CEO CFO

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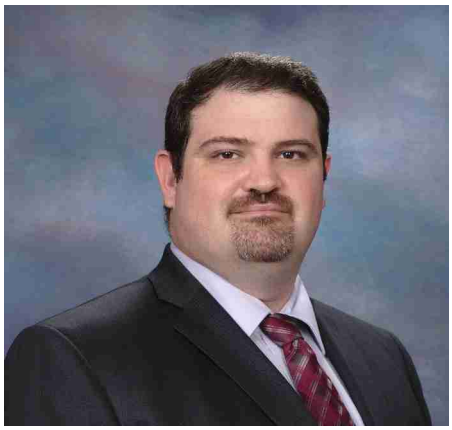
As a Regulatory Electronic Publisher for Pharmaceutical and Biotech Companies, Aquila Solutions, LLC is putting together All of the Paperwork Necessary for an FDA or EU Presentation of Biologics, Sterile or Combination Products



Joshua Boutwell
CEO

BIO:
Josh Boutwell, MBA, RAC brings over 15 years of experience in research, IT and regulatory affairs to Aquila. He received a BS in Biology from Georgia Tech as well as an MBA from Georgia State. During his career he has conducted research at CDC and Emory University and worked in the Regulatory departments of several companies before starting Aquila. He has worked on or managed over a dozen initial applications and thousands of eCTD sequences.

Josh founded Aquila Solutions in 2010 to assist small companies as well as any other sponsor who needs help to reduce the cost of publishing their application and to win approval for their product. While working for pharmaceutical and biotech companies Josh noticed that many small companies did not have the experience or resources to publish their own eCTDs or other electronic regulatory submissions effectively. He created Aquila and structured it to help small companies while still having the resources to support even the largest company.

About Aquila Solutions, LLC:
Aquila Solutions is a US-based company that specializes in electronic publishing for regulated products. We have successfully published applications for biologics, sterile products and combination products.

Technology
Electronic Regulatory Publishing

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Boutwell, would you tell us about Aquila Solutions?
Mr. Boutwell: We do regulatory publishing for pharmaceutical and biotech companies. Basically, it can take a decade or more for a company to develop a product—like a new pharmaceutical drug or vaccine; and if you are going to take a decade and spend hundreds of millions of dollars you have to have a lot of paperwork to prove it. What we do is take all of that paperwork and get it put together in a way that the FDA or the EU or anyone else can review quickly and come back hopefully with an approval.

CEOCFO: Is it common in the industry to use an outside source to put all of this together, particularly for the small and medium companies?
Mr. Boutwell: Absolutely. It is actually very common because it can take a lot of resources to set up an internal group. Small companies especially do not often have those sorts of resources to spare. Even large companies may plan to have a group that functions for day to day things but it can take several extra people to handle a major new products and may not want to keep on staff at all times. You typically need to get a project done within a few weeks to a few months. Aquila speeds up the publishing time while saving money for the sponsor

CEOCFO: Are you able to automate it? Are there programs or technology that put some of that together for you?
Mr. Boutwell: There are some. Most of the data is put together in Word documents and converted to PDF. The primary application for a brand new drug can be three hundred thousand to a million pages of PDF documents where you need to link together related content. If I am in one document and discussing the results for a study, the reviewer will need a link to go to that study to verify that the content is actually there. So a lot of the work is to just go through those hundreds and hundreds of thousands of pages of documents and make sure

that everything is internally consistent and correct. There are some tools that can help automate it, but there are not many since it is very contextual. Between the writing styles of different medical writers and different sources of information, there is no real software that is smart enough to be able to do that, and so we have to rely a lot on our own trained people to be able to go through and actually identify where the link should go.

CEOCFO: How do your people really stay alert and able to pay attention? It seems to be very tedious and maybe somewhat mind numbing.

Mr. Boutwell: Really, that is the significant challenge, and honestly from an internal staffing perspective, the single hardest thing to find is someone who can sit down and work for eight hours a day. That is a rare person. It also takes a lot of training and practice to be able to sit still and read through 400 pages an hour, hour after hour.

CEOCFO: Does the person who is doing this need the medical knowledge or training to pick out the right things?

Mr. Boutwell: When I am recruiting—now, most of the people I recruit tend to be either straight out of college, or in many cases still in college, and I look for someone with a science background; it does not have to be biology, but I do prefer biology or chemistry, and that is so that I know they have the science vocabulary to be able to essentially identify which words are important. I then will train them on how to pull out the information from the page most efficiently, and where it will go and how to create the links and everything like that. I do employ people with IT backgrounds, and actually one of my senior people has an international affairs background. I do not require a science background, but I do start there.

CEOCFO: How do you reach potential customers?

Mr. Boutwell: Just recently we attended the Drug Information Association (DIA) annual convention. We also are developing some programs to help sponsors, the owners of the products, use their applications more effectively. A few days ago we launched freeware viewer software which is currently available on our website at www.aquilasolutions.us/ectd-accelerator. That is our primary method of reaching potential clients.

CEOCFO: What is the competitive landscape?

Mr. Boutwell: There are a couple of very large competitors, and these are companies with several hundred to a thousand production people. Then there are a lot of companies that provide other support to the pharmaceutical companies known as CROs (clinical research organizations). A lot of times they may have an internal group that can do parts of the publishing. And then the largest single type of competition is actually consultants who advertise the service on their website, but do not have much of a background. It is very easy to list as a capability; it is much more difficult to do it well. There are two or three other companies that I am aware of that are like mine which are dedicated to this specific function.

"Aquila is an exceptionally flat company, meaning that while our competitors end up having project managers with one or two years experience, our managers have a minimum of seven years experience, and more often ten. The people who are managing the project have a lot more background in what can go wrong, and how to present things correctly which speeds the publishing time and saves our clients a lot of headaches."- Josh Boutwell

CEOCFO: When you speak with a potential client, what is the 'aha' moment? When do they realize you really can do it better, and that it is a focus for you?

Mr. Boutwell: It really varies from client to client. For instance, last January the FDA released a guidance document that essentially said, "When this becomes active we will not accept paper anymore. Everything has to be electronic." A lot of sponsors that we speak to are very nervous about this mandate because they perceive that it will take three hundred thousand dollars worth of software and a staff of five to be able to implement this. But at a recent conference we put together a small CD that has everything a company needs to go from paper to electronic. A lot of times the big 'aha' moment is when we can demonstrate that publishing in paper and mailing it in is dramatically more expensive than pretty much any electronic method; despite the perception that it costs more to set up electronic in the beginning. A lot of times, that is the real 'aha' moment. Then we mention that Aquila Solutions provides a free small sequence to new clients.

CEOCFO: Your website talks about consulting, is that a big portion of what you do? Is that a growing portion?

Mr. Boutwell: It really depends on the client. A lot of our clients end up using some of our consulting services, along with our publishing services. A lot of people do not have a good understanding of how to set up their drug applications; the best way to control the documents and to get things pulled together with a minimum of labor. So they will come to us wanting help with their application—actually assembling it and getting it ready for the FDA, and while working with them we will point out or demonstrate ways that they can improve. A lot of times they will expand the contract to include helping them set up their own internal systems.

CEOCFO: What surprised you most as the company has developed?

Mr. Boutwell: Honestly, the difficulty in finding people. Like I said, it is hard to find people that are able to look at this stuff for hours at a time, day after day.

CEOCFO: How is business today?

Mr. Boutwell: Actually, it is pretty good. We have signed on a couple of new clients with some really exciting projects, and we are always looking for more business. We are actually

very pleased with how things are growing right now.

CEOCFO: What is the genesis of the name Aquila?
Mr. Boutwell: Actually, the real genesis is my wife is a bird person. She loves birds. When I was trying to come up with a name—we are an electronic publishing company, so my mind was circling around writing implements and things like that, and I thought of quill, and then Aquila stuck in my head which is the constellation, and is actually the eagle that Zeus used to bring his lightning bolts into battle from Greek mythology. So I made my wife happy, and I have a tag in with writing implements!

CEOCFO: We do speak with many companies in drug development and a fair number of CROs as well as have readers in the business and investment community. Why should they consider Aquila Solutions?
Mr. Boutwell: The biggest case for Aquila is that we are actually exceptionally competitive, especially for small pharma. Just on a price point, we end up generally costing about 20% less than a lot of our larger competitors. The primary reason for that is that we are a dedicated company with very little overhead. We can afford to ask for less and still provide the high quality product that you need. Aquila is an exceptionally flat company, meaning that while our competitors end up having project managers with one or two years experience, our managers have a minimum of seven years experience, and more often ten. The people who are managing the project have a lot more background in what can go wrong, and how to present things correctly which speeds the publishing time and saves our clients a lot of headaches.

CEOCFO: Final thoughts?
Mr. Boutwell: The one thing I just want to make sure everyone is aware of is that we are releasing a freeware eCTD reviewer. This is actually the only specialized software that a sponsor needs to be able to utilize eCTD in-house. This is the one piece of software that does not come preinstalled on every single computer in the world. Up until now, this type of software has been available for a ridiculously high price point. The cheapest I found was $500 per person per year, with the most popular being $30k per company. We are providing a very fast and very small viewer as freeware off of our website.

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Free Your Data to Speed Your Review

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