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Issue: January 23, 2017

CEOCFO Magazine

Lyophilization Optimization Services for the Injectable Drug Market

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- Dr. Jeff Schwegman

CEOCFO: ***Dr. Schwegman, would you tell us about AB BioTechnologies?***
Dr. Schwegman: Currently, AB Bio Technologies is a research development group, focusing mainly on the injectable drug market with a specialization in lyophilization or freeze drying. We are a service provider to the industry, and therefore, we do not have any of our own drug products, but we take other people's products and develop formulations or in larger cases, help them diagnose problems with their current lyophilization cycles. We've also worked with companies in the diagnostic and tissue industries in regards to lyophilization of those products.

CEOCFO: ***Would you explain Lyophilization?***
Dr. Schwegman: Most people correlate lyophilization, or freeze drying, with freeze dried coffee. We are doing the same thing with injectable drug products; however, we do it to extend their shelf life of certain drugs that are unstable in water. Basically, we formulate as a solution, freeze the product down until it is a solid, and then create a high vacuum in the lyophilization chamber. This allows us to convert the ice crystals in the product directly to a vapor, skipping the liquid state. The water vapor leaves the product and migrates to a condenser, and what we are left with is a dried solid that is very porous. When a physician is ready to use the product, they just add sterile water and it is back to the original state for injection.

CEOCFO: ***Are there other particular areas where this is important and also areas where it could be used that it has not yet?***
Dr. Schwegman: This technique extends over all different drug types, including vaccines, AIDS drugs, cancer drugs, drugs to treat just about everything under the sun. It is all based on the stability of the molecule but it does not stop there. We have worked with clients to help them freeze dry foods, bio-diagnostic products, tissues, etc.

CEOCFO: ***What are the variables in the freeze drying process?***
Dr. Schwegman: The main variables we deal with in freeze-drying are time, temperature, and pressure. We now use a scientific approach to determining the best temperature and pressure through a technique called thermal characterization. We take a sample and through testing, can determine the glass transition temperatures, eutectic melting temperatures, and collapse temperatures, so we know so much more about the sample when we go to the freeze-dryer. Instead of running 15 to 20 cycles to try to find out what works best, we can develop a fully optimized cycle in three to four runs saving time and resources.

CEOCFO: ***Are companies coming to you because they understand you are a bit more advanced in the field?***
Dr. Schwegman: Yes. There are a handful of people in the world who really understand the science behind it, but many companies try to do it. These companies generally come to us because they have tried to do it and something is failing either in the formulation or the lyophilization process.

CEOCFO: ***You have recently announced expanding your service with pre-clinical manufacturing capabilities. Why now and what does that add for you?***
Dr. Schwegman: I have always wanted to get back into GMP (Good Manufacturing Practices) manufacturing. Now is just the right time; however, it is a very time consuming process as we have to have all our operating procedures in place, training, etc., and all of that documentation has to be GMP compliant. We built the company up on the R&D side, and now we have brought more people on board to help us through this process. It has been a long time coming and has been a lot of work, but to me, it is extremely exciting and our future is very bright as we're going to have a niche in the marketplace.

CEOCFO: ***Would the clients that come to you for the research part come to you for the manufacturing as well or is it a different set of people?***
Dr. Schwegman: That is the beauty of it. This is another piece of the business where I saw there was a need. When clients come to us for development, they always need to go to a facility for their Clinical Trials supplies, and they are always asking us where to go. When a client signs an agreement with you and they are happy with your work, they are more likely going to stay with you throughout the entire process, because it is easier, they trust you, and feel comfortable that you know what you are doing and can meet their needs in a timely, cost effective manner.

CEOCFO: ***How do you reach out?***
Dr. Schwegman: We have just started actively marketing our services. I teach all over the world on freeze drying and formulation, and teach courses, workshops, and webinars and write white papers for the industry on the topics. Up to now, all of our business has been word based on my reputation. Earlier this year, we hired a Business Development Director and she has been great about which trade shows to do, which news blasts to put out, etc. We now work with Sales Force, Mail Chimp and all these marketing things that are a little bit beyond me, but it has been very positive for new business. Small companies who need development services and early phase manufacturing services are looking for a small, nimble company that they can trust. These companies need to move at lighting quick speed as they go through Clinical studies, and we fit that need very well.

CEOCFO: ***How long is a typical turnaround?***
Dr. Schwegman: It is all across the board depending on the client's needs. If we are doing a quick thermal characterization study including DSC (Differential Scanning Calorimetry) and freeze dry microscopy, which give them the starting conditions for freeze drying, we can do that in a couple days for a nominal charge. We have clients all over the board in regards to size. We go from small clients, with maybe two people in the company, all the way to working with some of the major players in the industry. In regards to timing, projects will last anywhere from three days to a year and a half.

CEOCFO: ***Is pricing a factor for your clients? Do they understand that you might have to pay for quality?***
Dr. Schwegman: Absolutely, especially with the smaller guys. They may be working off of venture capital money, and it is very expensive. We have very low overhead, we own all of the equipment, and have no debt, so we can be very cost effective. First time clients will generally give us a small project initially to see how we perform, and then six months later we get an $80,000 project from them.

CEOCFO: ***Are you able to handle as much business as it comes in?***
Dr. Schwegman: We are now starting to feel the pinch a little, and I correlate it directly to the hiring of our Business Development Director, who is bringing in a lot of new business. We are located in a university town with several other pharmaceutical firms nearby. The beauty of that is that when we have a need for additional personnel, there are plenty of talented people that know of us and would like to work for a small, nimble company like ours.

CEOCFO: ***What are some of the challenges in Regulatory that you have learned to overcome or that you can help a client navigate?***
Dr. Schwegman: Being in R&D, we completely fly under the radar of the FDA, but getting into GMP manufacturing will put us right in their sights. It is not my area of expertise, so what we have done is hire a consulting company out of Indianapolis to help us work through those issues. If there is an issue with Regulatory or Quality Assurance, we use them as our experts.

CEOCFO: ***Did you always know that it is a better approach to get people that know expertise in particular areas?***
Dr. Schwegman: I started out doing everything in the company, but it got to the point where I had to look at the quality of life versus paying for someone to take over some of the responsibilities. I have sweated over every employee I have ever

hired, but I think that really shows how much I care about the success of this company and its continued growth. It is tough to let go to let go of certain responsibilities, but in my case, the people I have hired have not been a cold hire, meaning I knew them in the industry or they came very highly recommended form colleagues. That takes a lot of pressure off when bringing them on.

CEOCFO: ***Do you still maintain the teaching, presentations and traveling schedule or are you doing less of that as AB grows?***
Dr. Shwegman: No, I keep up with it, and there are a couple of reasons. Number one, it has been a great source for new clients and number two, I think it gives us a lot of credibility, as potential clients see me out there speaking on the topic or giving webinars as an expert in the field. It makes them feel more comfortable when they come to us that we know what we're doing and they feel safe having us work on their project.

CEOCFO: ***What else is upcoming for you?***
Dr. Schwegman: The GMP manufacturing is our next big thing, and beyond that we're already talking about another manufacturing facility that can make toxic drugs used for the treatment of cancer. This type of manufacturing is very specialized and not many companies do it, so it will be another niche market for us.

CEOCFO: ***Why choose AB BioTechnologies?***
Dr. Schwegman: We are experts in what we do, and we have a great deal of experience. We are a small company, we are nimble, and we can give you a decent price for a high quality product.