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Polymer Science Contract Research Lab providing Routine and Custom Analytical Testing Methodology Development, Product Design, Development and Failure of Medical Devices, Consumer Products and Raw Materials

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CEOCFO: ***Mr. Spiegelberg, what is the focus at Cambridge Polymer today?***
Mr. Spiegelberg: We are a contract research lab specializing in polymer science. We do a lot of routine analytical testing but our real forte is custom analytical testing methodology development, product design and development and failure analysis of devices, mostly in the medical space but we also work in consumer products and raw materials.

"When our clients see the broad scope of what we can offer, ranging from routine testing to consultation, to device development, to material selection and formulation, to risk assessment, to manufacturing issues such as clean line validation, to regulatory approval, they realize that we can assist them during every step of the product development cycle."- Dr. Stephen Spiegelberg

CEOCFO: ***Would you break that down about the areas you specialize in and how you came to focus on those arenas?***
Mr. Spiegelberg: One of the big areas that we have been working on in the past several years is new product development in the medical device field. We might be approached by a company who has an idea for a new permanent implant and needs assistance in developing that product. They will have a set of specifications and we will assist them in the design, material selection, testing protocols for screening and verification of the design and then ultimately for submission for regulatory approval. Then the follow-on studies for seeing how the product is doing in the field will also include training of sales staff and the end users about the features of the new design. We really got into this through the orthopedic industry. We were doing some consultation in testing for hip and knee replacements because we have particular expertise in the polyethylenes that are used in that field. We got to know the requirements for testing and regulatory approval, and in some cases, for failure analysis of the devices that did not work very well. Our experience with materials, testing, regulatory requirements and general engineering allows us to assist clients in every step of the product development cycle.

CEOCFO: ***Are there many changes in materials?***
Mr. Spiegelberg: We are seeing some exciting times with new materials coming into the medical arena. In the past, they have been more standard industrial materials that were repurposed for medical devices. Those have done very well, but

the newer materials we are seeing now are designed from the ground up with a specific application in mind for medical devices. These new formulations may have considerations for controlled degradation of the material in the body, of particular interest for drug release, temporary implants, and materials that mimic the mechanical properties of native tissue. We are currently working on hydrogel-based formulations that try to mimic native tissue such as cartilage, vitreous humor in the eye and the nucleus pulposus in the spine.

CEOCFO: ***So many products and drugs are approved, seem to be good for a while and then a problem is seen. What might be an extra step you take to insure there is as little risk as possible down the road?***
Mr. Spiegelberg: That is an excellent question. One of the key areas evolving alongside of new material development is how we test these novel materials. When a new type of polyethylene for hip and knee is introduced, orthopedic surgeons often ask how this new material is better than previous formulations, and whether it will be safe. Part of my answer is that testing procedures have improved dramatically, allowing for better evaluation of performance and safety. Now in addition to standard mechanical tests on polyethylenes, we know how to do simulated wear testing for hip, knee, and other joint spaces, and we are looking at the way that the material might respond to the body in terms of accelerated aging in a biomimetic type of environment. For instance, how does a satiety treatment device respond to the acidic environment in the stomach, or how will a device sitting in the spinal area respond to spinal fluid? These are areas where we are making some advances in test method development.

CEOCFO: ***Is that with new testing equipment, new technology or knowledge?***
Mr. Spiegelberg: All of the above. And then coupled with that is standardization of those protocols and that is where organizations such as ASTM, ISO, and AAMI are all very active in coming up with standardized protocols for how you test these materials and devices. These are all consensus organizations, so scientists, engineers and regulatory representatives get together and work out the science behind these standards, which helps the industry understand how to develop new safe and effective devices and materials. Cambridge Polymer Group is very active within ASTM and other standard organizations.

CEOCFO: ***You recently announced some new accreditation. Would you tell us about that?***
Mr. Spiegelberg: We received our ISO 17025 accreditation, which is an accreditation that is specific to testing laboratories.

CEOCFO: ***What about the patent for patient positioning?***
Mr. Spiegelberg: Patient positioning came out of discussions we had with an orthopedic surgeon several years ago who had just done a study that demonstrated only around 40-50% of total hip replacement surgeries have the hip cup positioning in the optimal position in the acetabulum of the patient. He felt that a low cost navigation system to guide the surgeon in properly positioning the cup in the hip would help improve those statistics. One of our engineers came up with an idea for a very low cost device that could sit outside the sterile field on the patient but would allow the surgeon to know the exact position of the hip during the surgery to help him or her position the acetabulum much better. We did some proof of concept studies on a really fast timeline. From the initial concept to the actual device verification was around four to five months. We have an issued patent on that technology and some pre-clinical results that look very promising and we are looking for a company to license this technology.

CEOCFO: ***Do clients typically work with you through the whole process or might they turn to you midway?***
Mr. Spiegelberg: We will often start working with clients when they have a problem. They will come to us with an issue in the field - use of a device or during manufacturing of the device. We will help them solve that problem, and then once they see how we work, they will start to bring us in more and more projects, typically earlier in the process of a medical device design or development.

CEOCFO: ***Are you looking to expand more in the arena outside medical devices or is that just if it comes your way?***
Mr. Spiegelberg: We perform food-contact analysis - people often forget the first letter of FDA stands for “food”. A lot of the testing that we do in the device or the medical area also translates to food-contact products, with some different requirements but the same sort of testing of leachables and extractables of plastic packaging into food products etc. We are also doing more work in pharmaceutical testing because we see that as a very large growth area, especially pharma coupled with medical devices or what are commonly called combination products. Having the ability to test both the medical device as well as the drug side of a combination product is very important.

CEOCFO: ***How do you navigate the waters when someone comes to you, having created a device and they are somewhat in love with their idea. Perhaps they do not want to hear suggestions or critique?***
Mr. Spiegelberg: They do. They get married to an idea and they cannot move beyond it. We are not always successful in getting our positions across to our clients. However, the folks that we are working with are scientists and engineers who have a fairly unjaundiced view of reality and if we present things in a logical manner and demonstrate what is known in the field, through publications, guidance documents and regulatory agencies or from our own experience, they will often recognize what needs to be done and modified. Sometimes it might not move forward because of cost considerations and they may decide it is not worth it, but often times they will move forward with those suggestions.

CEOCFO: ***Over the years, you have worked on so many projects. What stands out as exciting?***
Mr. Spiegelberg: One of the more exciting areas that we have been working on are tissue phantoms. These are the devices and materials that we make from hydrogel formulations. Hydrogels are a form of polymer that contains a large quantity of water and they operate well as tissue mimics because a lot of the tissues in our bodies are hydrogels as well, such as muscle, fat, cartilage and vitreous humor. We will make constructs out of our hydrogel formulations that mimic specific properties that a client might want such as the cutting behavior of a lesion in an artery or the elastic properties of annulus fibrosis. With these mimics, they will either train their sales staff or the surgeons they are selling their devices to by doing demonstrations in their offices with these tissue mimics, or they will test out new designs of devices in a tissue replicating system. Previously, they would have done this in an animal model. The downsides of that are the ethical concerns, costs and the fact that any animal tissue is going to go bad after a very short period of time, just a couple of days, whereas our tissue models can last for years. We are seeing a lot of exciting movement in that. We have been making some fantastic models for clients that are getting more and more complicated. Our latest is an eye model that is disturbingly realistic-looking.

CEOCFO: ***How do you reach out to people who may not know Cambridge Polymer?***
Mr. Spiegelberg: We have been actively working on our marketing strategy for the past five years. We have booths at trade shows and we pride ourselves in the fact that we have no dedicated business development people. All of our sales and business development people are scientists so that we can do problem solving on the fly for clients that we meet at trade shows or who cold call us. We find that a very effective approach. We also have a very active social media program where we do testing of systems that are of a current topic. Recently we did an analysis of chemicals that might be off gassed from basketballs to see if March Madness could be explained by a chemical response to new basketballs.

CEOCFO: ***Why choose Cambridge Polymer Group and what might people miss about the company?***
Mr. Spiegelberg: Often times our clients are surprised to hear the breadth of our offerings, particularly if they have only been working with us in one area. When our clients see the broad scope of what we can offer, ranging from routine testing to consultation, to device development, to material selection and formulation, to risk assessment, to manufacturing issues such as clean line validation, to regulatory approval, they realize that we can assist them during every step of the product development cycle. We will often get calls from existing clients who have no idea if we can help them but they do not really know who else to call, so they give us a ring. I would say sixty percent of the time, we can give them some assistance on their issue.