

Pharmaceutical Outsourcing™

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AN INTERVIEW WITH...Medhat Gorgy President & CEO PYRAMID Laboratories, Inc.

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Interview Partner:

Medhat Gorgy

President & CEO

PYRAMID Laboratories, Inc.

Currently providing quality, integrity and performance in contract manufacturing, product development, formulation, fill / finish, lyophilization and analytical services for both vial and syringe applications, PYRAMID Laboratories, Inc. maintains a proven track record of quality support for the pharmaceutical and biotech industry. PYRAMID's President & CEO, Medhat Gorgy, founded PYRAMID in 1988 as an analytical laboratory based on his skills and expertise. Twenty three years later PYRAMID's highly trained staff have over 130 years of combined experience and utilize the latest technology to aid in the implementation of new and innovative designs that assure clients meet their goals.

1. What are PYRAMID's areas of expertise?

PYRAMID provides expertise in formulation and process development, aseptic filling for vials and syringes, as well as lyophilization applications for clinical and commercial products. Our knowledge and advanced technological environment allow us to provide clients with highly skilled individual attention, professional service and documented high quality in the most efficient and cost effective manner. We guarantee performance, integrity and quality combined with a personal commitment.

2. Will you elaborate on the services PYRAMID provides to the industry?

PYRAMID provides the industry with experience for all phases of drug development. These services include, aseptic filling, liquid formulation development, lyophilized product formulation and cycle development, clinical and commercial vial and syringe fill / finish for clinical and commercial batches.

Also at PYRAMID, we provide supporting analytical services such as raw material, in-process and final product release testing. Furthermore, we specialize in method development, validation and stability studies.

3. What sets PYRAMID apart from other contract manufacturers?

PYRAMID's quality, integrity and performance combined with personal commitment set us apart from others. At PYRAMID we consider our clients as our partners and we have one common goal, success. We participate in all aspects of each project, providing expertise when necessary, and efficiently take projects through all phases of drug development without losing focus on quality.

Since the beginning, PYRAMID has been a quality oriented organization and not profit driven.

We are flexible with our client's needs and go out of our way to schedule their projects to meet their timeline; sometimes this is priceless. Our clients receive undivided attention, regardless of the size of the project.

4. How have strategic partnerships contributed to the overall development of PYRAMID?

PYRAMID's reputation in the pharmaceutical and biotech industries with virtual and large pharmaceutical companies has been a major contribution to our growth over the years. We guarantee that our client's receive highly skilled individual attention and that we transcend our business relationship. PYRAMID believes that our clients are our friends and colleagues and we treat them as such.

The partnership PYRAMID has developed with its clients goes beyond business. We care about their product just as much as they do. Based on our quality reputation and our past business and personal relationships, clients remain loyal to PYRAMID for their manufacturing needs.

5. How did PYRAMID transition from analytical to fill / finish services?

When PYRAMID was started in 1988, the company focused on analytical services and method development. Within a couple of years PYRAMID established such a respectable reputation in the industry that it wasn't long before a client told us, "If PYRAMID can't do it – no one can!" By the year 1994, based on our proven track record of quality, PYRAMID was approached by several clients to consider establishing fill / finish manufacturing services. In 2000, the fill / finish facility and manufacturing was launched. PYRAMID's laboratory not only supported our current clients in the performance of analytical services but also newly established manufacturing clients. Three years after the launch, clients urged us again to establish a larger commercial scale facility to maintain continuity with their project and utilize our expertise from development to commercial. Once again, by the year 2007 we launched our new, state-of-the-art commercial scale facility.

6. What makes a CMO successful?

A successful CMO should be focused on quality and performance. They will only accept projects within their areas of expertise and communicate their capabilities. If a CMO accepts a project outside their scope of knowledge, they may harm the client financially and ruin their project timeline.

A successful CMO will have the capabilities to be with a client every step of the way, from product development to formulation to commercial and supporting analytical services. Another attribute for a CMO is flexibility in scheduling. Clients utilize CMOs with the intent of receiving the best services for their product and meeting a client's timeline for services is essential to maintaining success.

7. What are the most important factors clients need to consider when selecting the right CMO?

A quality contract manufacturer should have experience and expertise in all aspects of manufacturing. This includes formulation, development, quality control and assurance. A CMO staff should be highly trained and educated in working with diverse products as well. The right CMO may not always be the cheapest but it is important to put quality over cost because manufacturing is one of the most important aspects of new drug product development in support of expensive clinical trials. In fact, no other choice is more important than finding the right CMO to ensure the project will be done correctly the first time.

There are several essential attributes clients need to consider when choosing the right CMO. These include the following:

- Industry Reputation
- Expertise, Trained Personnel & Management
- Regulatory & Audit History
- Accessibility / Site Visits & Tours
- Personal Commitment to Client's Goals & Objectives
- Capabilities – From Development to Commercial
- Management Involvement in Client Projects

Medhat Gorgy is the President & CEO of PYRAMID Laboratories, Inc. He holds a B.S. in biochemistry from Alexandria University, School of Science in Alexandria, Egypt. In 2009, Medhat was named the Small Business Person of the Year and in 2011 was recently awarded the Character Building Award by the U.S. Small Business Administration. The Character Building Award is provided to an individual whose faith and values carry throughout the organization and is reflected in the way they handle the company, employees, clients and finances.