

EHS Services for Biotechnology, Pharmaceutical and Medical Device Industries



Dean Calhoun - CEO

About Affygility Solutions

Since 2002, Affygility Solutions has provided environmental, health and safety services to the biotechnology, pharmaceutical, and medical device industry. Our services include the Affytrac EHS management tool, online training seminars, potent compound safety and categorization, occupational exposure limits (OEL) and acceptable daily exposure (ADE) values for active pharmaceutical ingredients, toxicology services and more. We've provided these services to small, mid-size and large companies throughout the world. All of the environmental, health, and safety professionals at Affygility Solutions have many years of professional and hands-on life science industry experience.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

CEOCFO: Mr. Calhoun, what was the concept when Affygility Solutions began and where are you today?

Mr. Calhoun: The concept when the company began is going to be a traditional environmental, health and safety (EHS) consulting practice. What I found out along the way was that consulting in and of itself is not a scalable industry. When I mean scalable it means how do you grow top-line revenues without growing your employee base significantly. There are many ways where you can grow to quite a sizeable company without having to hire a bunch of difficult to manage and expensive headcount. You can

do that through the use of technology and you can do that with low overhead. While we still perform, and always will perform some traditional EHS consulting, we have evolved more to a digital type of company where we deploy many of our services and offerings to our clients through digital technology.

CEOCFO: What services are you providing?

Mr. Calhoun: We focus primarily in the life science industry, which includes pharmaceuticals, biotechnology and medical device companies. The types of services that we do are webinars on potent compound safety, which is how to protect employees from potential occupational hazards in manufacturing pharmaceuticals. We also have a software product that helps the client manage all their occupational safety and environmental requirements. One of our offerings in which we are really quite proud of is a service called OEL Fastrac. This is an online service where people can go and search through our catalogue to find occupational exposure limit (OEL) and acceptable daily exposure (ADE) value monographs. They can order the monograph online, pay for it, and download these high-quality documents that describe the potential occupational hazards of some of these active pharmaceutical ingredients, and for approximately 1/10th the cost of having it done through a traditional consulting practice.

CEOCFO: Are there many companies with similar offerings or is it still unique to be much more digital and provide so much information?

Mr. Calhoun: We are unique in the digital offering. There are quite a few traditional consulting firms that perform it traditional way. What we have found is that trying to scale consulting is extremely expensive and inefficient, and that the only way to grow a consulting practice is to perform more billable hours. The only way to do that is to hire more headcount, unless you like working eighty hours a week which most people do not desire to do or can't do for an extended period of time. We are always looking at how we can take this to scale, meaning how can we grow our business and offering and add hundreds of more clients without hiring additional headcounts. That is what we constantly what we are looking at. In order to do this you have to have smart people, and you have to have people that understand technology and people that disruptive business models.

CEOCFO: How do you reach prospective customers?

Mr. Calhoun: Much of it is through online, email marketing and through other types of digital marketing. We also speak at traditional conferences. Fortunately for us most of the clients find us through word-of-mouth – they love our work and tell their colleagues.

CEOCFO: Are there typical companies that use your services?

Mr. Calhoun: We have some clients that are only ten person companies and we have some clients that are major multinational companies. We have clients all over the world and many of them I've never met, but that is the beauty of it being largely a digital offering is that we are able to deploy those throughout the world without having to spend a lot of time traveling.

CEOCFO: Are people using one service at a time and are there overall packages of services?

Mr. Calhoun: They may find us through a webinar and use just the webinar. Then once they have attended the webinar or bought one of our documents, then they may realize that they need some additional services such as onsite services to help them understand how they can control exposures to these compounds. In that case it becomes a traditional consulting project. It greatly depends on the need of the clients; some clients will buy one document from us and we do not hear from him again and others will continue to use the service over and over again. It just really depends on the need of that specific company.

CEOCFO: Would you tell us about the research on your end to provide all of this great information?

Mr. Calhoun: We have PhD occupational toxicologist and myself, an American Board of Industrial Hygiene (ABIH) board certified industrial hygienist (CIH) with over 28 years of experience. It takes a great deal of research for us to create the initial monograph. We research many public and private databases. In addition, we look at documents that are available directly from the pharmaceutical companies. It takes a great deal of professional judgment and experience to create these documents. That is primarily where we are getting our information. When it is all said and done, if you have hundreds of pages of scientific information, you have to have the experience to be able to go through the information in an efficient manner. You have to find the critical information that is important to the outcome of the document. You then have to communicate the information in a way that the normal person can understand, because you are dealing with scientific and medical terminology that your common manufacturing employee is not going to understand. You have to be concise in your writing and your offering, and you have to have an internal review process to make sure everything is correct. All of this we have done that quite well. We have also leveraged technology to its fullest extent. We also have a Chief Technology Officer (CTO) that is brilliant and he helps us streamline things.

“We are a classic American story where you got a couple people that are bright, that are basically working out of their garage if you will, that can build a great company and provide a valuable service to clients throughout the world.” - Dean Calhoun

CEOCFO: How do you decide where to focus?

Mr. Calhoun: We go out and talk to our customers. As a good friend of mine always said, “It always starts with the customer” and you have to understand what your customers needs are, not yours. It doesn't matter what industry your business is in as long as it starts with the customer. If you listen to the customer and you are solving a problem or a need for them, you are going to have a successful business. That is what we do. We listen to our customers and get requests and prioritize because we are a small company. It always, always starts with the customer.

CEOCFO: What has changed as you have developed the concept of how the company should work?

Mr. Calhoun: We are a virtual company. That means that we do not have a physical office. We found out years ago when we had an office is that we were never there. It was a total waste of expense because we were always traveling and going out and meeting customers and the way we operate was digital. We do not need an office; we can get together at various other places and if we need to have client meetings, we can meet at their offices. I think you are seeing that in many industries.

CEOCFO: How is business these days?

Mr. Calhoun: Business is great!

CEOCFO: What do you see a year or two down the line that might be different?

Mr. Calhoun: I see continued growth in this whole area of digital delivery of these documents and webinars. There is always continued pressure on the bigger companies to reduce travel expenses. Travel expense budgets at bigger companies seen to have been flat or even less than they have been in the past. People are always looking for ways to save overhead expenses so you will continue to see that pressure to reduce expenses, particularly travel cost.

CEOCFO: Do you see competition developing?

Mr. Calhoun: The beauty of a digital company is that you have to develop the intellectual property and you have to build the system such that it cannot be easily duplicated. I do not want to say you have to patented technology because patenting any kind of technology and software technology is difficult and expensive. But you have to build the intellectual

property, the proprietary technology that is going to make your business run smoothly and efficiently and that will keep the competition from jumping in your area.

CEOCFO: *Why pay attention to Affygility?*

Mr. Calhoun: I think Affygility Solutions is role model of what an entrepreneurial, innovative company can do. We are a classic American story where you got a couple people that are bright, that are basically working out of their garage if you will, that can build a great company and provide a valuable service to clients throughout the world. It does not take a great deal of venture capital; we are privately funded. You can build a company that can be very successful. I think that is why people need to pay attention to companies like Affygility Solutions. It is a small company that was built by pulling up your boots and doing a lot of hard work.

CEOCFO: *Final thoughts?*

Mr. Calhoun: I would encourage people that no matter what their industry is to go out and listen to their clients or potential customers and solve a real need. There are too many people that are building something for themselves but not for their customers. It all starts with the customers.

BIO: Dean Calhoun is an American Board of Industrial Hygiene Certified Industrial Hygienist (CIH). He has been an environmental health and safety professional for over 28 years.

Prior to starting Affygility Solutions, Dean was the Associate Director of Environmental Health and Safety (EHS) for Gilead Sciences, Inc., a biopharmaceutical company focused on developing pharmaceuticals for infectious, viral, and oncology applications. His experiences including development and implementation of global EHS guidelines, implementation and coordination of an executive management EHS Steering Committee, establishment of occupational exposure limits (OEL) for active pharmaceutical ingredients, industrial hygiene program management, and EHS auditing of research, manufacturing and contract manufacturing facilities.

Dean has spoken for a number of professional organizations including the U.S. Environmental Protection Agency, the Colorado Safety Association, the Bay Area Environmental Safety Group, the National Association for Environmental Management, the National Safety Council, the Occupational Safety and Health Administration, and the American Industrial Hygiene Association.

Dean has also presented at the HPAPI 2012 and 2013 conferences in Philadelphia, PA, and at the High Potent Drugs 2013 conference in Mumbai, India.

Dean graduated with a B.Sc. degree in Engineering from the University of Wyoming and has dual master degrees in Environmental Policy and Management, and Technology Management from the University of Denver. He is a member of AIHA, ASSE, and NAEM.

Dean can be followed on Twitter: [@affygility](https://twitter.com/affygility).

Affygility Solutions

**13498 Cascade Street
Broomfield, CO 80020**

303-884-3028

www.affygility.com