CEO CFO

Graematter

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Advanced Search Products and Services for Regulatory Professionals

Technology
IT Solutions

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Merle Symes
CEO

BIO:
Merle Symes has been managing or advising early-stage technology companies since 2001 and has been a partner or had equity positions in several new ventures. His last management role was as President and CEO of Ulrich Medical, a spine implants company, which he grew 65% over a three-year span at high levels of profitability. He serves as a mentor with Capital Innovators in St. Louis to IT ventures.

Prior to his work with early-stage technology companies, Mr. Symes served as Vice President, External Technology for Bausch & Lomb, which spearheaded the company's efforts in licensing technology and acquiring technology companies. He has served in various executive positions, both in the U.S. and Europe, for Wyeth and Monsanto and has served on the board of directors of both private and publicly held companies.

Mr. Symes has an MBA from the Wharton Graduate School and a B.S. in Chemical Engineering from the South Dakota School of Mines & Technology where he was honored with their Distinguished Alumni Award.

About Graematter
Graematter helps regulatory professionals turn information into intelligence with advanced search products and services.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Symes, what is the concept at Graematter?
Mr. Symes: We aggregate and integrate government documents in regulated environments into a single database with advanced search capabilities and analytics. We take fragmented, difficult-to-find information and make it easy to locate and utilize. We started with the FDA because the FDA has done a good job of making information available to the public but it has now become a massive amount of information and it is spread over more than 130 different databases and data sources. We have now integrated much of that information into an intelligence system that we call the Sofie System.

CEOCFO: What were the challenges in putting together a system that could combine all of the data?
Mr. Symes: The biggest challenge is that the data is in many different forms and formats and is difficult to integrate in a way that allows for easy search. It took our founder, Melissa Walker, several years to develop efficient methods for collecting, cleaning, normalizing, integrating and cross-referencing all of this information.

CEOCFO: You said that this is for regulatory people, so who would be using the database?
Mr. Symes: The initial target market is regulatory professionals that work in medical product companies, such as medical device, pharmaceutical and biotech companies.

CEOCFO: That is a huge market!
Mr. Symes: It is and it is addressing a huge unmet need within that market.

CEOCFO: Where are you rolling out the system?
Mr. Symes: We just launched the commercial version of the product two weeks ago with a press conference. We also just returned from attending three back-to-back national trade shows in three weeks where we introduced the system to the public. This followed a three month targeted advertising and public relations campaign.

CEOCFO: Has a similar system been tried in the past?
Mr. Symes: Graematter's Sofie™ System is unique. There are some systems that we categorize as *information* systems. But, they are fundamentally different in concept from our system, which we characterize as an *intelligence* system. They were originally created to serve various functions in the regulatory environment and have, over time, added three or four data sources from the FDA into their system. This does not compare

to the many databases that have been put into the Sofie™ System and, more importantly, they are not integrated. That means that they still have to be searched individually in the same manner as you would if you went to the FDA sites. Our system allows you to pull all of the relevant and related documents for a given search topic into a single search. This saves a tremendous amount of time but also greatly reduces the chances of missing critical documents.

Having an integrated system with many data sources also means that we can perform a number of different functions that have not previously been possible such as environmental surveillance, tracking trends and applying many other forms of analytics. I should add that it is also a patented system.

CEOCFO: When you are demonstrating, or when you are talking with a perspective user, do they believe it can be done?
Mr. Symes: Absolutely, the regulatory professionals are very knowledgeable and very skilled in what they do. When they see a demonstration of this system, they can observe that searches that typically take an hour, several hours or much longer to perform can be completed in a matter of minutes. When they see some of the other functionality and analytics, they know this is not possible with publicly available databases.

CEOCFO: Now, I'm assuming all of this information is publicly available.
Mr. Symes: Yes, that is correct.

CEOCFO: You mention sometimes that there are errors in the information. Are you able to correct those?
Mr. Symes: When it is an error that would be obvious to any knowledgeable observer and the correction is also obvious, then we correct it. When the correction is not obvious, we do not make any changes. However, the beauty of our system is that if a client comes across such an error, they have the ability within our system to pull up the original document in PDF form and confirm that such an error is in the original document.

CEOCFO: Are there typical applications for which this system will be used or is it a very broad range?
Mr. Symes: It is a very broad range. A typical use would be in preparation for a new product submission to the FDA. In that situation, a regulatory professional will use the system to review precedent cases and develop a proposal that they submit to the FDA. The better information they have, they more likely they are to develop a pathway for approval that is the shortest and most cost effective pathway with the greatest chance of success for product approval. Better information also helps assure that they will be able to justify this pathway to the FDA because the FDA has final say. The system has a wide variety of other applications, however, such as monitoring compliance to regulations, environmental surveillance, etc.

"With regard to our initial market, Graematter is addressing a major unmet need in a huge market. Over the longer term, there is a tremendous potential for the Graematter technology and approach to be used in a number of regulated environments." – Merle Symes

CEOCFO: Are you starting in the US or starting with a global launch. What is the plan?
Mr. Symes: There are two parts to that question – (1) where we will begin to market and (2) our product development plan. We initiated our commercial launch in the US because of the very large number of medical product manufacturers in the US. However, medical product manufacturers outside the US have an even greater need for this product because the US regulatory environment is the most rigorous in the world and the most intimidating to companies outside the US. In the not-too-distant future, we will expand our marketing activities outside the US.
With regard to product development, the initial products will apply to US FDA information but, at some point, we will be duplicating what we have done in the US with regulatory information from countries around the world.

CEOCFO: You have named it the Sofie™ System. What is the meaning of the acronym?
Mr. Symes: It is not actually an acronym. I think that there is a natural human tendency for people using an intelligence system to personify it to some extent. Sofie is derived from the Greek word meaning "wisdom", which is very fitting for our system. Someone in our organization coined the name "Sofie" and the system has been affectionately known as Sofie ever since.

CEOCFO: What is the timetable? What will you be doing three months from now, six months from now, a year from now? What's the plan?
Mr. Symes: We are just at the very beginning of our launch and have been very pleased with the response that we have been receiving from the trade shows and other promotional activities. We will be very busy over the next three months to six months doing all of the follow on work and signing up clients. We will also be continuing to expand our marketing activities and scaling up beyond that point. In the area of product development, we just released the Medical Device Module and it will be followed by the Pharmaceutical Module and eventually the International Module.

CEOCFO: Why did you start with medical devices?
Mr. Symes: We felt it was one of the areas of greatest need. It is a more fragmented area because you have so many different kinds of devices and the devices vary significantly. You also have two very different types of approval processes, typically referred to as the 510(k) Process and the PMA, or Premarket Approval, Process. Manufacturers prefer to use the 510(k) process, if possible, because it is shorter and less expensive but you have to be able to provide the data and information that will justify using that process.

CEOCFO: What did you learn in your previous ventures that has been most helpful so far at Graematter™, in getting things up and running?
Mr. Symes: I have been asked that question many times. You learn many different things over time as you work with different ventures. The two most important things that I try to convey to first-time entrepreneurs is that you first need to be prepared to have lot of tenacity and persistence. It will usually require all of the perseverance that you can muster to be successful. The second thing is that a new venture almost never goes the way you originally envisioned. You need to be very adaptive and very agile to be able to adjust to all of the unexpected situations and outcomes so that you can find the eventual path to success.

CEOCFO: Development and commercialization is always an expensive process. Will you be seeking partnerships or funding?
Mr. Symes: Finding funding is a never-ending process. We were very successful raising our initial seed capital last year and we will need to raise addition capital to scale up our organization and operations. We have one advantage, however. Even though we are participating in the high growth biomedical markets, we do not require as much capital as the typical biomedical/life sciences venture because we are fundamentally an IT type company and they require less capital. At some point, we may look for strategic partners to be part of the mix. That point is yet to be determined.

CEOCFO: What changed most from the initial concept to the final version?
Mr. Symes: Actually, there has not been that much change in the fundamental product concept itself. That is a tribute to Graematter's founder Melissa Walker and her years of experimentation with this. We have had two major realizations, however. The first is that once you do the work to break down every single document into its various fields and find ways to integrate them, you can do an incredible number of things with that information. We are just beginning to envision all of the analytics that can be added to this system.

The second major realization was that it was not going to require much training to learn to navigate the system because the simplicity of the design of the system makes it intuitively obvious to learn how to navigate. We did discover, however, that we needed to add significant training to help clients discover all of the new things that they can do which has not been envisioned before. We realized after showing it to some people that it was roughly the equivalent of handing someone a smart phone after they have only known a cellphone and somehow expecting them to immediately grasp all of the potential power of using all of the new functionality and the many apps that can now be developed for it.

CEOCFO: Why pay attention to Graematter?
Mr. Symes: With regard to our initial market, Graematter is addressing a major unmet need in a huge market. Over the longer term, there is a tremendous potential for the Graematter technology and approach to be used in a number of regulated environments.

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