

# Rising to Market Leadership: TCG Lifesciences

*We talk trends with Swapan Bhattacharya as India's CRAMS market heats up*



**T**CG Lifesciences Pvt. Limited is a global contract research and manufacturing services (CRAMS) company involved in drug discovery and development. The company started operations in 2001 in Kolkata, India and has grown to currently have a presence in the U.S., Europe, and Japan.

With more than 850 employees, TCG's services span chemistry, in vitro and in vivo pharmacology, analytical development and validation, and specialty chemicals. It offers specific, functional solutions to integrated projects across multiple therapeutic areas with specific focus on the following segments: inflammation and pain; infectious diseases; central nervous system; and oncology. TCG's research infrastructure includes world-class chemistry and biology laboratories, animal facility, electrophysiology laboratory, BSL 2 laboratory, and cGMP facilities at its R&D centers.

Contract Pharma recently had the chance to discuss trends in the CRAMS market as well as TCG's current and future plans for growth with Swapan Bhattacharya, the company's managing director.

**Contract Pharma (CP):** How would you characterize the state of the contract research and manufacturing services (CRAMS) market domestically and abroad?

**Swapan Bhattacharya (SB):** The global CRAMS industry has been growing at a fast clip, given the proliferation of drug innovation happening in the biotech space and the overall increase in prescription medication demand across the globe. The fastest growth is happening in the development phase as many drug candidates from the discovery stage are moving into the clinic. This is followed by high commercialization demand as the number of new molecular entities approved by FDA continues at a healthy rate. Furthermore, the boom in the commercially marketed products are giving rise to contract manufacturing and outsourcing opportunities in the CRAMS industry. Finally, the global demand growth for generic drugs are fueling the rise of APIs and intermediate synthesis and drug formulations.

The CRAMS industry is quite fragmented, with more than 1,000 players, largely concentrated in Asia. The growth continues to be

at a robust double-digit rate, with nearly 60 percent of commercial manufacturing being outsourced by the pharma industry. India has the largest number of FDA approved plants outside the U.S. and the domestic industry is growing at a 20% rate. India provides an attractive value proposition for outsourcing due its abundant trained and talented English-speaking manpower, lower costs, its large installed base of state of the art manufacturing facilities and efficient operations. In recent times, Indian companies have benefitted from the shutdown of many Chinese manufacturing operations due to the country's "go-green" initiative and the global pharma strategy to contain its exposure to China alone for their outsourcing needs.

**CP:** What are some of the crucial issues and challenges impacting pharma discovery, development and manufacturing and CRAMS in particular?

**SB:** The key challenges faced by the CRAMS industry are 1) stringent requirements laid down by regulatory bodies and their enforcement actions to monitor plant quality and operational standards, which require higher investment in systems, facilities and talent; 2) increasingly complex and multi-step synthesis requirements in drug development; 3) more robust tech transfer and analytical method validations; 4) lower profit margins due to price competition in the market; and 5) price controls and other policy prerogatives likely to be introduced in the U.S. and EU countries.

**CP:** In which area(s) is TCG observing the greatest growth from clients, and in which geographies are these firms based?

**SB:** Historically, TCG Lifesciences has operated primarily as a CRO with a focus on discovery and early stage development, including chemistry synthesis, in vitro and in vivo pharmacology and ADME/PK. In this segment, the bulk of the growth is coming from serving the needs of the emerging biotech industry, since most of the drug innovations that are happening today emanate from that source. These companies have limited internal laboratory infrastructure and people and rely highly on externalizing their research needs to CROs. It also helps bring down costs and their limited VC funds can be made to last longer.

TCG has expanded its drug development activities in the past few years which include an FDA approved manufacturing facility with nearly 200 KL capacity, pilot plant and analytical validation labs. This initiative has contributed to the dramatic growth in revenues and profits.

Our biggest market is the U.S., followed by Europe and Japan.

**CP:** What are the major trends moving the CRAMS market forward, and/or holding it back?

**SB:** Green chemistry and sustainability are the key drivers for change in the CRAMS industry moving forward. Therefore, the industry is transforming itself by focusing on catalysis, flow or continuous chemistry, bio-transformation, hazard minimization, energy efficiency, renewable feedstock and the like. All of these aspects require investments in technology, high end collaborative research involving industry-academic partnerships, change of mindset of investors/operators and governmental support. For-

tunately, such initiatives are likely to make industry more competitive and lead to lower manufacturing costs in the near future.

**CP:** What are some of TCG's key business highlights from the past 12 months?

**SB:** TCG Lifesciences achieved dramatic growth in revenues and profits of approximately 43% and 210% respectively in FY 2019 over the prior year. In the same period, TCG has been very active in expanding capacity in nearly all the domains we are involved with. These include: 1) nearly doubling of our manufacturing capacity; 2) 25% growth of lab scale chemistry capacity; 3) setting up of new analytical development lab; 4) expansion of ADME/PK testing labs; 5) creating a comprehensive oncology in vivo experimental suite and 6) creating a new animal facility which should get AAALAC accreditation in 2020.

**CP:** What is next for TCG in terms of its growth strategy?

**SB:** TCG is now focused on the establishment of an R&D Innovation Center in the U.S., with an experienced pharmaceutical team employing the latest synthetic chemistry, engineering and analytical technologies to offer green and novel, next-generation, development technologies such as flow or continuous chemistry, catalysis etc. which can revolutionize the current industry practices. This initiative will be uniquely positioned to serve the CMC needs of its biotech clients to rapidly supply GMP ready materials for first-in-man studies. It will also enable its clients to procure larger quantities of such materials from TCG's FDA approved facilities in India, using a seamless tech transfer process.

**CP:** Anything else you'd like to share with us about TCG and its plans for the future?

**SB:** TCG employs approximately 900 scientists in its discovery and development activities. In order to develop a larger talent pool, TCG has a very comprehensive corporate social responsibility program, which actively promotes and funds local, state and regional educational institutions to support STEM education to underprivileged students. It also provides hands-on training to post-graduate students and also employs them in most cases. Finally, we offer selected high performers with Master's degree the ability to undertake PhD program while employed with us. **CP**



Swapan Bhattacharya is the Managing Director of TCG Lifesciences (TCGLS) and is responsible for the executive leadership and overall management of the company. He co-founded TCGLS in 2001 and has helped the company to achieve a global leadership position in the research services space. He is also a key member

of the Governing Council of the TCG Centers for Education and Research in Science and Technology, a not-for-profit foundation in the process of spawning multiple centers of excellence in the frontier fields of translational neuroscience research, AI and quantum computing.