

# Drug Development<sup>®</sup> & Delivery

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## Platform Technologies: Not Just for Big Pharma

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Chain

# Drug Development EXECUTIVE



Medhat Gorgy  
President & CEO

PYRAMID  
Laboratories, Inc.



## PYRAMID: Prescription for Building Success Through Partnerships

Quality. Integrity. Performance. These words may best describe the foundation upon which PYRAMID was built when it was founded in 1988 as an analytical services and method development company. This foundation has grown ever stronger throughout the past 28 years as it has transitioned from a 600-sq-ft laboratory into a 70,000-sq-ft commercial manufacturing facility with the expertise and flexibility to provide analytical, development, and small- and large-scale aseptic manufacturing and filling services to small start-up biotechs, big pharmas, and everyone in between. Drug Development & Delivery recently spoke with Medhat Gorgy, President and CEO of PYRAMID Laboratories, Inc., to discuss his success in building futures with his clients and more importantly, the lessons he's learned along the way.

**Q: What sets PYRAMD apart from other contract manufacturing organizations?**

Since the beginning, I founded PYRAMID to be a quality organization and not profit driven. This is evident through the fact that PYRAMID remains a privately held company, which allows us to be flexible to our clients' needs and timelines, without having to answer to shareholders or a Board of Directors. Our project managers are involved in each project from the very first point of contact to the very last invoice. Our clients will never be approached by sales or business development people as we operate on word-of-mouth recommendations based on our reputation of quality, integrity, and performance. This approach has sustained our business for 28 years. Our team is highly technical with years of experience in designing drug development programs from the straightforward to the most challenging formulations or lyophilization cycles, and we back this up with a track record of incredible success.

PYRAMID builds relationships, and through these relationships, we develop partnerships. We are not just doing a job for our clients, we are building a future with them. PYRAMID understands the long-term benefits of successful development or the severe consequences of a failed project, not just to ourselves but to our clients and ultimately, to the patients. We participate in all aspects of each project, providing expertise when necessary, and we efficiently take projects through all phases of drug development without losing focus on quality.

**Q: What do you believe should be considered when evaluating a potential CMO?**

**A:** The primary point to consider is the type and complexity of the project and how it fits to the CMO's expertise and experience. Smaller companies that do not have in-house CMC experience should seriously consider engaging a CMC consultant to help evaluate CMOs, as a person with this type of background is able to ask the right questions and perform an on-site audit that is relevant to the project.

Also of importance is the team that is assembled for the first meeting. Are you speaking with sales or business development folks, or a team of highly trained, technical people

who can interpret your needs and create a well-thought-out program? Is the project manager involved from the first engagement through to the end of the project, and is that person experienced enough to translate your passion and vision into a successful project?

Is the proposal of sufficient technical detail or simply a list of line items? The right CMO may not always be the least expensive, but working with a CMO who partners with you to deliver a quality product on schedule can save time, money, and headaches as you enter expensive clinical trials.

**Q: We all have audit checklists, but what should clients be aware of during an audit that may not be written on a piece of paper?**

**A:** Behavior during an audit can be very telling. How quickly is the Quality Assurance group able to pull requested documents? How knowledgeable are they about their own documents? Are they able to pinpoint information within a document quickly, or do they have to read through it to find requested information? There is a difference between a team that has prepared for an audit and a team that owns their systems, and during an audit, it's important to look for the subtle differences between the two. A quality team that shows ownership and knowledge of their systems is a team that is prepared for unannounced inspections by the FDA.

**Q: What should clients learn from a CMO's regulatory history?**

**A:** Regulatory inspection history is clearly important based strictly on inspection outcome, such as the number and types of 483s that may have been issued, the frequency of inspections, and how frequently 483s are issued. Sponsors should always consider the seriousness of the substance of the observations. How many are serious and substantive observations, and are they still open? Or, are the observations relatively simple oversights? You should be able to evaluate and judge the company through analysis of the observations. It's also important to understand how a CMO responds to inspections, both positive and negative. Are inspections considered an opportunity to

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learn and improve quality systems or are they a finite target that the team works toward achieving, and when complete, all is forgotten until the next inspection? Who within the company is involved in the inspection? How engaged is upper management, and how frequently are functional area experts relied upon?

**Q: Can you provide a detailed example of what can happen when choosing a partner for the wrong reasons?**

**A:** Yes, of course, we have many examples. One that comes to mind is a company that PYRAMID worked with on a new project several years ago. This is a perfect example of what happens when selecting the wrong CMO. PYRAMID’s technical team met with the company to discuss the project, and while the company was impressed with our knowledge and recommendations, they chose a different CMO based solely on cost. About 10 to 12 months later, the company returned to PYRAMID lamenting the delays and struggles with the CMO, who claimed to have the expertise and equipment to manufacture their lyophilized product, but clearly they did not. Now the project was behind schedule, and the budget was climbing. Once again, the sponsor chose to work with yet another less-expensive CMO in an effort to recuperate some of their costs. Again, a year later, they returned to us frustrated and demanding help on a fast track because the new CMO could not maintain consistent weight checks nor keep air bubbles out of their solution during the filling process, therefore no product was manufactured, and clinical trials were delayed.

PYRAMID agreed to assist with the issues and took over the project from this point. The formulated bulk was shipped to us for evaluation, and we were able to quickly identify the root cause for their problems. In fact, within minutes of receipt, and upon first glance, our technical team determined the cause of the problem was air bubbles mixed with the slightly viscous solution that lead to fluctuation of fill weight checks. As the client experienced negative performance from the previous two CMOs, they requested confirmation studies to alleviate uncertainties that were born from ill-suited guidance. While we were more than happy to conduct these studies, they further increased the cost and unnecessarily extended the duration of the program. Risk-based decisions are made by sponsors every day, but sometimes saving a few thousand dollars can ultimately cost a great deal more in the long run, including delays in initiating clinical trials and subsequently delays in the regulatory path to approval and finally, to the patients who desperately need the treatment.

There are more examples that can be discussed to show that partnering with a CMO based strictly on cost may not be the wisest approach to a successful relationship and program, but this story clearly demonstrates how selecting a CMO based on cost alone, especially when due diligence points to a different direction, can be extremely consequential.

PYRAMID’s core values will not allow us to accept work that is outside of our areas of expertise and therefore, time and again, our clients speak only of successful projects. ♦

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