publications conveying her expertise and approaches to help others negotiate regulatory applications and meetings. In addition to her regulatory expertise and leadership, she provides a boundless supply of energy and enthusiasm. Her advice is always sage and her grasp of complex situations is quick and sophisticated.

Her background includes product development planning, global regulatory submission strategy, dossier preparation and submission, and postapproval life-cycle management. She specializes in eCTD submissions management, orphan drugs, radiopharmaceuticals, biomarkers, product labeling, and risk management planning.

Dr. Jenkins has the valuable skill of enthusiastically learning from her team and as such, has fostered a very open communication model

PASSIONATE. DIRECT.

With strong backgrounds in both regulatory affairs and statistics, Dr. Jenkins is able to see clinical trial results and regulatory options in unique ways that are not readily apparent to others.

whereby every team member is able to advance from the experience of other team members. She routinely holds work-share meetings to allow individuals to access the skills, knowledge, and time of their expert peers to exceed client expectations.

Although Dr. Jenkins' resume alone is remarkable, her true impact is on the positive influence she has on her teammates and clients. Co-workers say she has a very direct, no-nonsense approach to managing projects and teams. The underlying premise to her recruiting methodology is to attract exceptional people to the "A team" that she has cultivated and then lets each expert do his or her job. By providing support while simultaneously requiring accountability, she has created a culture where she constantly challenges her team to innovate and improve. She encourages people to "play to their strengths" and constantly hone their skills.

Her leadership style imparts trust and inspires loyalty. Many of her current team members have followed her to multiple companies in her career.

Not only has she led several high-profile well-known therapy development programs, she has also been the driving force behind substantial regulatory progress or unexpected regulatory approvals. Her view of the regulatory process is if the therapy works, there has to be a regulatory pathway for progress. This focus is what has driven her to developing consistently novel and productive regulatory strategies and solutions for the therapies both she and her team support.

Her consultative approach to quality regulatory services is predicated on three core and consistent actions: articulate the rationale behind the various aspects of the regulatory approval process; describe how to navigate the regulatory process in the most efficient manner; design and execute a regulatory strategy that offers a compliant, but aggressive path toward the team's commercial objectives.

This three-part approach imbues quality into her services and the knowledge transfer component leaves teams with a wealth of experience to reference as they progress through regulatory processes. Peers say the value of this method is immeasurable.

She has worked for large organizations such as Wyeth, Kendle, and CSC, and with small teams, but no matter the size Dr. Jenkins has a great passion for helping teams navigate the regulatory process. She is considered the "secret weapon" used by many pharmaceutical and biotechnology companies that need regulatory leadership.

"Each day, I'm driven by helping small companies move the regulatory yardstick for the product or products they are trying to develop," she says. "I define success by achieving milestones in development and having clients honor me with repeat business because of the value I bring to them. There is no greater compliment I can receive than when a client says that I'm "one of them.'" PV

GETTING TO KNOW...

Lisa Jenkins, Ph.D.

TITLE: VP, Regulatory Strategy and Content Development
COMPANY: Virtual Regulatory Solutions Inc.
EDUCATION: Post-doctoral fellow, Washington University; M.S. and Ph.D., Syracuse University; B.A., Juniata College
FAMILY: Fiancée Ken VanLuvanee, four children, one dog
HOBBIES: Skiing, running, lifting weights, reading, volunteer work
BUCKET LIST: Bicycle across the United States
AWARDS/HONORS: Finalist in TOPRA Support Category, 2014; Wyeth Above and Beyond Award recipient — 2003, 2004, 2005, 2006; Wyeth Team of the Year Award recipient — 2001, 2005; Wyeth Special Recognition award recipient — 2001; Recognition for Outstanding Faculty Impact by Graduating Seniors — 1999, 2000; Charles L. Cahill Award for Faculty Research and Development — 1998, 1999
ASSOCIATIONS: DIA; Juniata College Alumni Association
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