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INDIA'S BURGEONING BIOLOGICS CDMO MARKETPLACE

Roger Lias

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Outsourcing

India's Burgeoning Biologics CDMO Marketplace

by Roger Lias

The biopharmaceutical outsourcing market space is recognized widely as attractive. And yet, despite significant investment in vaccine manufacturing infrastructure catalyzed by the COVID-19 pandemic, Indian contract development and manufacturing organizations have yet to make their mark. No commercial-scale biomanufacturing capacity to match that of other countries is yet in place in India. Herein, industry veteran Roger Lias details the reasons for that situation and the trends that are changing India's biopharmaceutical outlook.

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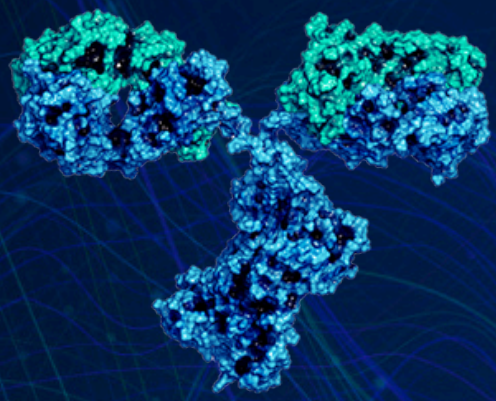

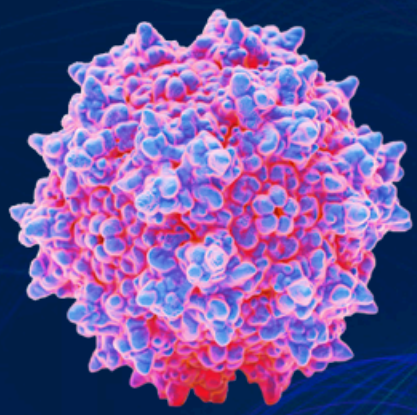

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India is known as "the world's pharmacy" based on a roughly five-decade history of manufacturing active pharmaceutical ingredients (APIs) and finished dosage forms for small-molecule drugs (**1**). Those capabilities have been propelled by demand for low-cost manufacturing, particularly in support of generic products. India remains the largest global supplier of relatively low-cost generic drugs, vaccines, and affordable medications for treating acquired immunodeficiency syndrome (AIDS) due to human immunodeficiency virus (HIV). India is home to the second highest number of US Food and Drug Administration (FDA)–approved manufacturing plants in the world.

Notwithstanding those successes, India has lagged noticeably in the manufacture of large-molecule/biologic drugs. While China and South Korea, for example, invested significantly in biomanufacturing infrastructure over the past two decades, India has not done so despite its similarly low-cost base. Considering the biologics contract development and manufacturing organization (CDMO) marketplace in South Korea alone, you find Samsung Biologics continuing to expand its mammalian cell-culture capacity and promising 1.3 million liters by 2032. Meanwhile, Prestige Biologics sits on over 150,000 L, and Lotte Biologics recently announced the addition of 360,000 L in capacity at its site in Songdo, Incheon (**2, 3**). Similar investment is underway at Chinese CDMOs, such as WuXi Biologics, which is home to over 260,000 L in 2022 and plans an increase to over 580,000 L by 2026 (**4**).

So the biopharmaceutical outsourcing space is recognized widely as an attractive market. And yet, despite significant investment in vaccine manufacturing infrastructure catalyzed by the COVID-19 pandemic, Indian CDMOs have yet to make their mark. No equivalently large commercial-scale biomanufacturing capacity is yet in place in that country.

"The World's Pharmacy"
(HTTPS://WWW.ISTOCKPHOTO.COM)

Background

I have participated in the remarkable growth of the biologics CDMO marketplace since the mid-1990s. In that time, I've witnessed supply-chain globalization driven by growing demands, expanding markets for biologic products, and the biopharmaceutical industry's quest to access current good manufacturing practice (CGMP) production capacity under economically beneficial terms. I also have directly supported two India-based CDMOs at an executive level and sourced biosimilar products and services from others. I have witnessed remarkable changes that, along with the changing geopolitical environment, lead me to believe that India may be emerging finally as a powerhouse in biomanufacturing.

But why has the country not already established a global presence in the biologics CDMO market? The necessary building blocks would seem to have been in place for some time. Dr. Reddy's Laboratories, which celebrated 25 years in the biologics space last year, launched its first biosimilar product — granulocyte colony-stimulation factor (GCSF) — in 2004. The company's facilities in

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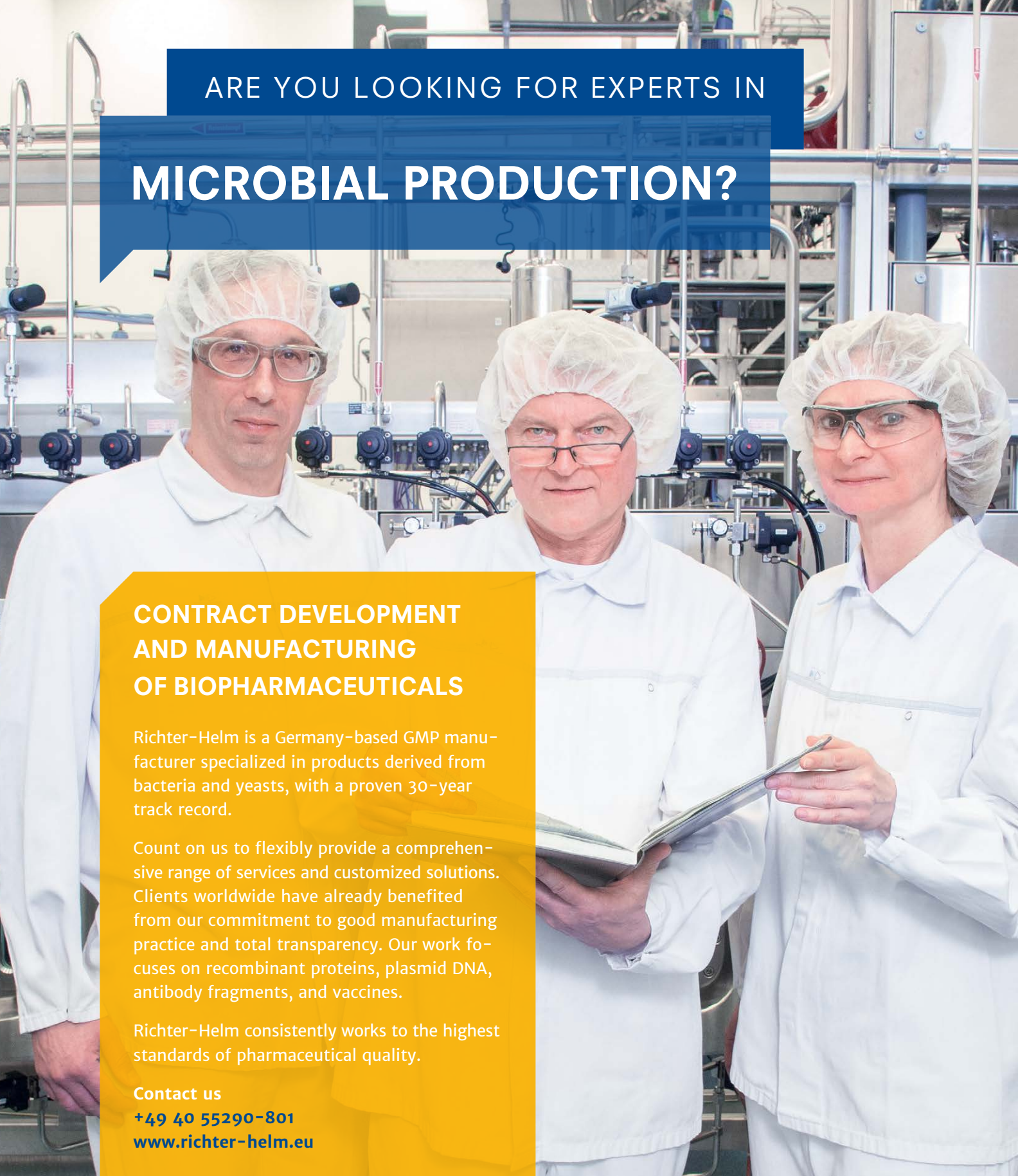

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Hyderabad are inspected by global regulatory authorities including the FDA, European Medicines Agency (EMA), and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA). Dr. Reddy's manufactures biologic products that are marketed in more than 25 global territories.

The Indian pharmaceutical market grew 6.8% during 2023 to 1.93 trillion rupees, roughly US$23 billion (**5**). So what explains the country's struggle to establish a biologics CDMO presence rivaling that of other Asian countries even as its own domestic market is growing rapidly? Two main contributing factors are a historic lack of domestic drug discovery for innovative products (including biologics) and a preference for near-term returns over longer-term growth when making capital investments.

India has contributed notably to the global biosimilars marketplace, but it has no significant "innovative biotech" presence and relatively few new biologic products under development. That suggests an inherent lack of historical pressure to develop biomanufacturing infrastructure or expertise and little domestic demand for CGMP manufacturing capacity. As recently as February 2024, Orchid Pharma (Chennai, India) received FDA approval to market its small-molecule drug Exblifep (enmetazobactam) for urinary tract infections, calling itself "the first Indian firm to have invented a product which has received a new drug approval from the US FDA" (**6**).

Biosimilar developers such as Dr. Reddy's, Biocon, Cipla, and Lupin have tended to develop captive capacity sufficient to meet internal demand — or have themselves outsourced manufacture. In many cases, such companies' first priority has been to serve the large domestic biosimilar marketplace. Understandably, they have thus prioritized meeting Indian regulations without focusing on approvals from more highly regulated markets, which typically is required to support a sustainable CDMO business. Biomanufacturing capacity in India largely has been built to support insulin manufacturing. Again, that tends to be inward focused and based on microbial expression systems that historically have been less in demand than are mammalian cell-culture systems in the CDMO marketplace.

Establishing biomanufacturing infrastructure is expensive and time consuming, and a lack of available capital probably also has contributed to the relative lack of biomanufacturing presence in India. My experience has been that Indian investors frequently want to start making returns more quickly than typically is possible in the biologics CDMO business. Timing has become a significant issue: Given small-molecule patent cliffs (and aided by the US Hatch–Waxman Act of 1984), Indian companies simply prioritized investments in that area during the 1990s and early 2000s to take advantage of near-term opportunities. Entrepreneurs in India built on the success of companies such as Dr. Reddy's, viewing the generic small-molecule marketplace as relatively low risk, and then successfully took advantage.

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The subsequent promise of a "sticky" future business with significant but later returns from biologics manufacturing simply has not been sufficient to attract necessary investment in India. Based on the necessary time to return on investment (RoI), India has not presented an attractive option for the levels of capital being injected into Korea's and China's biomanufacturing industries. Indian companies' general reluctance to leverage debt funding probably has contributed further to the current situation. Whether by accident or design, India has not contributed significantly to the growth of the global biologics CDMO market — but this is likely to change over the coming decade.

A Growing Economy and Government Initiatives

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India boasts a fast-growing economy, with its per capita gross domestic product (GDP) having grown by 55% between 2014 and 2023. The annual economic growth rate is predicted to remain at a minimum of 6% for some time. Alongside that growth, the value of companies listed on Indian exchanges surpassed $4 trillion in 2023. The National Stock Exchange of India is now the sixth largest such market globally, with a capitalization that grew at a remarkable 50% in the 12 months prior to February 2024.

India has invested considerably in its public digital infrastructure, including a QR-code based Unified Payments Interface platform that is making cash payments almost obsolete across the entire economy. That puts the country ahead of both Europe and the United States in such advancements. Meanwhile, significant investment also continues in "hard" infrastructure such as roads, ports, and airports. Government-backed, manufacturing-linked incentive programs for attracting new market players (including in the pharmaceutical sector) are valued at about $26 billion.

Like many other governments around the world, the current Modi administration in India has taken specific notice of the economic opportunity provided by biotechnology. A recently released draft of the National Biotechnology Development Strategy for 2020–2025 includes the goal of "harnessing the potential of biotechnology as a premier precision tool for national development and well-being of society" and the mission of "making India globally competitive in biotechnology research, innovation, translation, entrepreneurship, and industrial growth," with a target of becoming "a US $150 billion Bioeconomy by 2025" (**7**). One stated objective is "to position India as a strong biomanufacturing hub for innovative, affordable, and accessible products for the society and also for global markets." Supportive policies, workforce training, and establishment of (bio)manufacturing zones represent just part of the detailed initiative.

A Framework for Growth: Although India has lagged behind some other parts of the world, it has not been completely absent from global biologics outsourcing. The country has developed a significant presence in drug-discovery and contract research organization (CRO) services, especially localized around

the hubs of Hyderabad and Bengaluru. Now those are getting "forward integrated" into chemistry, manufacturing, and controls (CMC) development and manufacturing services.

Leading the way has been Syngene International, which was founded in 1993 but became a subsidiary of Biocon in 2002 (**8**). Syngene initially specialized in research and development (R&D) for small molecules before more a recent move into biologics and CGMP manufacturing. In December 2023, the company concluded its acquisition of a large-scale facility for mammalian cell-culture manufacturing located — originally designed for Stelis Biopharma's manufacture of the Sputnik adenoviral COVID-19 vaccine — located close to Syngene's Bengaluru headquarters (**9**).

An interesting new market entrant is Aurigene Pharmaceutical Services (Hyderabad), which is a step-down subsidiary of Dr. Reddy's Laboratories. Building on a two-decade history of providing discovery and CDMO services for small molecules to establish a comprehensive biologics discovery service offering, Aurigene also is leveraging 25 years of experience in biosimilar development and access to Dr. Reddy's globally approved large-scale CGMP facilities for both drug-substance and drug-product manufacturing. A new facility for process development and early stage CGMP manufacturing facility is scheduled to open in summer 2024 just north of Hyderabad — in the Genome Valley biocluster (where Aurigene is neighbors with Novartis, GSK, Sandoz, Lonza, Ferring, and others). Precise details are not yet available, but it is known generally that Aurigene is investing significantly and leveraging innovation with the intention of becoming a recognized, top-tier player in the global biologics CDMO marketplace.

The GVK Industries conglomerate also has turned attention on the biologics space, acquiring Aragen Bioscience in 2014 and subsequently rebranding its own biologics operations in India under the Aragen name (**10**). And in March 2024, Aragen Biologics announced that it was "operationalizing" the first phase of a $30-million biomanufacturing facility under construction in Bengaluru (**11**).

Enzene Biosciences, a subsidiary of Alkem Laboratories, also is moving into the biologics CDMO market from biosimilar beginnings. The company has developed a continuous-processing platform and recently acquired a former Bristol Myers Squibb US facility in New Jersey to supplement operations in Pune, India (**12**). Other established Indian companies that are offering CDMO services for biologics to varying degrees include Kemwell Biopharma (which claims to have been the first biologics CDMO in India) and Stelis Biopharma in Bengaluru as well as Shilpa Biologicals in Dharwad.

Laboratory technicians at Kemwell Biopharma
(HTTPS://WWW.KEMWELLBIOPHARMA.COM)

Market Dynamics and Drivers

The biologics CDMO market has become firmly established worldwide. Biologics represent a critical component of the overall pharmaceutical marketplace (with advanced therapies continuing the push). Over the past few decades, biopharmaceutical

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production processes have evolved and achieved industrial scale, and the concept of global manufacturing and compliance is well established — especially where it can deliver economic benefit through attractive cost of goods (CoG). This market and its associated risks are well understood.

However, the space continues to evolve. Over the past decade, Chinese CDMOs have established a significant global presence and share of the biologics CDMO market through the application of capital, government support, and some assistance from multinational biopharmaceutical companies. WuXi Biologics alone reported a dizzying CHN¥17.03 billion (about $2.4 billion) in revenue for 2023, the majority of that generated from the United States. Other companies — including Altruist Biologics, Chime Biologics, Joinn Biologics, MabPlex, and Pharmaron — also offer biologics services beyond the domestic Chinese marketplace (**13**). However, the well-publicized "China Plus One" strategic approach appears to be disintegrating based on changing geopolitics, which provides a significant opportunity for Indian CDMOs (**14**).

In addition to well-publicized tensions across the Taiwan Strait, current bipartisan promotion of the Biosecure Act in the US Congress is affecting companies such as WuXi AppTec (which is called out specifically as a "foreign adversary biotech . . . of US national security concern") and WuXi Biologics (compounding already significant market pressures) as Western customers seek alternatives and second sources (**15**). In 2024 alone, the latter company's market capitalization has dropped by ~50% so far.

Based on a highly attractive cost base, India is now uniquely placed within the global market to step in and potentially displace China over the next decade. Building and maintaining a sustainable biologics CDMO business will take much more than a favorable geopolitical climate, however. As I pointed out in a 2023 eBook, numerous factors combine to determine success or failure (**16**). One further point that could work in India's favor is its use of English as the universal language of business. Executives, management, technical subject-matter experts (SMEs), and the vast majority of general employees at Indian CDMOs all are fluent in English, making communication with the West significantly more straightforward than it may be for companies in other regions.

A People Business: I often point out that "assays don't develop themselves." Even as CDMOs offer access to specific capabilities, technologies, and capacity, their ability to deliver on all three remains critically dependent on the availability of suitably qualified and experienced staff and management. Much has been written recently about severe staff shortages in the biopharmaceutical space, where a general lack of experienced scientists, technicians, and engineers continues to threaten growth (**17**).

CDMOs could be critically at risk. In many ways, their employees are their product/service — and invariably we find talented people gaining experience very rapidly within CDMOs and then getting lured away by higher salaries and better benefits to big pharma

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and well-funded biotechnology companies. That gap is narrowing, however, as recent constraints in capital funding have triggered some layoffs that push good staff onto the job market. But staffing remains a critical issue across the industry, particularly in the advanced therapies space.

India is exceptionally well positioned to compete from that perspective based on its enormous workforce, with a large, well-educated, and increasingly experienced pool of talent applicable to biomanufacturing. At the ground level, the country is experiencing a remarkable growth in its middle classes, with parallel improvements in graduation numbers and rates for both secondary and tertiary education. Science, technology, engineering, and math (STEM) are particularly valued in India, which regularly turns out high numbers of remarkably talented scientists and engineers (as a visit to nearly any high-technology company in the West will confirm). The Organization for Economic Co-operation and Development (OECD) ranks India as fourth globally in graduating PhDs (more than 24,000) each year, and that number is growing rapidly. For perspective, the United States produces about 68,000 PhD graduates annually, many of them from outside the country.

Alongside standard curricula, we now find universities and government agencies as well as private enterprises in India offering and sponsoring specific education (from short courses to degree programs) that directly supports biomanufacturing. Among myriad examples are initiatives such as the government Department of Biotechnology's Biotech Industrial Training Programme, Allele Life Sciences' Industry Ready Training initiative, and the National Biotechnology Education Center's Innovatebio initiative (**18, 19**).

In addition to appropriate education, vital experience in direct discovery, CMC process development, and biomanufacturing is growing rapidly in India. That partly comes from domestic growth over the past two decades and partly from applicable experience gained in vaccine manufacturing — as well as a "reverse brain drain" that is bringing Indian nationals home who have contributed to the growth of biomanufacturing at recognized companies in North America, Europe, and elsewhere. In many ways, that phenomenon mirrors the Chinese "Thousand Talents" program, but it is happening naturally without the need for government incentive (**20**).

Business Economics: Cost is a clear driver for considering whether to engage CDMO services in India, especially for late-stage development and manufacturing of commercial supplies. Despite not yet boasting the large-scale volumetric capacities available in South Korea and elsewhere, India already offers an attractive CoG based on considerable advantages in costs associated with labor, energy, land, and construction.

Experience shows that labor is one of the few significant, controllable costs in biomanufacturing with CGMP compliance. Although such costs are rising in India in parallel with the country's economic development, they remain dwarfed by the relative costs in North America, Europe, and other territories that

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participate in the global biologics CDMO marketplace. Information specific to biomanufacturing is difficult to come by, but in 2023, a Reshoring Institute review of general manufacturing labor costs comparing labor rates across 13 countries concluded that India, Mexico, and Vietnam remain lowest cost and that "China can no longer be considered a low-cost country, as its labor rates have significantly increased" (**21**). Although such statistics do not apply directly to a highly trained biopharmaceutical workforce, labor rates in India for production workers are ~6.2% of those for the United States and Germany and 15.4% of those in China.

Water and energy costs — significant components of biomanufacturing CoG — also are generally attractive in India. Although the current geopolitical situation is causing considerable fluctuations, consider the cost of household electricity per kWh in 2022 as an illustration: India paid $0.07 and China $0.08; equivalent costs in the United States and Germany were $0.16 and $0.44, respectively (**22**).

A post-COVID survey carried out by real-estate advisory firm Savills India showed that even as industrial construction costs rose subsequent to the pandemic (and varied significantly across eight major hubs in India), they remained highly attractive relative to costs in most other markets (**23**). As of the first quarter in 2022, construction ranged $453–465/m^2 for general manufacturing in Indian cities and $291–$299/m^2 for grade-A warehousing. An interesting review published by Gleeds provides similar post-COVID data for costs in India associated with construction, materials, freight, fuel, and so on (**24**).

The supply chain for equipment, materials, and consumables associated with biomanufacturing is now essentially a single global market. Areas remain where local sourcing can deliver benefits to CDMO customers in India. I found it interesting to witness first-hand how Indian manufacturers adapted to supply chain challenges during the pandemic, including through rapid development of the original equipment manufacturer (OEM) marketplace for disposable bags, tubing sets, and such.

The **SUPPLY CHAIN** for equipment, materials, and consumables associated with biomanufacturing is now essentially a single global market. Areas remain where local sourcing can deliver benefits to CDMO customers in India.

Advanced and Next-Generation Therapies

India is developing a track record in the efficient production of advanced therapeutic modalities. Aurigene Pharmaceutical Services, for example, is spearheading developments in the cost-effective manufacture of bi- and multispecific antibodies. Other companies are advancing cell/gene therapies (CGTs). A recent *Nature* news article reports that ImmunoACT's NexCAR19 — a cancer therapy based on chimeric antigen receptor (CAR) T-cell technology — now is manufactured in India at ~10% of the cost of comparable commercial products elsewhere in the world (**25**). That achievement was made possible by a collaboration involving the Indian Institute of Technology (IIT) in Bombay, Tata Memorial Centre in Mumbai, and the US National Institutes of Health (NIH) Clinical Center in Bethesda, MD.

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Along with evolving government regulations and initiatives, an emerging domestic market for biopharmaceutical innovation is helping India rapidly develop expertise and manufacturing experience in CGTs. As noted above, the first domestically developed products are already approved. Meanwhile, companies such as Biocon, Reliance, and Dr. Reddy's (with its Aurigene Oncology subsidiary) are investing in the space through collaboration and licensing agreements (**26, 27**). Established Indian CDMOs increasingly offer services in support of the CGT sector, and some specialist players such as Yapan Bio are emerging.

Equipment and instrumentation suppliers have taken notice. It is no coincidence that Miltenyi Biotec recently opened its first office in India and announced plans for an Innovation and Technology Center "CGT Centre of Excellence" in Hyderabad — to provide both training and easy access to "expertise, research, and manufacturing solutions" (**28**). In 2023, Cytiva opened a similar "experience center" in Pune after its Biopharma Resilience Index showed that 65% of biopharmaceutical executives in India believe that the manufacturing of biologics in their country is likely to increase significantly (15% higher than the global average) in the near future (**29, 30**).

Innovation, Technology, Digitalization

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India is recognized as a global hub for information technology (IT) and digitalization, and biomanufacturing hubs are located adjacent to Hyderabad's Hi-Tec City and Bangalore's Electronic City regions. As pharma 4.0 initiatives continue to expand, Indian CDMOs will be well positioned to take advantage in areas related to compliance, automation, artificial intelligence and machine learning (AI/ML), digital twinning, and big data.

I have observed in-house digital capabilities in India that exceed those that I have seen at US-based CDMOs. Aurigene Pharmaceutical Services' Aurigene.AI drug-discovery platform was developed fully in house by combining advanced physics-based simulation, generative and predictive AI models, and computer-aided drug design into one platform (**31**). Although developed initially for small molecules, its capabilities can be applied to antibody discovery, for instance, and to design "manufacturability" into product candidates from the start. Digital expertise also is being applied in India to the rapid development of high-yielding and economically production processes through automation and reduction of the design-window for design-of-experiments (DoE) using ML.

Aurigene also brings considerable history, experience, and expertise for the application of high-density culture methods using alternating tangential-flow (ATF) cell-retention systems to achieve high productivities. Enzene also claims similar performance through application of its EnzeneX continuous manufacturing schemes based on a ballroom facility.

Intellectual Property and Investments

China undoubtedly has suffered from a mixed reputation regarding respect for intellectual property (IP) — which is part of discussions about the US Biosecure Act. India sometimes gets painted with the same brush. Although some criticism might have been warranted historically, India has implemented fully its National Intellectual Property Rights Policy (IPR, first announced in 2016), which is enforced by the Department for Promotion of Industry and Internal Trade (DPIIT) (**32**). The country is party to relevant global IP and trade agreements including Trade Related Aspects of Intellectual Property Rights (TRIPS), the World Intellectual Property Organization (WIPO), the Paris Convention for the Protection of Industrial Property, and the Patent Cooperation Treaty (PCT).

Equally important is that the major publicly traded multinational corporations supporting leading Indian biologics CDMOs are active in the global biopharmaceutical marketplace. They treat IP at least as seriously as do their peers in highly developed markets. Use of personal data in India is protected under the government's 2023 Digital Personal Data Protection Act.

Investment: For a number of reasons, India has not yet attracted significant investment in biomanufacturing. Such money has come from major corporations, traditional family promotor offices, and industry conglomerates (although not remotely on the scale of South Korea's chaebol). All that may be about to change as biomanufacturing opportunities in India achieve increasing global visibility and as Indian CDMOs become more willing to consider outside investment to support growth. For example, Stelis Biopharma raised $125 million in a series C funding round led by TPG Growth and supported by other long-term investors such as Route One and Think Investments (**33**).

Prescient & Strategic Intelligence points out that (small-molecule) "Indian CDMOs are already more profitable than those based in the Western hemisphere, with EBITDA [earnings before interest, taxes, depreciation, and amortization] margins as high as 35%, in contrast to the maximum 20% achieved by European and US-based CDMOs" (**23**). And the investment community has taken notice. In addition to private and other equity investors, opportunities for Indian CDMO operations are attracting the attention of established market players. Companies such as Catalent and Recipharm have invested into sterile-injectables capabilities in India. Can biologics be far behind? Recent attendance at the JP Morgan Healthcare Conference in San Francisco, CA, and the Drug, Chemical, and Associated Technologies Association's DCAT Week in New York City certainly have confirmed a high level of interest.

India is party to global **INTELLECTUAL PROPERTY** and trade agreements including TRIPS, WIPO, the Paris Convention, and the PCT.

Compliance and Sustainability

India has thousands of active pharmaceutical ingredient (API) and small-molecule/generic manufacturing facilities, ranging from small, locally owned operations to divisions of multinational corporations. The country also boasts the world's second highest

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number of FDA-inspected facilities (behind the United States). Such inspections occasionally lead to regulatory actions that generate headlines in the trade press, but what is less frequently reported is the very high level of compliance maintained by India's industry leaders, including those in the biopharmaceutical space.

Note that Aurigene's large-scale commercial CGMP contract biomanufacturing campus produced its first commercially approved biologic in 2004. Currently it releases biologics to more than 25 global markets. The facilities are inspected by the FDA, the EMA, and numerous other global regulatory agencies. Earlier this year, the site was approved by the MHRA for manufacturing a product for the UK marketplace. Aurigene quality systems are fully digital, operating with high levels of data integrity and reliability based on data recording in accordance with Good Automated Manufacturing Practice (GAMP 5) requirements (**34**).

Regular audits by recognized multinational customers and industry consultants have lent further credence to the claim that the quality management systems and standards maintained at top-tier Indian biomanufacturers and CDMOs are no different from those at companies in the United States or Germany.

Sustainability and diversity are increasingly important criteria for companies issuing requests for proposals (RFPs) to prospective CDMOs. I have been impressed by the performance of Indian biomanufacturers/CDMOs in these vital areas. Dr. Reddy's/Aurigene has been publishing environmental commitments and sustainability reports for two decades (far longer than most multinational CDMOs). The organization has been recognized as part of the World Economic Forum's Global Lighthouse Network for implementation of industry 4.0 technologies and by the *Financial Times* as an Asia–Pacific Climate Leader in 2023 (**35, 36**). In addition, the company was listed in 2023 among others in the Dow Jones Sustainability Index, the Bloomberg Gender Equality Index 2023, and Standard and Poor's (S&P) sustainability yearbook (**37–39**).

A Bright Future

A confluence of market maturity and growth, geopolitical events, a talented workforce, changing investment dynamics, an attractive cost base, and delivery of global commercial compliance levels sets the stage for India to make good on its mission of becoming a significant global bioeconomy. Excitement among investors, executives, employees, and other stakeholders in the biologics CDMO ecosystem in India is palpable. I predict significant growth over the coming decade. Can it be long before India is the world's *bio*pharmacy?

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About the Author

Dr. ***Roger Lias*** (rogerlias@aurigeneservices.com) is global commercial head of biologics for Aurigene Pharmaceutical Services and a respected executive and advocate for the contract development and manufacture of biologics. In addition to supporting multinational organizations such as Lonza and Diosynth, Lias has been a member of the founding management teams at KBI Biopharma and Cytovance. He was chief executive officer of Avid Bioservices and Stelis Biopharma before most recently contributing to the rapid growth of Vibalogics and sale of that company to Recipharm in 2022.

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