CEO CFO

PharmaSys COMPLIANCE SOLUTIONS

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Specializing in Compliance and Validation for FDA, EMA and Health Canada Regulated Industries, Quality Consulting Company PharmaSys, Inc. is helping Small, Startup Biotechs bring their Drugs and Medical Devices through Registration and Regulatory Processes and Get them to the Market

Healthcare
Quality System Consulting

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Charles Lankford
CEO

BIO:
Charles Lankford is CEO and co-founder of PharmaSys, Inc. With headquarters in the Research Triangle Park area of North Carolina, PharmaSys provides life science consulting services to the international community of pharmaceutical, medical device, biotech and clinical research firms. Services include GxP auditing, quality system design, process development, validation, compliance, commissioning, NDA/ANDA support, 510(k) support and BA/BE study support.

In his current role, Mr. Lankford provides strategic direction for the company and acts as a senior auditor/consultant. Charles has served as validation project manager for a multitude of projects and has performed numerous compliance audits of laboratories, clinical research organizations and manufacturing facilities. He is s recognized as an authority in the fields of validation, FDA regulations, BE/BA studies and quality assurance; is a frequent lecturer at professional societies and universities; and is a contributing author of Clean-In-Place for Biopharmaceutical Processes and Computerized Systems Used in Non-clinical Safety Assessment, Current Concepts in Validation and Compliance.

Before forming PharmaSys, he served as Senior Director of Information Technology for Insite Clinical Trials. Previous assignments with Lockheed Missiles & Space Company, Johnson & Johnson, Burroughs Wellcome and Glaxo Wellcome have contributed to over 30 years of experience in the engineering and compliance fields.

He holds a BS in Electrical and Computer Engineering from the University of Alabama in Huntsville and has continued his educational experience through professional development programs at Duke University, ASQ, ISPE, DIA and PDA.

About PharmaSys, Inc.:
PharmaSys specializes in compliance and validation for FDA, EMA and Health Canada regulated industries. Headquartered in Cary, North Carolina, near Research Triangle Park, PharmaSys provides qualification, validation and compliance in the R&D, clinical, pre-clinical, manufacturing, distribution and post-market surveillance. We specialize in computerized systems, pharmaceutical equipment, facilities, utility systems, manufacturing systems, and laboratory systems.

In operation since 1998, PharmaSys has developed a reputation within the industry as a world-class firm that provides superior service. With experience across North America, Europe, and Asia, PharmaSys has the in-depth knowledge and experience needed to conduct qualification, validation and compliance projects across the globe.

With years of experience in the pharmaceutical industry, each PharmaSys professional brings unique abilities to each engagement. Our goal is to work directly with industry leaders, providing unparalleled service and support.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Lankford, how would you describe PharmaSys today?
Mr. Lankford: We are a company that helps pharmaceutical companies, biotech companies and clinical trial organizations comply with FDA and foreign regulations related to drugs and medical devices. By FDA regulations, I mean the Federal Food, Drug and Cosmetic Act or Title 21 of the

Code of Federal Regulations. We are not attorneys. We help them technically. There are regulations called good manufacturing practices, good clinical practices, and good laboratory practices. We help our customers put these systems in place and manage them. Basically we are a quality system consulting company.

CEOCFO: Are there many companies in that specific arena? What is the competitive landscape?

Mr. Lankford: There are a few companies that offer our services and they're spread across the country. Most are quite small, in the 10 to 100 employee range. Most have a core group of management personnel on staff and hire jobbers to complete their projects. I do not believe in that model because jobbers do not have a vested interest in our success and they tend to move on to new projects before the current projects are completed. We use staff employees. We also compete with large engineering firms that do our work as a sideline. We compete with independent jobbers who work in the industry. Validation is actually the testing and putting the documentation together to test, not the drugs, but the equipment and systems that are used to make drugs, develop drugs, distribute drugs and track information about the drugs. When I say drugs, I am including medical devices, nutraceuticals and to a lesser extent, cosmetics. There is quite a bit of competition in our geographical region, Research Triangle Park, North Carolina, because we are in one of the top biotech areas of the country. There are many people who do this type of work from a validation viewpoint. However, from a compliance viewpoint we have just a few competitors. Typically, the competitors are individuals who have retired from the industry, or from regulatory agencies.

CEOCFO: Do most potential customers realize that they should be checking the compliance and that they need a firm like PharmaSys or are is it still somewhat not as well understood?

Mr. Lankford: Most of the established firms do have an understanding of what they need to do to stay compliant and bring their drugs to market. By established firms, I mean large pharmaceutical firms and the established biotech firms. The people that do not understand that they need firms like ours to help them are the very small, startup biotechs that generally come out of academia. They are scientists and aren't always familiar with compliance issues, what it takes to get a drug to market and the registration of the drug or the medical device. This is where our expertise can help the most. There are also foreign entities that want to market drugs in America that do not understand what it takes to get their drug to market and get through the FDA inspection process. Those companies know that they need help and contact us.

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- Charles Lankford

CEOCFO: How do you reach potential customers? How do you get them to know about you and to understand the need for the services as well?

Mr. Lankford: One of the main ways is through word of mouth. We have built a solid reputation over fifteen years in the business. Our potential clients hear of us from other people that they know in the industry, or possibly, a person who may have used our services with one company has gone on to another company and they bring us into that company. Secondly, there are professional society conferences and trade shows that we attend. We attend three or four national shows every year. Thirdly, we present on technical and compliance topics using various media. We are presenting a web seminar this spring on thermal validation and a technical presentation this summer on validating web-based software at the DIA Annual conference in Boston. Another way that we reach out to potential customers is our presence on the web. People who may not have heard of us, or it is not cognizant to them that they have heard of us, will do a search on a topic and we will show up on the search. We may have written a white paper or we may have a presentation posted on the web that directs them back to us. We are currently experimenting with social media, which takes a lot of effort to manage. The average CEO, CFO or CSO does not have a lot of time to look at social media sites so we are not seeing the results that we would like. It is a long-term process to build the brand. Over the last fifteen years potential customers have seen the name PharmaSys show up again, again, and again. Then, when they do an Internet search on one of our services, we show up and it rings a bell with them. As long as we give all of our customers a positive experience, we are good. It only takes one unhappy customer to offset ten happy customers. We guard our reputation very closely.

CEOCFO: How do you keep up with the trends, the new regulations, the changes, the potential changes?

Mr. Lankford: We continually research what goes on with the FDA. We go to society conferences, particularly those where FDA and foreign regulatory agencies speak. The FDA has a great website. It is www.FDA.gov, and anyone can go to it and find out anything that they want to know. The FDA is very open about sharing information with the public; everything from what drugs or foods may be on a watch list or are to be recalled, to potential wrong doers or problems in specific areas. Staying current takes a lot of research and we spend some time every day looking at current events related to our industry. One of the great things about being a consulting company or a company like ours is that we get to go see many different customers and we see the trends in the industry. Not just

what the regulatory bodies say, but what the operating companies do in the industry. It is a constant learning experience, to be honest. If we do not stay up on it, we will fall behind the times and will not be relevant anymore. It is a lot of research.

CEOCFO: What are the skills and the intangibles you look for in your people? What do they need to do the right job at PharmaSys?

Mr. Lankford: That is a good question. First let me say that our employees or our employee pipeline are the most important assets that we have. It is what differentiates us from our competitors. But employees are more than assets, they are people as well. Loyalty to our employees and, in turn, loyalty by employees to the company is everything to us. A competitor told me just the other day that he viewed our industry and his company as a "revolving door for employees". I do not see it his way. I want to retain and develop talented employees and stand behind them. I sleep better at night thinking like this. The perfect employee is someone who has spent five or six years in the industry, basically working for one of our customers in various technical service roles. It could be engineering. It could be operations, where they are actually supervising the manufacture of the drugs. It could be in quality assurance or product development. Potential employees need to have some experience in the validation area, basically testing manufacturing or information systems. Ideally, we would like engineers, but we have a wide variety of people who have other industry experience. One of our best people has a forestry degree; he spent twenty years in the telecommunications industry before he came to us. I would say that follow up and professional service, with an understanding to be able to break down a complex problem into a series of simple problems, put simple solutions in place and then combine those simple solutions back into a complex solution is one of the most valuable aspects of the job.

CEOCFO: Would you give me just a brief example of how the process works? A company comes to you and says "this is what I need." How do you do what they want?

Mr. Lankford: A company will call us and tell us they think they have a potential problem. We will deploy one of our consultants to visit the site, wherever they are, to understand the problem. We then write a proposal for our services to remediate the problem. The process can vary from us going in and developing the plan for their validation program, or we can do the whole project turn-key meaning we will perform an evaluation of the problem, develop a remediation plan, execute the plan and represent them in front of the FDA to defend work. Sometimes the potential customer will issue a request for proposal to several companies, we will bid on the work, the company will reduce the number of bidders to a short list, we may then get a chance to provide a presentation outlining our approach and benefits and finally a contract will then be issued to the winner. Large companies often require that we are approved vendors before we even get to bid. On average, an engagement lasts six weeks, sometimes longer. We have an employee doing validation of equipment at a biotech company who has been traveling from Atlanta to the Bay Area for six months now. We have just re-engaged her there for another six months. This engagement is for supplemental staff support. I will give you an example of a cleaning validation project. Cleaning validation is done to make sure that there is no "carry over" of one drug to another drug, or any harmful substances from cleaning solutions in the next drug manufactured in a piece of equipment. For instance, if a company makes aspirins and also makes codeine, they do not want codeine in their aspirin. The company COO, who is already a customer at another site, called us on the phone and asked if we can help them revise their cleaning processes and cleaning validation program to reflect the best current industry practices. We had a couple of telephone calls, visited the site and we are currently working on the project. It will take three to six months to complete all of the activities. In another example, we are subcontracted by one of our customers; another private company, to perform FDA compliance audits for the NIH, the National Institute of Health, of clinical manufacturers of potential vaccines for the AIDS Virus, or HIV. Typically, they will obtain a task request from the government, they will then send it to us and other firms, and we will respond with a proposal. They will select the final auditors that are best qualified from the pool of consultants and award a task order for the audit. If we win the task order, we will contact the company that we are auditing, gather the information, have a pre-audit meeting, and go do the audit. It is not a financial audit; we are evaluating the entire manufacturing and distribution processes to confirm that they comply with good manufacturing practice. We make a determination of their compliance at that point, and then we write a report that includes suggested remediation points and give it to the client. The client will then give it to the company that we have audited and distribute it to the NIH. I guess I am saying that each engagement process differs from one client to the next and from one situation to the next. The larger the customer, normally the more steps it takes to get and start the job. We pride ourselves on rapid deployment and do everything possible to get through the process quickly to meet the client's needs and their timeline.

CEOCFO: How is business these days?

Mr. Lankford: The recession has been a challenge but business is good for us! We are a small company, and to be honest, I do not want to jinx us, but our business model is almost recession proof, as long as we do not get too ambitious and try to grow too large, too quickly. We have been very fortunate through the years. We have been blessed to work with good people and have good clients. Another reason I believe we are almost recession proof is that during hard times our client companies lay people off. They reduce their workforce to the point where they do not have the people to run their business. When that happens, they use our services to continue to operate. They see us as a workforce that they can get rid of

when they do not need us. When business is good our client companies are generally building new manufacturing plants, expanding their older plants or changing their plants around to manufacture different drugs than what they are already manufacturing. This requires equipment upgrades and validation testing as well as compliance work. Our clients usually do not have enough people to do the extra work, because they have gone lean in the past years. They cannot scale up with the necessary expertise to bring their new plants on-line quickly and get approval as fast as PharmaSys can deliver it; so they hire us. Once the projects are done and the workload is reduced to a steady state, we go on to another company and they do not have to hold highly paid specialists on their books for routine operations. Basically, we are like 'Shock Troops'. We are a rapid deployment organization.

CEOCFO: Why should investors and people in the business community pay attention to PharmaSys? What makes you an exceptional company?

Mr. Lankford: That is a good question. We have a high level of expertise, and a high level of commitment. We believe that experience counts in our business. We run our business in a stable manner. We have not grown too fast, but we do take opportunities to grow. I would say that it is the management and the people. The reason that they should pay attention to us is that we have been around much longer than most companies like ours in our business space. For some reason other similar companies seem to come and go every seven or eight years. We are celebrating our fifteenth anniversary in July under the same management and ownership. We provide a top service. Our customer service is second to none. We help companies maintain a safe product, and we are proud of what we do. On another note, I would like to comment on the relationship between small companies and large companies that they do business with. For the relationship to work, it has to be a win-win situation. To truly provide long-term value to the larger company, the smaller company has to stay healthy and turn a fair profit. That means that the larger company has to use fair business practices when dealing the smaller company. Our best customers know this and do not use their size as a bullying point. They pay us a fair price for our services and expertise, have reasonable payment terms and pay their bills on-time. They are also loyal to us and do not usually go to a competitor over a few dollars. On the other hand, some of the larger companies do not really understand the relationship. They tend to be price driven and do everything possible to get a lower price even to the detriment of the smaller company. They also force long payment terms and tend to do everything possible to not pay within the contracted terms. They sometimes give themselves discounts and they simply refuse to pay late payments because of their size. If we litigate, we risk losing all of our business with them so we capitulate. Fortunately, we have been blessed with enough good customers to off-set the bad.
