ceocfointerviews.com

Issue: June 4, 2018

CEOCFO Magazine

Q&A with Christopher Rush, President of FDA Quality & Regulatory Consultants LLC providing Specialized Quality and Regulatory Consults with Global Experience for Pharmaceutical, Medical Device and Biotech Companies

Christopher Rush
President

FDA Quality & Regulatory Consultants LLC
www.fdaqrc.com

Contact:
Christopher D. Rush
(866) 400-8996, ext 700
chris@fdaqrc.com

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

"The work we perform has a direct impact on the approval of life changing medicines for the global population."- Christopher Rush

CEOCFO: ***Mr. Rush, what is the idea behind FDA Quality & Regulatory Consultants, LLC?***
Mr. Rush: FDA Quality and Regulatory Consultants was founded to help customers solve problems through a collaborative risk-based discussion with quality assurance oversight, regulatory affairs strategy and compliance support. FDAQRC has two customers, our clients and our consultants and without one, we would not have the other. Customer Service is our number one focus at FDAQRC.

CEOCFO: ***What are some of the challenges in all of the areas that you address?***
Mr. Rush: I would say that the challenges that we face is the globalization of work. The industry that we work in has become much more globalized and so there is the need for harmonized application of regulations and quality oversight throughout all processes. From early clinical development through post commercialization, there is the need for quality in every step. One of the biggest challenges that we face is companies that do not have a quality plan up front and through inspections by regulators or customer complaints, they become aware of a major problem. Then we come in and help with remediation actions and preventative planning. It would more efficient with improved quality and risk reduction to plan ahead.

CEOCFO: ***Are you surprised that companies do not have a quality program in place, and that it is not general knowledge that you should?***
Mr. Rush: I am surprised that there are still companies out there that do not think about risk assessment, quality and regulatory strategy along the way! I think it has certainly improved, but there are still certain geographical regions, where quality is seen as a cost center, and the need for quality assurance or quality oversight is not a high priority. Sometimes you get lucky and these values are implemented from the top-down, but more often than not, an issue arises. The price of implementing quality at the beginning could have saved a company, not only the bottom line, but heartburn and other regulatory issues that pop up down the road.

CEOCFO: ***Would you walk us through a couple of typical examples of different instances when an organization might turn to you and how you have made things easier for them?***
Mr. Rush: My best-case scenario for opportunity would be for someone to come to us early on in development. Once the investigational product has passed through R&D, we can develop a quality plan around the transfer from the laboratory to

the clinic. We can help them understand where they need to start the quality process; that quality should be implemented through the whole phase of development.

One of the big things that global regulators have really grasped on to lately has is vendor oversight. Many companies are completely virtual these days without a comprehensive staff. There might be a couple of staff members that are overseeing all of the outsourced work. However, we have definitely seen an increase from global regulators in their oversight requirements and what their expectations are. Therefore, if we are brought in early on, we can help the company develop that vendor oversight program and build in quality expectations based on the identified risks in the beginning. Then, as the company is moving through the clinical phases of research, we can implement the risk-reduction strategy.

In addition, we perform a number of quality remediation projects. For example, company may have a known quality issues, either identified during an global regulatory inspection, during an internal review or through a customer complaint. At that point, we will come and help them fix any problems that has been identified.

Our typical project is a non-financial audit, although we assist with the development of quality systems and processes as well.

CEOCFO: ***When you are crafting a plan for a company what might you look at that less knowledgeable people in your industry would not take into consideration?***
Mr. Rush: Typically, when a company is ready to submit an application to a regulator, they will want to perform inspection readiness activities. For a late phase research study, the industry standard is to look at the number of high enrolling sites for a site inspection readiness audit. Where we have seen greater impact to expand our scope to not only review those sites that have the highest enrollers, but also those sites that have a high number of drop outs or other outliers that might show that there is something amiss. We tailor our projects to each individual client as each situation is unique. This industry is not a one size fits all solution.

CEOCFO: ***Would you tell us about your global reach and how you serve people worldwide?***
Mr. Rush: The work we perform has a direct impact on the approval of life changing medicines for the global population. Patient safety plays a significant role at FDAQRC.

Regarding our global reach, we have a network of approximately three hundred and fifty global consultants. We work with these independent consultants on a routine basis as they are familiar with the local language, customs and regulations in the region. Our independent consultants are vetted and on-boarded according to our rigorous quality management system. We utilize an electronic system (FDAQRConnect) internally for resource identification, but FDAQRConnect also functions as a tool for our clients to review our resources background and location. Our clients can read the bio sketches of qualified individuals. We have individuals throughout the globe that we can utilize when and where we need them. The primary reason for is to keep the cost down since it is more cost effective to use a local consultant than flying someone from the USA. Aside from keeping expenses down, it also allows that individual who has knowledge of the local regulations, local culture and local language, to conduct a better review of the information that is in that region or country. Last year we conducted audits in fifty-six countries; the US plus fifty five others. For the majority of those audits, we used individuals that were in those countries.

CEOCFO: ***What has changed in your approach over time? What have you learned as FDAQRC has been around?***
Mr. Rush: We have learned the value of our project managers. We have five full time project managers here at FDAQRC. The project managers are ex-FDA employees or industry professionals. They have been in the industry for at least 10 years. They are all home based, non-travelling employees. Their responsibility begins once the contract is signed. They are responsible to follow the project through to the deliverable phase. They are the first point of contact for our customers. The project managers are not on the road conducting audits. They are in their offices working on projects, helping our auditors with logistics, reviewing deliverables and helping clients with general consulting question. We have really put a big emphasis on finding not only the right personality, because it does take the right personality for someone to be in this role, but also having the right experience and the ability to manage multiple projects at one time, manage multiple personalities, and multiple timelines. In addition, we want someone that enjoys the work that we do, enjoys talking about quality and talking about regulations. It definitely takes a special person for that.

CEOCFO: ***We came upon FDAQRC at Interphex 2018 and we know you do a lot of conferences. How do you stand out at conferences when there are many companies looking for attention?***
Mr. Rush: First and foremost, we are very aware of our brand and the need to stand out in the crowd. Our marketing is very coordinated. All of our marketing material, our swag, our booth have the same theme and tone. We receive more

compliments on our brand and it is a good way to bring people in to the booth, because at some conferences, we can be one of a dozen or more quality consultancy firms. Therefore, having a very professional and polished look, and having a very consistent message can be a definite draw during a conference. Besides Interphex 2018, we exhibited at four other conferences in the last month. We try and involve the entire FDAQRC team. We are all very consistent on our message. We know what our capabilities are. We are always continuing to improve in what we can offer, but our core values are very customers service focused. We have very strong ethic morals and we treat our customers with respect. We at FDAQRC have two customer types. We have the clients who are the sponsor companies, who are vendors, who are CROs and government agencies. Then we have our consultants. Those are those individuals that, for the most part, are doing the work for us. Without one of the other, we do not have much of an offering.

CEOCFO: ***Do companies come back to you repeatedly for different products or perhaps for regular reviews on their facilities? What are the engagements like?***
Mr. Rush: We have seen a definite increase in repetitive business in the past two or three years. We still have new clients, however, over the last couple of years, where we have seen the most growth has been through companies that we have worked with and developed a relationship with over the last several years. These clients are coming to us and they are telling us, “Each quarter, we will have this many audits and would like you to conduct them” or “We are introducing new clinical study and we know we need these audits done and we need this work done.”

This has really helped us to grow FDAQRC. It is still important to get out on the road and meet new clients, although these trips tend to lean towards managing client relationships as opposed to making new relationships.

CEOCFO: ***What is next for FDA Quality & Regulatory Consultants, LLC?***
Mr. Rush: We are looking to expand our service offerings further into manufacturing and pharmacovigilance audits. We are also looking to grow both organically and through a possible acquisition in the US or possibly Europe. We have a number of other initiatives that we are working on, especially around our computer systems, to enhance the offering that we have with our clients.

CEOCFO: ***What is the takeaway for our readers, many of which are in health? Why choose FDAQRC?***
Mr. Rush: With FDA Quality & Regulatory Consultants, you will get quality from the top down. I have worked at the US FDA conducting field inspections. I worked in pharmaceutical companies and I worked with CRO companies. The vast majority of our employees have worked in a quality organization, either in the laboratory, the manufacturing floor or clinical site. They understand the language. They can all talk the talk and walk the walk. We have a great relationship with our customers, both the consultants and the clients, and we understand their goals and objectives.