

Compliance Implementation Services is guiding their Life Sciences and Pharmaceutical Manufacturer Clients through today's Complex Regulatory Environment to a "Culture of Compliance", using their Deep Understanding of Industry Laws and Regulations



Business Services
Life Science



Jim Collins
Co-Founder and CFO

BIO:

Jim Collins earned a degree in Accounting and Finance from Rider University in New Jersey. After receiving his CPA in 1990, Jim left the world of accounting for a position at Barnett International (a division of PAREXEL Consulting), where he worked for 14 years as VP of Operations. While at Barnett, Jim desired building a company where the culture is based on performance, growing professionally and financially, and helping clients navigate around the complexities of the changing regulatory environment.

In 2004, he achieved that goal and co-founded Compliance Implementation Services (CIS), a consulting firm that focuses on helping pharmaceutical manufacturers with commercial and clinical regulatory compliance. In the eight years since founding CIS, Jim and his co-founder Toni Barsh have grown CIS to over 100 life science professionals with five offices across the US.

About Compliance Implementation Services

Compliance Implementation Services (CIS) is a leading life sciences consulting firm specializing in compliance and commercial strategies for pharmaceutical, biotech, and medical device companies, from clinical, through manufacturing, commercial contracting, commercial compliance, and Government Programs.

CIS provides its clients with a deep understanding of industry laws and regulations, innovative and practical applications, and custom solutions to guide them to a "Culture of Compliance" that is both meaningful and sustainable.

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

CEOCFO: Mr. Collins, what is the focus at CIS?

Mr. Collins: At Compliance Implementation Services, we are a consulting firm focused solely on life sciences and pharmaceutical manufacturers. We help them with the regulatory compliance issues that they face in today's healthcare system.

CEOCFO: What types of companies do you work with other than life sciences? Is there a common thread across the board?

Mr. Collins: The majority of our clients are pharmaceutical manufacturers, so they are the large-scale or niche service. They go after the hundreds of emerging pharmaceutical manufacturers that are coming into the market place and are entering into a regulatory environment that is just as stringent on them as it is on the Mercks and Pfizers. A good example would be if you are a small biotech or a manufacturer and you are launching your first drug into the marketplace. Once you get regulatory approval to sell that drug, you have seven years to make your money. Along the way is a great deal of regulatory restrictions and obligations that you need to follow. If you are going to work in that environment, you need to have just as much scrutiny to audit and maintain regulatory approval as the bigger boys. If you are launching your drug, you might not have all the expertise and systems to help you navigate the regulations. The two options are, you can go invest in all that and find the people, or you can outsource it and come to CIS where we have all that regulatory expertise and operational capability. We are working with 150 to 200 different manufacturers, so we know the best way to do it. We help these companies navigate and launch so they are spending their time developing their product rather than worrying about all the regulatory operational hurdles that they need to have in place.

CEOCFO: What are some of the challenges that people would not an-

ticipate which you are able to get a jump on?

Mr. Collins: In today's environment if you are watching the marketing of a drug, the government as a customer is roughly 50% of the market when you factor in Medicaid and Medicare, the military, the prisons system. For you to choose to be in that government space, the government gets the best price and the best price is extremely complicated. There are discounts, which you are giving the wholesalers. You are giving rebates and all kinds of incentives to people in the marketplace. When you are dealing with the government, they care about one thing, what your best price is and if they get a discount from that. Having a handle on how to report that and work with the government as a customer is extremely complicated. At CIS, we are the gold standard in the industry. The regulations are constantly changing. We have people on board that follow the regulations, we speak about the regulations, call the regulations. If a company comes to us, they know we know how to do it for them. We know how to guide them through that. We have the operational support as they expand to grow with them. It is cost efficient to work with CIS. The cost of non-compliance is extremely expensive to the point where the government will shut you down for non-compliance, so we give them the assurance that they can focus on their business and we can make sure that they are compliant, which in this industry is a must.

CEO CFO: Do you see a trend towards outsourcing of the regulatory and compliance requirements?

Mr. Collins: Absolutely, look at the pharmaceutical manufacturers. They outsource whatever they can, especially when it comes to compliance, and that makes a lot of sense to outsource. It gives you the flexibility of knowing you have experts handling it for you but also gives you the flexibility if you are bought or purchased or expand, there is very little capital infrastructure that is laid out when you outsource.

CEO CFO: What is your geographic reach?

Mr. Collins: Most of our focus is US based in Philadelphia, Raleigh, San Francisco, San Diego and Boston. Those tend to be the hubs of where the manufacturers and biotech companies are. Many of our larger clients are global companies, so we are working with them on a global basis as well as in the US. There are many foreign companies trying to sell their products and enter the US market. We are a perfect alternative for them to come in and understand the regulatory navigational space and how to do that. We can help them and do it for them.

CEO CFO: What is the competitive landscape?

Mr. Collins: We are unique in that this is our only industry that we work in. We compete with many of the lar-

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ger big four type consulting firms where they have divisions within the company that deal with parts of each of the spaces that we deal in. We tend to go from the clinical development of drugs, to the commercialization of drugs, to the ongoing corporate compliance requirements of running a business. We go more horizontally across all the issues where many of our competitors may be in only one area. They tend to be the larger firms in certain spots but we are the most unique in that we can go from start to finish with a manufacturer and help them with their compliance needs from start to finish, which has really helped us grow.

CEO CFO: How do you reach potential clients and do they realize the breadth of your offering and appreciate your specialization?

Mr. Collins: I think they are looking for companies that can help them. Especially with the companies that are about to launch their first product, it is getting them customers prior launch and educating them once you market your drug. Many of these companies are scientists and developers that are very good at what they do but they have never experienced or they are not fully aware of what is involved after they are in the market. We spend an enormous amount of time trying to reach the companies early in their development phase and prelaunch phase and educate them. We do it by going to conferences, we have blogs and websites and we do webinars. We are out there educating the industry and it is a dynamic industry, as much as we can. Our client base has gone from one or two clients when we started the company in 2004 to 200 today.

CEO CFO: Are many biotech and life science companies that have a scientist as a founder often reluctant to give up any facet of the operation? How do you get them to let you do your job?

Mr. Collins: When you get to the level of CEO, CFO and compliance officer, we are very good at articulating the landscape that they are

about to enter and the risks involved of not being compliant in that space. There are heavy regulatory fines and criminal fines. Once we get there and they understand it and they do the ROI, that is part of being in this healthcare industry and it is part of the price of operating. Then once it gets down to what is my best solution, I can build it or outsource it, we have many clients, which we have helped along the way, so that helps them make a decision relatively quickly. Much of their decision is based on if their product is approved. Once they are approved, they have to be up marketing and they have seven years to make their money before it goes to generic. We are an instant solution for them and a highly qualified one.

CEO CFO: You have recently added to your team. Do you see the need for additional people?

Mr. Collins: Our business has been growing about 45% to 50% every year for the last five years and I think that is due to the complexity of the overall healthcare system and the marketplace. We have been able to organically add on different areas of expertise. I see us continuing to grow at that pace. With the US Supreme Court ruling approving healthcare reform, I think after the election, many changes are going to come down to the marketplace, which many of the manufacturers are going to have to adjust to. They can reach out to CIS to help them prepare and maintain compliance. It is going to be huge not only for the manufacturer but it is going to be a great opportunity for us to continue to grow our business and expand our capabilities.

CEO CFO: What do you see ahead a year or two from now?

Mr. Collins: I would see us continuing to have a very strong presence in the US on helping the small and mid-size as well as the larger companies with the commercialization of their products. I also see us expanding into Europe within the next couple of

years and putting CIS offices and locations across the globe.

CEO CFO: You mentioned the upcoming healthcare changes; how can you plan as an organization when clearly nobody knows what is going to happen?

Mr. Collins: It is understanding what the changes are, the impact of the changes and the timing of the changes. It is critical and part of our job is to be in touch with the agencies, in touch with regulatory bodies. I see that in 2013, it is going to be massive changes in the healthcare system that are going to impact everybody in the US including our client base which is the pharmaceutical manufacturers.

CEO CFO: What surprised you most as the company has grown and developed?

Mr. Collins: The complexity of the regulatory environment that the pharmaceutical manufacturers need to navigate through is becoming much more complex than it was ten years ago. That is not a trend, it will continue to happen. With regulatory changes clients are always going to be looking for companies like CIS to

help them through the changes. It is always going to be a regulated environment and we are a very good partner for our clients. We are a very good cost-efficient solution to ensure compliance with regulations.

CEO CFO: Our readers are primarily in the business and investment community. Why should they pay attention to CIS?

Mr. Collins: We are one of the unique consulting firms where we go across multiple different regulatory areas for our clients rather than specialize in one niche. We are an end-to-end compliance solution for companies launching and commercializing their product. The healthcare industry is getting more and more dynamic. There are going to be more opportunities for people to startup businesses, be successful, and help the challenge of this healthcare system. I think there is going to be increased competition and increased market share for many companies who are trying to do what we are doing.



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