WAGING A BATTLE AGAINST CANCER

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MEET YVONNE

Meticulous and highly motivated, **Yvonne Sun '06** spends her days pouring over paperwork. Not sales reports or stock projections, but test reports and compliance materials that will bring new technologies, treatments, and hope to cancer patients.

Leading a quality assurance team at a Boston biopharmaceutical firm, Yvonne builds the bridges that transport new medicines and immunotherapies from the laboratory to the marketplace.

Choosing a path

Yvonne recognized her aptitude for math and science early in life and earned undergraduate degrees in biotechnology and biology. Pursuing a career in biotechnology, Yvonne held positions of increasing responsibility at several Massachusetts firms before taking on her current role as Senior Quality Assurance Manager at Ziopharm Oncology.

Ziopharm's research and development projects focus on developing new gene and cell therapies that harness the power of the body's immune system to fight blood cancers and solid tumors. These immunotherapies stimulate immune system cells to locate, target, and destroy foreign cells in the body.

As a quality assurance manager, Yvonne is responsible for quality control of the company's clinical trials focused on chemistry, manufacturing, and controls. "My primary function is to ensure manufactured clinical material meets predefined specifications for the following attributes: safety, integrity, strength, purity, and quality. A large portion of what I do is to review and ensure various departments operate within FDA guidelines and regulations."

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"TO GOD THROUGH SCIENCE"

These words graced the façade of Mendel Hall for 60 years. In service to the relief of human illness and suffering, this maxim stands ever true.

Yvonne embraces a spirit of persistence in her work. According to the Pharmaceutical Research and Manufacturers of America, “… it takes at least ten years for a new medicine to complete the journey from initial discovery to the marketplace, with clinical trials alone taking six to seven years on average.”

“A typical day is reviewing lots and lots of documentation, such as executed manufacturing batch records and test methods including their results,” Yvonne shares. “Although no one in Quality wants a deviation to occur, I find it the most enjoyable to be a part of an investigation team. I love making process improvements and defining root causes to why an issue occurred and how we are going to fix it.”

Gaining momentum

Building on her Rivier foundation, Yvonne became a certified Root Cause Analysis and Incident Investigator and earned a Graduate Certificate in Regulatory Affairs, Biologics, and Medical Devices. Her studies focused on the ways new drugs, treatments, and medical devices are evaluated and regulated by the FDA, equipping her to manage the regulation process. Hard work and her credentials prepared her to take on the management role at Ziopharm, and they will be especially useful as the company enters the next phase of clinical trials on a promising new cancer immunotherapy.

Ziopharm announced recently that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for its Controlled IL-12 program, a treatment for recurrent or progressive glioblastoma multiforme in adults. This disease recurs in almost all patients. Presenting as brain tumors, recurrent glioblastoma multiforme is an aggressive and life-threatening cancer of the central nervous system for which there are currently few treatments and no cure.

The FDA's Fast Track Program is an expedited drug development and review process for new drugs that will treat serious conditions and have demonstrated the potential to fill an unmet medical need. A drug granted Fast Track Designation is eligible for priority review and accelerated approval, if it meets the necessary criteria.

Yvonne and her team will play a key role in the Fast Track process. “My goals are to help put in place the appropriate critical quality attributes and critical process parameters to meet Phase III expectations,” she shares. Phase III clinical trials are the final hurdle before a drug receives FDA approval as a therapeutic option.

Making a difference

The results from previous clinical trials are promising. The Controlled IL-12 program drove T cells deep within a tumor for weeks to months at a time, initiating and sustaining an attack on the cancer cells. Recurrent glioblastoma patients treated with the Controlled IL-12 program experienced shrinking tumors and improved survival rates.

“This means everything to me,” says Yvonne. “I love waking up knowing that I am working towards treatments and cures to bring a level of quality of life which [patients] didn’t have previously … I feel as though everyone has had some direct or indirect experience with cancer, and it continually impacts so many lives in both positive and negative ways.”

Yvonne focuses on the positives. Her work is truly making a difference in the lives of patients, helping each to wage and, with hope, win their internal battle. ■