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Q&A with Robert Munroe, Co-Founder of Founders Science Group, LLC providing Consulting and Contract R&D Services to the Pharmaceutical and Cosmetic Industries with an FDA registered GMP Compliant Testing Facility



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CEOCFO: Mr. Munroe, what is the vision behind Founders Science Group?

Mr. Munroe: The vision is to provide quality technical services to the pharmaceutical and cosmetic industries.

CEOCFO: What does that mean day-to-day?

Mr. Munroe: We provide contract R&D services, quality services and consulting services to the pharmaceutical and cosmetic industries.

CEOCFO: Would you walk us through a typical engagement - what people are looking for and how you are able to help them?

Mr. Munroe: A simple example of what we might do is. If we have a client who needs to have an improvement on a packaging for a commercial product that they have, there may be a poor consumer experience with the packaging, it does not spray or dispense properly or issues of that nature. We will take the product in house, apply our experience and expertise to modify that packing to provide that client with a package for that product that the consumer can enjoy. If it was a dispensing issue, after we are finished the product will dispense better, not sputter or things of that nature. Another example is our client may have a product with poor stability. It will go bad while in the consumer's home or go bad while sitting on the shelf at the retailer. We will take that product and make modifications and improvements to it so that they can have what is called better expiration dating and it will last longer. It will either last longer while it is sealed and for sale, or last longer after it has been opened. Those are two areas that the regulatory agencies, the FDA and the FDC are looking at with more scrutiny to make certain that once a product goes into a consumer's home, it lasts more than a reasonable time after it has been opened. A consumer would not want a product to just go bad instantaneously. We work on concerns like that. One of the other things we can do for people who are in the development stage, prior to them having a commercial product is we can help support them with the analytical testing that is required so they can understand that they actually have a product that is ready for the additional effort to file and register this product with the FDA. Registering products with the FDA is a time consuming and expensive process, so they want to do this work in advance of going through that process. We will support all the necessary research and development work to help our clients understand that they have created a product that is ready for the effort to file.

CEOCFO: Why would a company even have a product that would not last very long on the shelf or in the home? Do we really need the FDA to tell us that it is not a good idea?

Mr. Munroe: You are right. Do we need the FDA to tell us that? Probably not, but one of the things that can happen is there are certain products that a consumer may receive that needs to be refrigerated. One of the reasons you refrigerate a

product is to increase the stability or the shelf life. This need for refrigeration creates a burden for the consumer and the supply chain. The product has to be shipped refrigerated, stored refrigerated, it goes to the consumer and is refrigerated. This is a really useful area where an improvement in product stability may be beneficial to the consumer, the retailer and the manufacturer, having a product that has better stability so that you have eliminated this need for refrigeration. There are also some products that are used, say in the bathroom or in a moist or humid environment that can be subjected to potential microbial contamination. Although it may be a product with a long shelf life while it is sealed, once it is opened, it can become subject to contamination from the consumer i.e. putting their hands in a cream, touching their fingers to a “tip” things of that nature. We can work with those clients to help them create a product that is less likely to become contaminated through the normal use of the product.

CEOCFO: *Why would a company turn to you for packaging design rather than go right to a packaging company?*

Mr. Munroe: If you go to a packaging company, just one specific supplier, the options you will be exposed to are going to be limited to what that supplier has experience with and may have in their house and shelves. Whether they are a tube manufacturer, a bottle manufacturer. Sometimes you want to have something that is significantly novel, something that is a little bit outside of the box. That is why you would go to a development house like us who could maybe help put together two or three different aspects from multiple container closures and combine them in one container closure that will help improve the product dispensing, the stability or the consumer experience. Additionally we have created a unique container closure system that is so revolutionary we have applied for a patent. This is part of the benefit of coming to a research organization like ours, to have that “out of the box” approach to helping you create product and market differentiation.

“We are very good at what we do. I think when new clients come and talk to us and present us with a problem or challenge they are facing, they realize that we have the experience to help them.” - Robert Munroe

CEOCFO: *How does your knowledge help come up with a solution that makes the most sense across a variety of areas?*

Mr. Munroe: Between myself and Ronald Gurge, PhD., the co-founder of the company, I have over twenty years of experience in the pharmaceutical space in the quality control and research and development side and Ron’s experience is on the product development side with small and large companies; Gillette places like that. Between these two different skill sets, we can offer our clients a wide array of experiences that they may not get if they just go to the manufacturing houses themselves.

CEOCFO: *Why might you look at from your experience that others do not understand?*

Mr. Munroe: We develop testing methods for other clients to use for them to release their own products. Because of our experience working in both R&D environments and commercial production environments, we create methods that transfer well to a production environment. In a production environment, you cannot have a method or scientific procedure that is so difficult to run or perform that it cannot be done routinely on a day to day basis quickly and efficiently. Efficient rugged methods are necessary in a commercial environment because manufacturers are going to be making products on a daily basis and need to get these products out into the commercial stream very quickly. They cannot have a process that takes days to perform. That is on the methodology side. Then as you continue to the manufacturing side, this is where Ron’s experience is beneficial. It is the same concern, of how do we make this manufacturing experience efficient for the manufacturers, something that is robust and can be done day in and day out and not have variability in the final product. Every time a manufacturer performs a manufacturing procedure, they need to get the same exact product without deviation or variation. Then when you go one step further to the consumer experience, we try to create products that are predictive about the consumer experience. For example, we know that consumers do not like to refrigerate products. That is a problem for them. If a product is an aerosol, the necessity to spray aerosols upright is something that we try to avoid with unique and ingenious packaging designs. This creativity allows a consumer to spray and aerosol at any angle, which is more predictive of how a consumer may spray aerosols. When creating lotions and creams that are to be in tube presentations, We would gravitate towards a “tottle” presentation, this is a modern twist on a tube/bottle configuration and helps to reduce the need to “roll” a tube from the bottom up to ensure that all of the contents are dispensed. This is a relatively new trend in cream/lotion presentations, from the metal tubes of yesterday that were subject to cracking at the seams and allowing the product to leak or go bad prior to it being fully consumed.

CEOCFO: *Would you tell us abbot your facility expansion this past year? Why now?*

Mr. Munroe: We are a small company and we are relatively new. We have been in business for three years and we have seen tremendous growth over the past 36 months. We continuously add services that our clients are requesting from us.

Our reason for expansion is we just needed to grow to be able to provide additional services. One of the big services that we are bringing on right now is ICP/OES (inductively coupled plasma optical emission spectroscopy). There is a new and growing requirement by the FDA and other regulatory agencies, that all products be tested for specific heavy metals like lead, arsenic and mercury. In the past, the testing was a semi quantitative test. They did not necessarily ask you which heavy metals were in your product, just if there were any heavy metals in it above a certain level. Now the expectation is specifically which heavy metals are in your product and at what levels. This is a new service we are bringing on, which is a pretty intensive operation for both space and capital, so we built a room for this purpose, put in facilities for this. This is one of the more direct reasons why expansion was necessary now, in addition to other services being brought on.

CEOCFO: *Are there often changes in equipment or procedures that you might use in testing or is it fairly static over time?*

Mr. Munroe: It is both. For the routine testing, those kinds of instrumentation have been in existence for my 25 years in the industry. The computer and data acquisition side has grown over time to become a little more complex, but the methodology and technology has remained the same. However, on the research and development side, there is always new instrumentation being put into service to help you get more specific and granulation to the types of test that you are performing. For example, the early heavy metals test informed you that heavy metals were present but we do not know which ones. The new heavy metals test indicates exactly which heavy metals are present and can provide quantitation down to the PPB, parts per billion and parts per trillion. I would not say, we stay on the bleeding edge of new technology, as a small company, we cannot afford do that, but we do our best to stay on the cutting edge of the industry needs so that we can be relevant and provide services that are of current importance.

CEOCFO: *How do you reach potential clients and jump of the page if someone is doing a random online search?*

Mr. Munroe: In all honesty we do not do very well with that. A majority of our work to date has been word of mouth and existing clients who referred us to other clients. We only have very limited experience with using the search engines and social media to garner new clients including leveraging SEO search engine optimization. I think for our industry and for what we do, it does not work that way for us. We use face to face meetings. We go to trade shows, conferences and these types of organized events and try to make people aware of our existence and what services we can provide them.

CEOCFO: *How does Founders Science stand out at a trade show?*

Mr. Munroe: We are very good at what we do. I think when new clients come and talk to us and present us with a problem or challenge they are facing, they realize that we have the experience to help them. I have worked on both sides of this. I have spent about 20 years on the other side of this where I am out there looking for service providers, and many times when you speak to service providers, they will basically run it through their sausage grinder and see what comes out on the other end and they just do the same thing regardless of the problem they are faced with. Having the experience and staff that we have here, we can look at a problem and really sit down and digest it and provide our clients with a tailored response to the experience they are having as opposed to just running it through the standard battery of test and hoping for the best. My staff and I have worked together for over ten years, so even though this company is only three years old, we have been working together as a team for over a decade. We have some relationships here where we can really work with one another to provide the right kind of information and questions to get our clients the best answer in the shortest amount of time.

CEOCFO: *What if anything has changed over your approach in the last three years?*

Mr. Munroe: I think over the last three years, not a lot. It is still pretty new for us. I think that is a question that is probably best suited for the next two to three years, but with our business model and our approach to providing clients with good services, we think we understood what we wanted to do when we started this and that rule still applies.

CEOCFO: *Are there particular projects that you would prefer given a choice?*

Mr. Munroe: No, I think if you work in this kind of environment, you tend to like variety. There are two main types of projects that we do. One is the routine manufacturing support and the other is research and development. They both have their up sides. It is nice when you get a nice mix. The research and development projects are very challenging and they can be very engaging and they really test your knowledge, experience and ability to apply experience to problem solving, but sometimes it can be burdensome. Then when you get the routine products they can almost be a break, it kind of helps to lighten the load a little and you can attack the routine products. If you do those too long, they become a little more repetitive, so then it is nice to switch back to the R&D. For us and our staff, we do both of those types of projects for our clients and it offers a nice mix. Nobody burns out with an excessively challenging product; they can always move over to something a little more routine, and by the time that gets to be repetitive, you can always move back to something that is R&D. This also allows us to offer fresh and engaged staff for our clients.

CEOCFO: *Why choose Founders Science Group?*

Mr. Munroe: I have worked for over twenty years on the other side of this trying to get service providers to give me the kind of service that companies like this, pharmaceutical companies, cosmetic companies and medical device companies need. About three years ago, I was in a position to have the freedom to start this company and I knew that those services were not being provided with the level of attention that people needed. Having been on the other side, I knew what I needed to provide to my clients to help them to be successful, and in turn, this company would be successful. The three years we have been running, that is exactly what we have been doing. We have been getting great feedback from our clients with regards to our responsiveness, communication, the knowledge base that we provide to them. That is why and how we are doing it and it seems to be working.

