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The Rise of India's CRDMO's From Transactional Outsourcing to Value-based Parnerships

(Source: An article by Anju Ghangurde for Scrip Citeline)

India's contract research, development, and manufacturing organizations (CRDMOs) are undergoing a major strategic transformation, evolving from low-complexity, transactional outsourcing vendors into integrated, value-based partners for global biopharmaceutical innovators.

This shift marks a critical inflection point in India's life sciences trajectory as the sector moves beyond generics-led growth toward deeper innovation, advanced manufacturing, and collaborative R&D.

A new report by EY Parthenon and the Organization of Pharmaceutical Producers of India (OPPI) highlights that Indian CRDMOs are rapidly building sophisticated capabilities, including advanced manufacturing platforms, biologics production, analytics integration, and the adoption of AI-enabled tools to accelerate discovery and development timelines.

These investments allow Indian players to offer end-to-end services across drug discovery, development, and commercial-scale manufacturing while sharing greater strategic responsibility with clients rather than simply executing assigned tasks. The outsourcing model is shifting from "send us a task" to "partner with us in co-innovation," signaling deeper, more strategic collaboration across the value chain.

Several forces are accelerating this transition. Global supply chains are diversifying in response to geopolitical uncertainties, increasing demand for India as an alternative or complementary partner to China for critical drug development and manufacturing services.

Global biopharma companies are also seeking partners with specialized scientific and digital capabilities. Indian CRDMOs are responding by expanding into advanced modalities such as antibody–drug conjugates (ADCs), peptides, biologics, CAR-T and cell therapy discovery platforms, and GLP-1 drug substance and fill-finish services.

This strategic focus is reflected in deal flow: multi-year partnerships increasingly include investments in capacity expansion and technology enhancement. Examples include Theranym Biologics' major investment to support Merck's biologics manufacturing needs, Gland Pharma's contracts supporting GLP-1 products, and Aurigene Oncology's collaborations to advance autologous CAR-T therapies addressing solid tumor challenges.

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IFPW's 2026 CEO ROUNDTABLE
April 15th & 16th at the offices of
The Business Roundtable in Washington D.C.
Registration opens February of 2026

In Brief...

- Japanese drug wholesaler **Alfresa Holding**s signed an expanded strategic business alliance pact with **China Resources Pharmaceutical Commercial Group** to support licensing of Japanese pharmaceuticals and medical devices in the Chinese market. China Resources, the country's third-largest pharmaceutical wholesaler first entered into the agreement with Alfresa in 2019 and boosted the collaboration in November of 2023 with a view of promoting the licensing of Japanese drugs in China.
- **Johnson & Johnson (J&J)** is acquiring **Halda Therapeutics** for US$3.05 billion to bolster its oncology pipeline, particularly in prostate cancer treatment. The acquisition centers on Halda's RIPTAC platform, which uses a novel "hold and kill" mechanism to target cancer cells and overcome resistance. Halda's lead candidate, *HLD-0915*, demonstrated promising phase 1/2 results in metastatic castration-resistant prostate cancer (mCRPC) patients, showing significant reductions in prostate-specific antigen levels with manageable safety concerns. J&J plans to accelerate the ongoing study and integrate Halda's pipeline and platform to expand its cancer treatment capabilities. The deal is expected to close within months, further strengthening J&J's position in oncology and beyond.

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U.K.-U.S. Trade Deal Excludes Tariffs on Drugs & Includes Promise of U.S. Investment

(Source: An article by Frasier Kansteiner for fFercePharma)

On December 1, 2025, the U.S. government announced a landmark trade agreement with the United Kingdom, exempting U.K.-origin pharmaceuticals, pharmaceutical ingredients, and medical technology from industry-specific tariffs for at least three years. The agreement also includes a commitment from the U.S. to refrain from targeting U.K. pharmaceutical pricing practices during President Trump's term. In exchange, the U.K. will increase the net price its National Health Service (NHS) pays for novel treatments by 25% and revise its drug valuation framework, including changes to the National Institute for Health and Care Excellence's (NICE) "quality-adjusted life year" metric.

The deal aims to enhance biopharma investment in both countries and address concerns from major pharmaceutical companies about the U.K.'s undervaluation of innovative medicines. Earlier in 2025, companies like Merck, Sanofi, and AstraZeneca had expressed dissatisfaction with the U.K.'s life sciences investment climate, leading to paused or withdrawn R&D projects. AstraZeneca, in particular, has benefited from a "three-year grace period" from U.S. pharmaceutical tariffs and plans to list its shares on the New York Stock Exchange in

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CRDMOs *(cont'd.)*...

Similar alliances across Syngene, Piramal Pharma Solutions, Laurus Labs, Sai Life Sciences, Divi's, and Enzene illustrate a sector-wide move toward higher-value, innovation-aligned offerings.

Indian CRDMOs are also expanding globally to support clients more closely and meet regulatory expectations. Syngene's acquisition of a biologics manufacturing site in the United States and earlier acquisition of a multi-modal biologics facility in India demonstrate how leading firms are building international footprints and scaling biologics capacity to 50,000 liters and beyond .

These developments strengthen supply chain resilience, improve quality assurance, and enhance strategic flexibility for global partners.

A significant multiplier in this evolution is the rise of global capability centers (GCCs) operated by multinational pharma companies in India. Roughly half of the world's major life sciences companies now maintain GCCs in the country, which increasingly function as centers of excellence in R&D, data analytics, advanced digital platforms, IP protection, and quality governance rather than purely cost-efficiency hubs.

Their expanding roles raise expectations for compliance, quality, and data integrity among Indian suppliers, creating "reverse pressure" that elevates industry-wide standards.

CRDMOs, CDMOs, and GCCs collectively strengthen India's broader life sciences ecosystem by stimulating adjacent sectors such as packaging, automation, validation services, and digital manufacturing, while simultaneously enhancing talent pipelines and embedding global best practices in quality, safety, and regulatory compliance.

As these pillars converge, they help position India not only as a global manufacturing hub but as an emerging engine of biomedical innovation.

However, the report emphasizes that India's longstanding reliance on low-margin generics is unsustainable for long-term growth. Rising global scrutiny around compliance, data integrity, and manufacturing quality—particularly for older facilities—poses additional challenges that require modernization and regulatory agility.

To fully unlock the next phase of growth, industry leaders underscore the need for significantly increased R&D investment, ideally above 10% of revenues, and for talent development initiatives that integrate academic, industry, and government collaboration.

The overarching conclusion of the OPPI–EY analysis is that India's future in global pharmaceuticals will be shaped by "purposeful partnerships" that connect scientific excellence, digital innovation, scale manufacturing, and global market needs. Executives interviewed for the report describe partnerships as the "currency" of India's innovation decade—a mechanism through which the nation can shift from merely supplying medicines for the world to discovering and manufacturing transformative therapies that shape the future of global healthcare.

In total, the advancement of India's CRDMOs represents both a national opportunity and a global recalibration of the innovation and supply ecosystem. With continued investment, regulatory modernization, and strategic alliances, India is poised to assert a far more influential role in the global biopharmaceutical landscape.

U.K.-U.S. *(cont'd.)*...

February 2026.

This agreement is part of a series of country-specific trade deals by the Trump administration, which previously negotiated similar agreements with Switzerland, Japan, and the EU, capping import tariffs on drugs and exempting generic medicines from duties. The U.K.-U.S. deal is expected to safeguard medicine access, drive investment, and improve the valuation of innovative treatments.

In Brief (cont.)

- **Regeneron Pharmaceuticals** will invest US$2 billion to transform a former magazine factory in Saratoga Springs, New York, into a drug manufacturing facility, as part of its broader US$7 billion U.S. manufacturing expansion. The project will nearly double Regeneron's production capacity in New York and create at least 1,000 full-time jobs. The facility, located on a 1-million-square-foot property, will focus on producing drugs for infectious diseases and cancer. The acquisition complements other expansions in New York and North Carolina, reflecting the company's strategy to bolster domestic manufacturing amid U.S. pharmaceutical import tariff concerns. Separately, the company has secured two long-awaited approvals for *Eylea HD*, gaining a new indication and a more flexible dosing option for the eye disease drug.
- **Cleveland Clinic** conducted a Phase 1, first-in-human clinical trial using CRISPR-Cas9 gene-editing therapy to treat lipid disorders resistant to current medications. The one-time infusion safely reduced LDL cholesterol by 50% and triglycerides by 55% within two weeks, with effects lasting at least 60 days and no serious adverse events reported during short-term follow-up. Presented at the American Heart Association's Scientific Sessions 2025 and published in the *New England Journal of Medicine*, the study highlights the potential of this therapy to revolutionize treatment for high cholesterol and triglycerides, offering a durable alternative to daily pills or monthly injections. Further trials are needed to confirm long-term safety and efficacy.
- **Abbott** has announced a US$23 billion acquisition of **Exact Sciences**, a leading company in cancer diagnostics, marking its largest merger to date and a significant expansion into cancer screening and precision oncology. Exact Sciences, known for its *Cologuard* at-home colorectal cancer test and innovative blood-based tests like *Cancerguard* and *Oncodetect*, is expected to generate US$3.2 billion in revenue this year with over 5 million tests performed. The acquisition will double Abbott's diagnostics market to over US$120 billion, positioning the company as a leader in preventative, predictive, and personalized cancer diagnostics.

(Sources: Drug Store News, FiercePharma, Pharma Japan, Scrip Citeline and World Pharma News)