

Strategic, Regulatory and Technical Consulting Assistance for Biologics



Howard L. Levine
President

BioProcess Technology Consultants, Inc. is the recognized worldwide leader in providing CMC consulting services to the biopharmaceutical industry. Founded in 1994, BPTC provides technical, regulatory, and strategic consulting services, specializing in all aspects of CMC, including development of biopharmaceutical manufacturing processes, quality control testing and characterization of biopharmaceutical products, management of cGMP manufacturing operations, validation of manufacturing processes and facilities, and regulatory support. BPTC helps its clients develop cost-effective, reproducible manufacturing processes for biopharmaceuticals, provides expert analysis and advice on the choice of appropriate expression systems and on the production, testing, and validation of cell banks for production. BPTC also assists companies with the development, scale-up, and validation of fermentation or cell culture processes, purification methods, product formulation, aseptic processing, and product stability for all types of biologic products, including monoclonal antibodies, recombinant proteins, vaccines, and cell and gene therapy products. In addition to providing consulting services to companies developing biopharmaceutical products, BPTC also supports vendors and service providers serving the biopharmaceutical industry and regularly assists companies with technical due diligence in support of product licensing or acquisition. BPTC also maintains bioTRAK™, a proprietary database of biopharmaceutical products on the market and in development for the treatment or prevention of human disease, companies developing and marketing these products, facilities used to manufacture these products, and related manufacturing, regulatory, and sales information. BPTC's highly experienced consulting team delivers actionable insight directed to its client's needs and mission.

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

CEOCFO: Mr. Levine, would you tell us the concept for BioProcess Technology Consultants?

Mr. Levine: BioProcess Technology Consultants is a consulting group providing strategic, regulatory, and technical consulting assistance primarily in the field of biologics or biopharmaceuticals for the development, manufacturing, and commercialization of those products.

CEOCFO: What do you understand about the whole process that others might not quite know as well?

Mr. Levine: All of our consultants have worked in various positions within the biotech and pharmaceutical industry. The average consultant has on the order of twelve to fifteen years of experience working in some aspect of quality control, quality assurance, process development, manufacturing as well as regulatory and supply chain. This broad experience allows BPTC to provide a full spectrum of services to our clients and helps enables us to see the big picture as well as the details of what they require.

CEOCFO: Is there a typical engagement or an example of how you work with a company and what you are able to facilitate for them?

Mr. Levine: There is not a typical engagement. Our services and our contracts are customized based on our clients' needs and requirements. Each of our clients has different requirements based on their resources, particular products, and particular issues that they are facing. The majority of our clients are small to medium sized companies who have products either just coming out of research or in early-stage clinical trials. We work with them to help finalize their manufacturing processes, to develop appropriate quality control, release specifications and the appropriate analytical methods for testing the product against those specifications, and helping to prepare the various regulatory submissions required to move the product first into clinical trials and then to progress beyond that.

CEOCFO: How do you account for personalities when you are working with one or two men organizations?

Mr. Levine: It is important to understand the particular needs of the client. Personalities do play a part, however, even if it is a small company, there are investors involved and sometimes we get to work with companies through the investors

rather than directly through the company itself. We try to make sure that the individual scientist that we have been working with understands that we are there to help them and facilitate moving their program from where it is today to where it needs to be tomorrow. There are occasions when we may be brought in someone other than the scientists we are working with who initially have some resentment to the fact that this molecule is their baby and they feel that they know more about it than anyone else. They feel that an outsider cannot possibly help them. We try to explain to them that they are the experts in their particular molecule but there are certain requirements and regulations that are to a large extent, independent of the molecule. We are there to help guide them through the path with their unique molecule through the regulatory pathway.

CEOCFO: *Is it getting easier or more difficult and do you expect with changes in the healthcare system that there will be differences as well?*

Mr. Levine: There has not been a great deal of change and we continue to work with people providing them with the same types of services. The regulatory requirements have changed over the years and today there is far more pressure on the economics of bringing a product to market and selling that product. We find ourselves doing a lot more work helping to improve process efficiencies, helping companies to understand the cost of manufacturing of their product, and looking for ways to reduce those costs. Ten or fifteen years ago, when we first started, those types of issues were less common than they are today so that is one of the major changes. The industry as a whole has matured and the people that we are working with generally have a better understanding of the requirements and the needs for drug development and in some regards it makes it easier for us because they understand they need additional resources.

CEOCFO: *Do you work among specific manufacturers?*

Mr. Levine: We often work with people who are looking to outsource some component of their development, manufacturing or quality control. Often small companies do not have the infrastructure for manufacturing. One of the things we do quite often is work with people to identify and qualify appropriate contractor/manufacturers and once we have selected a manufacturer we often continue to manage that contractor to ensure that they are delivering product on time and on budget that meet specifications.

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CEOCFO: *You mentioned several areas where you might be working for a company where there have been changes. Are there typical areas where most stumble in the process?*

Mr. Levine: I think in the past, many companies would rush too early into trying to manufacture a product for clinical trials. Their processes were not fully developed and as a result there were failures in manufacturing. People understand the need to make sure you have a robust manufacturing process upfront so that that they are paying more attention to that. We have seen people stumble in defining the specifications for the product or the science and defining appropriate analytic methods to measure those specifications. Potency is a big issue with biologic products because they it is often based on a biological activity which may not be as precise as other chemical or physical assays.

CEOCFO: *How do you reach potential customers and how do they find you?*

Mr. Levine: Most of our business is through word-of-mouth or through our consultant's collective networks. All of our employees have spent significant amount of time in the industry, so everybody has a network of contacts and they are known to others in the industry so we often receive phone calls or emails from people who we know or from people who may have moved from one company to a new company. We are also frequently invited to participate in conferences. When our consultants go to conferences to give a presentation or be part of the panel, they get exposure to the audience and often times somebody sitting in the audience will be listening to one of our consultants and they will approach us. We get a fair amount of business through our website so we spend a significant amount of time trying to make sure that our website is up-to-date and is providing meaningful and relevant information. We try to include not only a description of our consulting services and bios but we also try to include practical, meaningful information and reprints of all the articles and presentations that we make. Many people have told us that they found this a valuable resource.

CEOCFO: *What is your geographic reach?*

Mr. Levine: We are truly a global company. The majority of our clients are here in the US but we have clients all over the world. We do business with companies in Europe, Asia, South America and Africa. We often work with a US-based client who is working with a partner or a contractor in Europe or in Asia and we may travel to those locations on behalf of the partner. And, we do work with US subsidiaries of Asian or European companies.

CEOCFO: *Does instinct play a part in your business?*

Mr. Levine: Yes it does. When you sit down with someone and they will describe a particular problem that they are facing or an issue that they need help with, quite often your immediate reaction is that I have seen something similar. That could be both positive and negative; positive in the sense that to the extent that you might be able to solve a problem faster than otherwise but at the same time you have to be careful that you do not neglect the nuances of each situation. Every milestone and situation is different. If you try to take a cookie-cutter approach and do exactly the same thing each time, you are not necessarily serving your clients in the best possible way. You have to rely on the experience of the team and their gut reactions but you also have to pay careful attention to the particular needs of a project or issue.

CEOCFO: *How do you spend your time as CEO?*

Mr. Levine: My time is split between providing consulting services to some of our clients and managing the business. The consulting side is working with our consultants and our clients in the same manner as the other consultants. From the business side, I spend time working with our sales and marketing director to make sure that we have our marketing materials up to date and that we reaching out to the right people and providing the right information and message. I also spend time working with and providing assistance or guidance to our consultants. Then there is the administrative side of the business; things like payroll that need to be dealt. Even though we have a bookkeeper to help with our accounting and a director of sales and marketing to help with our business development, there are sometimes things that they need help with. As a CEO of a small company, you wear many hats.

CEOCFO: *What are the intangibles you look for in your people?*

Mr. Levine: I look for people who are creative and who have the ability to think outside of the box. We talked about seeing things that you have seen before but oftentimes you may see things that you have never seen before. As a consultant, you have to be able to look at a situation and say well I have not done exactly that before but I have these various pieces of experience and knowledge that I can bring to bear on solving a particular problem. You want people who can think quickly on their feet and can react and adapt to the situation as needed. I look for people who have good communication skills. As a consultant, you spend a great amount of time trying to convey to various people what needs to be done and we need to be able to present it in a clear and concise manner whether that is in an oral presentation or whether a written report or slides or whatever. You have to present in a way that will be clear and understandable to the clients. Oftentimes scientists are not always trained to be the best communicators, so you might have somebody who is quite brilliant at the bench but not able to communicate his results in the most clear and concise manner and that person is probably not going to make it.

CEOCFO: *How might the company look different a year or two down the road?*

Mr. Levine: It will probably be bigger. Our business has expanded quite a bit in the last year or so and we continue to see it growing. I think we will also be doing more projects in the emerging markets, so I see more work being done in places like India and China and such where we are already working but those are the areas that are really growing especially in the area of bio pharmaceuticals.

CEOCFO: *What accounted for the growth surge and was there a deliberate strategy?*

Mr. Levine: I think it was an effort on our part. We decided that we did want to grow the organization, so we did a little bit more outreach for projects. I think it is also a result of turnaround in the financial markets. The biotech industry is very venture finance driven. When we went through the market crisis a few years ago, there was not much money coming into biotech and the money that was coming in were either going out of business or downsizing and putting projects on hold. As a consultant who is helping companies move products forward, if those companies were not moving products forward, then there is not going to be much of demand for consultant services. As the financial markets have improved and more money has come into the biotech industry, you see more companies that put programs on hold and now they come back with the resources to move the products forward and reach out to consultants.

CEOCFO: *Why pay attention to BioProcess Technology Consultants?*

Mr. Levine: What we bring to our clients is a team of consultants who have a broad base of experience. You can go out and hire an individual but no matter how bright and experienced an individual is their experience is going to be limited. A company may go out and find a consultant who is the best possible QC consultant or manufacturing consultant but that individual is not going to be able to be an expert in everything. Whereas BPTC as a team of consultants had many individual experts covering the spectrum of activities that our clients are working in, so we are able to provide a team of people to address their needs across the board not just in particular niches.

BIO: Howard L. Levine, Ph.D., President and Principal Consultant of BioProcess Technology Consultants, Inc. (BPTC) has over 30 years of experience in successful product companies and as founder of BPTC, the leading CMC (Chemistry, Manufacturing and Control) consulting group in the biopharmaceutical industry. In addition to leading BioProcess Technology Consultants, Dr. Levine is also Managing Director of BPTC Europe, a wholly owned subsidiary of BPTC, established in September 2010 to provide local consulting services to the European Community. Prior to founding BioProcess Technology Consultants, Dr. Levine was Vice President of Manufacturing Operations at Repligen Corporation where he was responsible for all process development and manufacturing activities, including production of therapeutic proteins, monoclonal antibodies and recombinant Protein A. Dr. Levine was previously Director, Pilot Plant Operations at Xoma Corporation where he was responsible for the development and manufacture of monoclonal antibody products for clinical trials. He has also held positions in process development and manufacturing at Genentech and Amgen. Throughout his career, Dr. Levine has assisted in the development of over 20 different biological products and the successful commercialization of three of these products. Dr. Levine is currently a member of the Editorial Advisory Boards of the Journal of Preparative Biochemistry and Biotechnology, Biopharmaceutical Processing, BioPharm Magazine, and Bio/Pharmaceutical Outsourcing Report. He is also a member of the Scientific Advisory Board of Pall Corporation and a member of the Board of Directors of Protein Sciences Corporation. Dr. Levine has been an invited lecturer on manufacturing strategy, downstream processing, and commercialization of biotechnology products. He holds a Ph.D. in chemistry from the University of Chicago and completed a post-doctoral fellowship at Harvard University.



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