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MELINDA LIGOS

The Accidental Entrepreneurs



Tim Shaffer for The New York Times

Kirk Gallion, left, Dr. Neal Walker and James Walker, principals of Octagon Research Solutions.

NONE of the founders of **Octagon Research Solutions** had aspired to become entrepreneurs. But on a chilly fall night in 1999, two of them stumbled upon an idea so promising that they knew they had to give it a shot.

James Walker, then an independent consultant to pharmaceutical companies, and Kirk Gallion, a consultant employed by Accenture, were pulling an all-nighter to redo an electronic application to the Food and Drug Administration for a new drug from a pharmaceutical company. The

application, prepared by a technology vendor, “was just awful,” Mr. Walker said. After they spent half the night trying to fix it, a light bulb came on. “I turned to Kirk and said, ‘Wouldn’t this be easier if it was just done right the first time?’” he recalled.

The two hammered out the idea for a company that would use technology to help speed up and simplify the approval process for new drugs. Because the F.D.A. was pressuring pharmaceutical companies to send applications electronically, and because the life-sciences field was

booming, they figured that they were on to something.

A former executive at **Schering-Plough**, Mr. Walker had a regulatory background, and Mr. Gallion had technical skill. To round out their expertise, they enlisted the help of Mr. Walker’s twin brother, Neal, who was about to start a career as a dermatologist. “We felt like we had an unbeatable combination,” James Walker said.

They learned quickly that starting a company meant personal sacrifice. Neal

Walker and his wife, Christy, spent many nights debating whether he should turn down lucrative offers to practice dermatology to join Octagon as chief medical officer. She was especially wary because she had just put her husband through medical school. "We felt like I was giving up quite a bit," Neal Walker said. But they decided to take the risk.

James Walker, the new company's chief executive, gave up living on his own and moved back in with his parents so he could pour all his money into the business. And Mr. Gallion, the chief technology officer, traded in his comfortable office space at Accenture to work out of a coat closet in his two-bedroom apartment. "My daughter was 2," he said. "This was the only place where I could get some work done without her climbing all over me. It was extremely

An irresistible idea leads consultants to start a business.

cold in the winter and wicked hot in the spring." He put up with it for six months, until Octagon got an office.

In November 1999, one month after it was started, the company got its first major client. With homemade brochures and references from former colleagues, the founders gave a presentation to **AstraZeneca**, the pharmaceutical company, and snagged a contract to help it with an F.D.A. application. **Johnson &**

Johnson soon signed on, and other deals followed. "We had uncovered such a niche need that we really didn't have any competitors," James Walker said.

In May 2000, Octagon moved into its first office, a small room atop a Dunkin' Donuts shop in King of Prussia, Pa., a Philadelphia suburb. Space was not the only problem; the office was infested with wasps. "You'd just hear buzzing and then, all of a sudden, someone would run by," trying to escape a swarm, said Mr. Gallion, now 31.

Though the business was growing, money was tight. Neal Walker, now 33, bought office furniture at a yard sale, and the partners met with clients in the doughnut shop. Slowly, the founders added to their staff, often by persuading a friend or former colleague to take a big salary cut in return for stock options and the adventure of joining a start-up.

A typical application for F.D.A. approval of a new drug contains a staggering 300,000 pages of clinical-study results and other information. Companies send all that paper to the F.D.A., then reformat it and send it to 100 or so other regulatory agencies in the United States and abroad. By handling all this data electronically, Octagon says, it can cut the compilation time in half.

"They've got an edge because they're not just technologically savvy; they actually have a full grasp of what the F.D.A. looks for," said Mary Alice Raudenbush, vice president for regulatory affairs at **Endo Pharmaceuticals**, a Chadds Ford, Pa., maker of pain medication. The company hired Octagon to help submit its first two

applications in 2001. "Octagon helped us save thousands of trees," she added.

Ms. Raudenbush said it probably would have taken her company two or three years to complete the process, instead of Octagon's one. She said the applications were currently under "active review" by the F.D.A.

Octagon now has 70 employees, an expanded headquarters in King of Prussia and a second office in Boston. Last December, it received \$3.8 million in venture capital from a group of investors including the **Edison Venture Fund** to help finance a product that will allow project managers at pharmaceutical companies to view the latest status of their electronic submissions. It projects revenue of more than \$5 million this year and close to \$8.8 million in 2004.

For all their success, the three founders sometimes worry about the future. "Even when things are going right, I'm questioning myself and the business," Neil Walker said. "Sometimes I think, 'How can a small fish accomplish such a large task?'"

Mr. Gallion has become accustomed to tight space and long working hours. He says he recently set up shop in a client's office in the company phone booth because "there really wasn't anywhere else for me to go." And he has become accustomed to the frantic pace. "In those early days, you're always thinking the workload is going to lighten one of these days," he said. "In truth, we all work just as hard as we did in the very beginning. That's just the nature of having your own business."