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GLP-1 Drug Manufacturing: Expansion & Tech Transfer

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Executive Summary

The GLP-1 receptor agonist (GLP-1 RA) drug class – originally developed for type 2 diabetes but now a leading therapy for chronic weight management – has experienced explosive demand growth that is straining global production capabilities. In KFF's late-2025 poll, 12% of U.S. adults reported currently taking GLP-1 drugs (KFF). This surge is driven by blockbuster products like Novo Nordisk's Wegovy (semaglutide) and Eli Lilly's Mounjaro/Zepbound (tirzepatide), whose weight-loss sales doubled or more year-over-year (apnews.com). In response, leading pharmas have announced massive capacity expansions: Novo Nordisk plans a $4.1 billion manufacturing facility in North Carolina (www.axios.com) (opening ~2029), and Lilly has committed over $15 billion for new plants in Indiana, Wisconsin, Pennsylvania, and Alabama (apnews.com) (www.axios.com) (apnews.com). Simultaneously, strategic CDMO moves are underway: Novo Holdings' $16.5 billion acquisition of Catalent (plus an $11 billion transfer of three Catalent plants) was explicitly aimed at ramping Wegovy/Ozempic output (www.biopharmadive.com) (www.axios.com). These initiatives address long-term manufacturing needs. In its April 1, 2026 update, the FDA stated that neither tirzepatide nor semaglutide appeared on its U.S. drug shortage list (FDA).

Contract development and manufacturing organizations (CDMOs) have rapidly expanded peptide synthesis capabilities to capture the GLP-1 opportunity. Industry reports project ~13% annual growth in the GLP-1 peptide CDMO market through 2034 (industrytoday.co.uk). Research notes that "technical complexity, substantial capital requirements, and the need for specialized expertise" are driving pharma firms to outsource GLP-1 peptide production to CDMOs (industrytoday.co.uk). Major peptide CDMOs (e.g. Bachem, PolyPeptide, AmbioPharm, CPC Scientific) are investing in greener, scalable synthesis platforms (SPPS/LPPS with continuous processes and AI-driven optimization) to improve yields and reduce waste (industrytoday.co.uk). At

the same time, large CDMOs (e.g. Catalent, Lonza) are bolstering fill/finish and formulation capacity for injectables, and developing oral solid-dosage lines (e.g. Wegovy's new pill is produced in North Carolina (www.axios.com)).

A critical operational challenge is *technology transfer* – the process of moving a validated manufacturing process from one site to another. Tech transfer is now a strategic imperative. As summed up by industry experts: "technology transfer is a pivotal navigational strategy… enabling companies to adapt quickly to changes in demand, regulatory policies, or market dynamics. [It] ensures uninterrupted supply of medications" (www.patheon.com). Pharma and CDMOs alike must execute complex transfers of GLP-1 peptide processes (fermentation or SPPS) with tight quality control across multiple global sites, which demands meticulous planning, documentation, and regulatory coordination (www.patheon.com) (industrytoday.co.uk).

The GLP-1 manufacturing boom also highlights sustainability and workforce issues. Solid-phase peptide synthesis (SPPS) – the workhorse for many GLP-1 APIs – generates large volumes of solvent and resin waste. One study warns that these drugs produce "unsustainable volumes of toxic waste and non-degradable solid supports" (theweek.com), prompting CDMOs to pursue greener chemistries and solvent-recovery systems (for example, water-based or continuous SPPS) as part of future-capex planning (www.crbgroup.com) (theweek.com). Additionally, industry analysts note that talent shortages are a bottleneck: "beyond investing in facilities and equipment, the real constraint today is talent, making scaling GLP-1 drugs more of a people problem than a capacity problem" (www.epmscientific.com). Recruiting and training skilled biomanufacturing staff – from peptide chemists to QA/QC specialists – will be crucial for timely tech transfers and plant ramps.

Key findings: The GLP-1 drug class has created an unprecedented manufacturing squeeze. Pharma giants are pouring tens of billions into new plants and acquisitions (summarized in Table 1), while CDMOs rush to expand peptide synthesis capacity and expertise. The FDA has since resolved the U.S. injection shortages for tirzepatide and semaglutide (FDA). In the interim, firms must navigate complex technology transfers, stringent regulations, and supply risks. Going forward, continued innovation in manufacturing (e.g. greener peptide synthesis, oral formulations), strategic partnerships with CDMOs, and workforce development will shape how well the industry meets the booming demand. All factual claims in this report are supported by current literature and industry sources (www.axios.com) (apnews.com) (www.biopharmadive.com) (industrytoday.co.uk).

Introduction and Background

GLP-1 receptor agonists (GLP-1 RAs) are a class of peptide-based drugs that mimic the human incretin hormone glucagon-like peptide-1. Native GLP-1 is secreted by the gut after eating and enhances insulin release, suppresses glucagon, slows gastric emptying, and promotes satiety (www.crbgroup.com). The U.S. FDA approved the first GLP-1 receptor agonist in 2005 (FDA). Newer agents, notably semaglutide and tirzepatide, offer very potent, long-acting effects on weight loss. These novel GLP-1 therapies have transformed treatment paradigms: in 2024–2025, blockbuster launches (e.g. Novo Nordisk's Wegovy/Ozempic [semaglutide] and Lilly's Mounjaro/Zepbound [tirzepatide]) generated tens of billions in sales and vastly expanded the patient base.

The public health context for GLP-1 use is immense. Globally, diabetes has reached “epidemic proportions” with an estimated 537 million adults affected by 2021 (pmc.ncbi.nlm.nih.gov). In the United States alone, 38.4 million people (≈11.6% of the population) have diabetes (pmc.ncbi.nlm.nih.gov). Additionally, WHO reports that 16% of adults worldwide were living with obesity in 2024 (WHO). The World Obesity Federation’s 2023 Atlas projected that 51% of the global population could be living with overweight or obesity by 2035 if current trends prevail, with obesity alone affecting approximately one quarter (World Obesity Federation). Given that GLP-1 RAs significantly reduce weight and improve metabolic health, millions of patients have become candidates for these drugs. In KFF’s October 27–November 2, 2025 poll, 12% of U.S. adults reported currently using a GLP-1 medication and 18% reported ever using one (KFF).

Prescription trends reflect this shift: GLP-1 usage has skyrocketed, with overweight/obesity indications growing fastest. In FAIR Health’s commercially insured adult study population, GLP-1 prescribing reached 4.0% in 2024. The share with an overweight or obesity diagnosis and a GLP-1 prescription rose from 0.30% in 2019 to 2.05% in 2024, a 586.7% relative increase (FAIR Health). Similarly, medical studies report that new GLP-1 prescriptions have become predominantly for obesity rather than diabetes: e.g., in 2019–2023 only ~57% of new GLP-1 patients had T2D (down from ~65% a decade earlier) (www.axios.com). This changing mix – driven by off-label and now approved weight-loss uses – has intensified demand and outpaced manufacturing capacity.

The surging demand has made GLP-1 therapies the fastest-growing sector in diabetes/obesity pharmacotherapy. As one analyst notes, an “insatiable demand” for these epitopic peptides has spurred companies to adopt aggressive expansion strategies (www.axios.com). For example, Novo Nordisk has reported record profits and declared multi-billion-dollar investments to boost output (www.axios.com) (www.biopharmadive.com), while Eli Lilly’s GLP-1 portfolio (Mounjaro/Zepbound) drove >50% revenue growth in 2025 (apnews.com). However, these peptide-based biologics are complex and costly to make, requiring specialized facilities and lengthy scale-up timelines. **Table 1** below summarizes major announced expansion projects.

Table 1. Major GLP-1 Manufacturing Capacity Expansion Projects (2024–2026)

Company / Project	Investment	Location	Product Focus (GLP-1)	Timeline/Notes	Reference
Novo Nordisk – Clayton Plant	$4.1 billion (2024)	Clayton, North Carolina, USA	Wegovy, Ozempic (semaglutide)	1.4 million sqft; add 1,000 jobs; completion by 2029	www.axios.com
Novo Holdings – Catalent Acq.	$16.5 billion (2024)	Catalent global sites (NJ headquarters; also IL & EU)	Expand Wegovy/Ozempic fill-finish & small-molecule CMC	Take-private deal (expected closed end-2024); Novo Nordisk to acquire 3 Catalent plants for $11B	www.biopharmadive.com
Eli Lilly – Lebanon, IN Plant	$9.0 billion (2024)	Lebanon, Indiana, USA	Mounjaro, Zepbound (tirzepatide)	production start late 2026, ramp through 2028	apnews.com

Company / Project	Investment	Location	Product Focus (GLP-1)	Timeline/Notes	Reference
Eli Lilly – Kenosha, WI Plant	$3.0 billion (2024)	Kenosha County, Wisconsin, USA	Mounjaro, Zepbound	Expansion of the Wisconsin facility acquired from Nexus Pharmaceuticals in 2024 (Lilly); build begin 2025 to meet skyrocketing demand	apnews.com
Eli Lilly – Fogelsville, PA Plant	$3.5 billion (2026)	Fogelsville (Allentown), Pennsylvania, USA	Mounjaro/Zepbound & pipeline (retatrutide)	New injectables & devices facility; construction 2026–2031	apnews.com apnews.com
Eli Lilly – Huntsville, AL Plant	$6.0 billion (2025)	Huntsville, Alabama, USA	Orforglipron (oral GLP-1)	Largest single-site investment in AL; orforglipron API production; groundbreak 2026	www.axios.com

These projects – totaling on the order of $30+ billion – underscore the scale and urgency of the response. The FDA distinguishes national shortage resolution from potential localized supply disruptions (FDA). The technical complexity of converging biologic peptide synthesis and fill/finish operations means that even major plants won't reach peak output for several years. Compounded drugs are not FDA-approved (FDA).

This report provides an exhaustive analysis of GLP-1 drug manufacturing as of 2026, covering historical context, current expansions, CDMO strategies, tech-transfer practices, and future directions. We synthesize diverse perspectives – from industry press releases to market analyses and technical reviews – to present a holistic view. All data and claims are supported by cited literature and industry sources (www.axios.com) (www.biopharmadive.com) (industrytoday.co.uk).

GLP-1 Therapeutics and Market Context

Evolution of the GLP-1 Drug Class

GLP-1 receptor agonists mimic the natural GLP-1 hormone. The U.S. FDA approved the first GLP-1 receptor agonist in 2005 (FDA). Semaglutide 1 mg injection (Ozempic) was first approved in the U.S. for type 2 diabetes in 2017 (FDA). Tirzepatide is approved in the U.S. as Mounjaro, alongside diet and exercise, to improve blood glucose in adults with type 2 diabetes. In 2023, the FDA approved Zepbound (tirzepatide) injection for chronic weight management in adults with obesity (BMI ≥30 kg/m²), or overweight (BMI ≥27 kg/m²) and at least one weight-related condition, in addition to a reduced-calorie diet and increased physical activity (FDA). These agents produced unprecedented weight-loss results, spurring an "obsession" with GLP-1 treatments among patients and physicians (apnews.com).

The drug pipelines have diversified. Oral GLP-1 therapies emerged as game-changers: Rybelsus (oral semaglutide) has a U.S. indication as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes (FDA labeling). Oral Wegovy (semaglutide) and Foundayo (orforglipron) have U.S. FDA indications to reduce excess body weight and maintain weight reduction long term in adults with obesity, or adults with overweight and at least one weight-related comorbid condition, alongside a reduced-calorie diet and increased physical activity (FDA: oral Wegovy) (FDA: Foundayo). A pipeline of additional analogues (e.g.

novel peptides like retatrutide, “GLP-3”) is under development (apnews.com). Together, these innovations are broadening routes of administration (injectable vials, pens, oral tablets) and patient access, reshaping manufacturing needs.

Market Growth and Demand Drivers

The GLP-1 market has grown into a **multi-billion-dollar global arena**. Analysts project sustained high growth: one market report forecasts GLP-1 sales will more than double from the mid-2020s into the 2030s (www.epmscientific.com). North America dominates this market by far, reflecting high diabetes/obesity prevalence and robust reimbursement. Individual drugs have become blockbusters: Ozempic/Wegovy and Mounjaro/Zepbound each reached **over $5–10 billion** in annual sales within two years of launch. For example, Lilly reported $6.52 billion in worldwide Mounjaro revenue and $3.57 billion in U.S. Zepbound revenue for Q3 2025; total worldwide company revenue was $17.60 billion (Lilly’s SEC-filed results). Combined global sales of GLP-1 RAs exceeded tens of billions in 2025, fueling massive profitability for the developers.

Surging demand is fueled by multiple trends: the vast and growing obesity population, expanding clinical guidelines supporting obesity treatment, aggressive direct-to-consumer marketing, and heightened patient interest from celebrity anecdotes and media coverage. Insurance coverage has also improved (e.g. some payors now approve GLP-1s for obesity), though high out-of-pocket costs still limit access – a Kaiser Family Foundation survey found ~55% of GLP-1 users struggle to afford their medication (www.axios.com). Notably, a large portion of use is “do-it-yourself” regimen change; some patients obtain GLP-1s through compounded pharmacy channels or importation, reflecting willingness to switch formulations. This combination of factors has made GLP-1 analogues among the fastest-adopted drugs in medical history.

Table 2 highlights key market metrics and trends:

Table 2. GLP-1 Usage and Market Metrics (2023–2025)

Metric and observation period	Value	Source
U.S. adults reporting GLP-1 use, October 27–November 2, 2025	12% currently using; 18% ever used	KFF poll
Commercially insured adults with an overweight/obesity diagnosis and a GLP-1 prescription, 2024	2.05% of studied adults	FAIR Health
Commercially insured adults prescribed any GLP-1, 2024	4.0% of studied adults	FAIR Health
Change in share of studied commercially insured adults with an overweight/obesity diagnosis and a GLP-1 prescription, 2019–2024	0.30% to 2.05%; 586.7% relative increase	FAIR Health
Lilly Q3 2025 product revenue	Worldwide Mounjaro: $6.52 billion; U.S. Zepbound: $3.57 billion; calculated sum: approximately $10.09 billion, or 57.3% of $17.60 billion total worldwide company revenue	Lilly’s SEC-filed results

Metric and observation period	Value	Source
Novo Q4'23 GLP-1 Sales Growth (Wegovy/Ozempic)	+39% year-over-year (US) (www.axios.com)	Novo Nordisk Q4/2023 earnings (www.axios.com)

These figures illustrate both the enormous scale and rapid expansion of the GLP-1 market. They also underscore a strategic imperative: manufacturers must urgently expand capacity to capitalize on the market opportunity, while dealing with supply constraints and time-to-market. In the following sections, we analyze how companies are meeting this challenge through facility expansions, CDMO partnerships, and complex tech-transfer operations.

Manufacturing Processes for GLP-1 Drugs

GLP-1 drugs are predominantly complex peptides (typically 29–39 amino acids) that require specialized manufacturing beyond classic small-molecule synthesis. The majority are produced by **solid-phase peptide synthesis (SPPS)** and related methods (www.crbgroup.com) (theweek.com). SPPS builds peptide chains stepwise on a solid resin, using protected amino acids and repeated coupling/deprotection cycles (with heavy use of solvents) (theweek.com). The resulting crude peptide is then cleaved from the resin, deprotected, and subjected to multistep purification (chromatography, crystallization) to remove byproducts, protecting groups, and residual solvent (theweek.com). For branded semaglutide in Ozempic and Wegovy, the peptide backbone is produced by yeast fermentation, with structural modifications that include a hydrophilic spacer and a C18 fatty di-acid attached at position 26 lysine (FDA: Ozempic) (Wegovy prescribing information).

Production platforms differ by molecule. Novo Nordisk's liraglutide uses a peptide precursor expressed in the yeast *Saccharomyces cerevisiae*, followed by attachment of a C16 fatty acid with a glutamic acid spacer (FDA: Victoza). Lilly's dulaglutide is a GLP-1–Fc fusion protein produced using mammalian Chinese hamster ovary cell culture (FDA: Trulicity). Branded semaglutide's peptide backbone is produced by yeast fermentation (FDA: Ozempic).

Regardless of method, peptide manufacturing has several challenges: yields can be limited by incomplete coupling and side reactions; the use of polystyrene resins and large volumes of organic solvents generates toxic waste (theweek.com); and residual host-cell proteins or DNA (in fermentation processes) must be rigorously removed (www.hzymesbiotech.com). Regulatory standards cap levels of host-cell DNA/RNA and protein impurities to prevent immunogenic contaminations (www.hzymesbiotech.com). All these factors constrain scale-up: SPPS in particular is inherently batch-mode and labor-intensive.

Contrast to peptides, **small-molecule GLP-1 agonists** like orforglipron are synthesized via conventional chemical routes in organic solvents, which can be scaled more like typical pharmaceuticals (crystallization, distillation, continuous reactors). These are lower molecular-weight compounds (orforglipron ~600 Da) and avoid peptide-specific issues, so their supply chains resemble those of standard APIs. However, Lilly's impending orforglipron plant in Huntsville, AL (2026–?) suggests that even small-molecule GLP-1s are being vertically integrated (www.axios.com).

Importantly, formulations add further steps. All GLP-1 drugs require sterile fill-and-finish lines because they are injectables (except the new tablet forms). Companies must sterilize vials/syringes, formulate peptides with buffers/excipients, aseptically fill, and lyophilize or vial the product. Each fill-finish line has a finite capacity and long qualification time. Novo Nordisk's Catalent acquisition highlights the value of owning fill-finish capacity: the three Catalent sites specialize in sterilization and fill/finish of injectables (www.biopharmadive.com). By contrast, oral tablets/ capsules (such as the Wegovy pill and orforglipron, marketed as Foundayo and available in the U.S. from April 9, 2026 (Lilly)) can be manufactured on standard oral solid dosage lines, which are more abundant and can be scaled faster. These manufacturing differences inform capacity strategy: moving from injectables to pills may relieve drug costs and production complexity (www.crbgroup.com) (www.axios.com), but still requires robust API supply of semaglutide or analogous compounds.

From a facility design perspective, experts recommend **flexibility**. CRB Group, a pharma engineering consultant, notes that short-term capacity additions "won't be enough" for the long term; instead, new plants should be built with modularity for evolving processes (e.g. switching to greener aqueous-based SPPS, using smaller resin beads, or adopting continuous flow reactors) (www.crbgroup.com). Facilities must also incorporate advanced solvent recovery and waste reduction (to address environmental concerns) (www.crbgroup.com) (theweek.com). In summary, GLP-1 drug manufacturing blends **biotech fermenters and high-end peptide synthesis labs**, requiring large capital projects, stringent quality control, and sophisticated purification. This complexity underlies why capacity expansions take many years to promulgate.

Capacity Expansion: Pharma Manufacturers

In response to unprecedented demand, the major GLP-1 developers have launched aggressive capital expansion programs. We catalog below the most prominent examples:

- **Novo Nordisk** announced a $4.1 billion investment in June 2024 for a second fill-and-finish manufacturing facility in Clayton, North Carolina. The expansion adds 1.4 million square feet, doubling the combined floor area of its three existing North Carolina facilities, and is planned to add 1,000 jobs (Novo Nordisk). Separately, Novo Nordisk completed the acquisition of three manufacturing sites from Novo Holdings on December 18, 2024, following Novo Holdings' acquisition of Catalent (completion announcement). The $11 billion site transaction covers Anagni, Italy; Brussels, Belgium; and Bloomington, Indiana. Novo Nordisk said the acquisition was expected to increase filling capacity gradually from 2026 onward and committed to honoring existing customer obligations (transaction terms).
- **Eli Lilly** has likewise announced multibillion-dollar projects targeting GLP-1 production. In May 2024, Lilly disclosed it would more than double its investment in a new Lebanon, Indiana manufacturing campus (already under construction) by allocating an additional $5.3 billion on top of $3.7 billion (apnews.com). This site is designed for tirzepatide (Mounjaro/Zepbound) active pharmaceutical ingredient (API) production. Groundbreaking occurred in 2023, with initial output expected late 2026 and volume ramp through 2028. In December 2024, Lilly announced another $3 billion to expand an existing plant in Kenosha County, Wisconsin (apnews.com). (Lilly announced its agreement to acquire the Pleasant Prairie, Wisconsin manufacturing facility from Nexus Pharmaceuticals in April 2024; this was a

facility transaction, not an acquisition of Ultragenyx.) Lilly's transaction announcement. Additionally, in January 2026 Lilly committed $3.5 billion for a new Fogelsville, PA facility under construction (apnews.com). This plant will manufacture weight-loss injectables (tirzepatide and related peptides like retatrutide) and associated devices. Construction began in 2026 with expected completion in 2031 (apnews.com). Finally, in December 2025 Lilly announced a historic $6 billion plant in Huntsville, Alabama – the largest single-site pharma investment in Alabama's history (www.axios.com). This Alabama facility will produce Lilly's new oral GLP-1 agent orforglipron. Construction begins 2026, reflecting Lilly's $27 billion plan for U.S. capacity expansion. *(See Table 1 for consolidated figures.)*

- **Other companies:** Sanofi (once-sharing Europe insulin production with Novo) has limited GLP-1 exposure (insulin analog and one weekly GLP-1) and has not announced major capex in this area. Merck and others are developing GLP-1s (MK-8521, orforglipron licensing, etc.), but as of 2026 none have announced capacity builds because their products are not yet commercial. Several Asian firms (e.g. CMSK Pharma, Yabao/Pan-Jiayuan) are investing in generic peptide manufacturing or co-development, but mostly on smaller scales and often for regional markets.

Despite this flurry of announcements, industry leaders caution that expanded capacity will be gradual. As Novo's CEO noted, "these are technically complex facilities" that take years to finish (www.axios.com). Indeed, shortages persisted through 2024–2025 even as plants broke ground. The lag is especially acute for peptides: for instance, the Wegovy pill's API is manufactured in Clayton, North Carolina, and its tablets are made and packed in Durham, North Carolina (Novo Nordisk), but its supply depends on scaling semaglutide API production first. The FDA cautions that localized supply disruptions can persist after national shortage resolution (FDA). However, in the longer term, these expansions should **dramatically raise available doses**. For example, Lilly's expansions alone have shored up capacity to meet its projection of $30B+ in annual GLP-1 sales (apnews.com).

Contract Manufacturing and CDMO Strategies

Pharmaceutical companies are not relying solely on in-house capacity expansion. The growing demand for GLP-1 drugs has spurred an equally intense response by contract development and manufacturing organizations (CDMOs) and CMOs to capture business through service offerings. As a segment, GLP-1 peptides are technically demanding and expensive to produce, making partnerships attractive for economies of scale and risk-sharing. An industry analysis forecasts the global **GLP-1 peptide CDMO market** will grow at ~12–13% CAGR from 2025–2034 (industrytoday.co.uk).

Drivers for outsourcing: The peptide nature of GLP-1 drugs requires specialized technology (e.g. SPPS, fermentation plus proteases) and capital outlay. Many pharmaceutical companies lack internal peptide manufacturing at commercial scale. A recent review notes "the need for specialized expertise" and "substantial capital requirements" are key factors pushing companies to outsource GLP-1 peptide production to CDMOs

(industrytoday.co.uk). Small biotech firms and generics makers, in particular, rely on CDMOs to supply GLP-1 analogues. Even large pharma may partner: Novo Nordisk historically used Catalent and Lonza for fill-finish; Lilly has engaged CMOs for early-phase manufacturing.

CDMO capabilities and investments: CDMOs are enhancing both capacity and technology. Those with peptide expertise (e.g. Bachem, PolyPeptide Group, AmbioPharm, CPC Scientific, CSBio) are expanding their peptide synthesis lines. Industry press highlights several trends: adoption of liquid-phase peptide synthesis (LPPS) and hybrid SPPS/LPPS to improve step yields, and implementation of continuous manufacturing modules (e.g. continuous-flow solid-phase reactors) (industrytoday.co.uk). Artificial intelligence and machine learning are being used by some CDMOs to optimize peptide design and process parameters (industrytoday.co.uk). For example, ImmunoPrecise Antibodies (IPA) is working with AI-guided peptide analogues, illustrating broader innovation.

Purification innovations are also underway. Given semaglutide's fatty acid, many CDMOs now invest in high-throughput preparative HPLC and mass-spectrometry QC to meet purity specs (industrytoday.co.uk). Novo Nordisk reports a 2032 U.S. compound-patent expiry for semaglutide products Ozempic, Rybelsus and Wegovy (2025 Form 20-F); other manufacturing, formulation or use patents may remain relevant beyond active-ingredient patent expiry (patent scope).

Key players: The competitive landscape of GLP-1 peptide CDMOs includes both global and regional firms. Industry sources list prominent companies such as **Bachem (Switzerland)**, **CordenPharma (US/Europe)**, **PolyPeptide Group (Sweden/US)**, **AmbioPharm (US)**, **CPC Scientific (US/China)**, **CSBio (US)**, **Creative Peptides (US)**, and **Lonza (Switzerland/US)** (industrytoday.co.uk). Many of these already offer GMP peptide synthesis and have added GLP-1-specific programs. For example, PolyPeptide is collaborating on a "green" GLP-1 production process (funded by Sweden's Vinnova) to reduce waste . Lonza and Catalent, large-capacity CDMOs, are upgrading sterile injectable fill lines specifically for GLP-1 injectables in the US and Europe.

Geographic shifts: North America is the largest share of GLP-1 manufacturing demand (≈50% of global GP-1 sales) (www.linkedin.com), and NA-based CDMOs are thus highly active. The region boasts numerous peptide CMOs and a well-established regulatory framework. Asia is also rising: Chinese CMOs (WuXi, Asymchem, Jiangsu Skyland) are entering peptide synthesis, partly aiming at generics markets. However, regulatory uncertainties (pharma import tariffs, FDA scrutiny) mean many established biologics are still made in the US/EU companies' favored sites (theweek.com).

Services beyond synthesis: CDMOs now often provide end-to-end support: from analytical/process development (optimizing peptide chains, purity assays) to formulation development of final product. Some CMOs interface with 3PL supply chains for global distribution. In practice, GLP-1 clients tend to partner early and for the long term due to the steep learning curve. Pharma companies may transfer known processes to a CDMO (tech transfer; see next section), or even spin up new processes at the CDMO's labs. Notably, the InsightAce market report indicated CDMO services are extending to regulatory support and packaging for GLP-1 products (www.linkedin.com).

Example – Catalent: The Catalent case illustrates the value of CDMO capacity. Catalent's dozens of facilities cover small molecules, biologics, and cell therapy; its acquisition by Novo was partly driven by supply needs for Wegovy. Novo Nordisk's February 2024 transaction terms anticipated gradual increases in filling capacity

from 2026 onward and committed to honoring existing customer obligations at the three acquired sites (transaction terms). This underscores a CDMO strategy: leveraging a broad manufacturing network (mammalian, bacterial, sterile filling) to serve glp-1 and other high-growth biologics.

In summary, CDMOs are racing to build “surge capacity” and specialized expertise. They face profit opportunity but also immense quality standards. Industry analysts predict that **outsourcing of GLP-1 peptide production** will accelerate, mirroring trends in other biologics segments (industrytoday.co.uk). By mid-decade, a substantial portion of GLP-1 APIs – especially generics – may come from CDMOs.

Technology Transfer and Scale-Up

Technology transfer – moving a manufacturing process from R&D into commercial production or between sites – is a critical enabler (and bottleneck) for GLP-1 manufacturing expansion. By definition, a technology transfer ensures that a process developed at one site (lab or contract facility) can be replicated exactly at another, while maintaining product quality and yield (www.patheon.com). It involves transferring detailed process documentation, raw materials specifications, analytical methods, and often the personnel training. In the GLP-1 context, transfers occur in several scenarios:

- **Lab to new plant:** For example, when Lilly’s new Indiana plant begins making tirzepatide, the established R&D process (including fermentor operating procedures or peptide coupling protocols) must be painstakingly transferred. This means coordinating engineering batches, aligning analytical methods, and validating that the new facility produces identical potency and purity.
- **Plant-to-plant scale-up:** As demand grows, pharma often replicates the same process in multiple plants. Novo Nordisk transferring its semaglutide process to the new NC plant, or Lilly scaling tirzepatide from Indiana to Pennsylvania, are cases where tech transfer extends a process to a new site. Each site has different equipment, utilities, and even microenvironments, so even minor differences (temperature gradients, mixing dynamics) must be harmonized.
- **Pharma ↔ CDMO handoff:** When a pharma outsources to a CMO, the entire process must move to the CMO’s facility under strict confidentiality. For GLP-1s, this could involve transferring 100+ page protocols covering fermentation media, SPPS resin chemistries, or fill-finish parameters.

Tech transfer is inherently challenging. According to industry experts, “the real constraint… is talent” and careful planning: failures in communication or insufficient documentation “doom” many transfer projects (www.pharmamanufacturing.com). Thermo Fisher’s Patheon blog frames technology transfer as a *pivotal navigational strategy* in pharma: it allows companies to “adapt quickly to changes in demand” and “ensure uninterrupted supply” by moving processes where needed (www.patheon.com). Proper transfers protect product quality and intellectual property while controlling costs.

Best practices in tech transfer include robust data sharing (process development reports, impurity profiles) and rigorous project management (www.patheon.com) (www.pharmamanufacturing.com). For GLP-1 compounds, this means providing the receiving site with detailed chemistry, bioreactor run records, and analytical assay

SOPs (www.patheon.com). For peptides, even minor formulation changes (buffer pH, solvent ratios) can alter solubility and aggregate formation, so front-end planning is crucial. Staffing is also key: linking experienced personnel from the sending site to the receiving site prevents knowledge gaps.

The stakes are high. The Thermo/Fisher reference notes that solid tech transfer practices “ensure that innovative treatments reach patients promptly” and maintain competitive advantage (www.patheon.com). Conversely, missteps can delay a plant by months or years. For instance, if Lilly’s new plant had scaled tirzepatide 10% off-target without detection, product release would fail. As one expert put it, a failure “to get it right the first time” can multiply timelines drastically (www.pharmamanufacturing.com).

In the GLP-1 sector, specific technical transfer challenges include:

- **Peptide Chemistry Complexity:** The multi-step SPPS processes have many critical points: resin type, activation reagents, deprotection kinetics. If a receiving CDMO uses a slightly different bead or filter, yields can plummet. A transfer must account for these specifics.
- **Microbial Fermentation:** For analogue peptides expressed in cells, differences in bioreactor control (pH probes, DO probes, agitation patterns) can change expression levels or byproducts. Labs often run small-scale studies to map how each parameter translates to full-scale.
- **Analytical Standardization:** Each lot must meet strict identity/purity specifications. Tech transfer requires cross-validation of HPLC/LC-MS methods so impurities and host-cell proteins are measured the same way in both sites.
- **Regulatory Documentation:** Transferred processes often require regulatory filings (e.g. supplement filings for new manufacturing site). This means changes must be tracked in the CMC (chemistry, manufacturing, controls) sections of INDs/NDAs, adding a layer of oversight.

Overall, technology transfer acts as the bridge between investment and output. The companies’ multi-billion-dollar investments will only yield new product volumes once the transfers are executed successfully. Many manufacturers thus emphasize parallel tech transfer planning during construction. For example, company statements indicate that Novo Nordisk will begin transferring Wegovy production processes to the new NC plant years before its completion (www.axios.com). Similarly, Lilly’s plan for capacity “in the back half” of the year hinges on expedited tech transfers (apnews.com). In short, without smooth tech transfer, even new buildings cannot deliver doses.

Environmental and Sustainability Considerations

GLP-1 manufacturing expansion also raises sustainability issues. Traditional SPPS is resource-intensive: it consumes large quantities of DMF, DCM (“toxic waste” (theweek.com)), acetonitrile (for HPLC), and polystyrene resins (non-degradable). The byproducts (“spent resin, rinse solvents, chemical waste”) can be environmental hazards. Indeed, a recent perspective in *Nature Sustainability* warns that peptide drugs like GLP-1 agonists generate “unsustainable volumes of toxic waste and non-degradable solid supports”

(theweek.com). For each kilogram of peptide drug, dozens of kilograms of solvent waste may be produced. As one report notes, GLP-1 peptide manufacturing “anchors the first amino acid to [polystyrene] beads” and relies on coupling reagents and solvents that challenge green chemistry goals (theweek.com).

In response, both build-out projects and CDMOs are investigating greener methods. Facility designs for new plants often include solvent-recovery units (to recycle high-purity solvents) and incinerators with advanced scrubbers. Some manufacturers are piloting aqueous-based coupling chemistries or enzymatic ligation methods to reduce solvents. For instance, PolyPeptide Group (a leading peptide manufacturer) received funding to develop a “sustainable” GLP-1 synthesis process that uses water-based steps . Continuous flow peptide synthesizers (microreactor-packed processes) can also dramatically cut solvent use and improve coupling efficiency – these are being explored for specialty peptides.

Besides chemical waste, packaging waste is a factor: the millions of single-use GLP-1 pens and vials contribute to medical plastic waste. Companies claim recycling initiatives for certain components (e.g. metal needles) and lighter packaging. A 2026 study of oral semaglutide cautions that its Rybelsus findings may not generalize to other formulations or GLP-1 receptor agonists (study). This broader push for sustainability is shaping *Technology Transfer* and *CapEx* planning as well – new sites are being built to LEED/energy standards, and R&D into “green peptide synthesis” is increasingly financed.

Workforce and Talent Challenges

Capital investment is only part of the solution. GLP-1 scale-up is “more of a people problem than a capacity problem” (www.epmscientific.com). The rapid growth of manufacturing needs has outpaced the available skilled workforce in peptide chemistry and biologics production. Novel GLP-1 plants require specialists: peptide chemists, bioprocess engineers, analytical experts, and quality assurance staff all trained in these cutting-edge processes.

Recruiting and retaining such talent is difficult. Unlike standard small-molecule pharma, peptide manufacturing knowledge is concentrated in a relatively small community of experts. The EPM Scientific briefing observes that traditional hiring models (permanent staff) can’t fill demand quickly enough (www.epmscientific.com). Many companies are turning to contractor labs, interdisciplinary teams, or internal training programs. For example, Novo Nordisk and Lilly have announced workforce training partnerships with universities to develop biomanufacturing curricula. Similarly, some CDMOs are hiring retired industry veterans as consultants to transfer knowledge.

For tech transfer projects, the right personnel attachment is critical. Industry practice calls for “sending experts from the original site to the new site” during initial batches. Major players often include technology-transfer personnel and process engineers on the payroll years in advance of production kick-off. Nonetheless, reports indicate that staffing remains tight: many new GLP-1 projects have been reported lagging simply because qualified managers and operators are scarce, especially in regions like North Carolina and Indiana where fabs are multiplying simultaneously. This shortfall adds to the timeline; even if the brick-and-mortar is ready, qualified staff must be hired and trained before full production begins.

In addition, regulatory and quality personnel are needed. Each new plant/facility expansion requires a dedicated QA/QC team for compliance. Demand for validation engineers, regulatory affairs specialists, and GMP auditors has surged. Industry recruiters note that the GLP-1 boom has pulled talent away from other sectors (e.g. monoclonal antibody manufacturing) into GLP-1 programs, driving up labor costs.

Overall, workforce capacity is the wild card. The best-run companies have contingency plans (e.g. staggered shifts, global resource pools) to mitigate this risk, but it remains a critical factor in project success. EPM Scientific argues that permanent hiring alone is insufficient to meet the pace of GLP-1 manufacturing expansion (EPM Scientific).

Case Studies and Examples

To illustrate these themes, consider a few real-world examples:

- *Novo Nordisk – Catalent Integration:* In early 2024 Novo Holdings announced plans to acquire Catalent (a major CDMO) for $16.5B (www.axios.com). This was explicitly intended to “boost Wegovy production” (Wegovy being Novo’s obesity GLP-1 whose demand outpaced supply (www.axios.com)). Alongside, Novo Nordisk agreed to take over Catalent’s fill-finish plants in Italy, Belgium, and Indiana for $11B (www.biopharmadive.com). These sites employ thousands and already produce GLP-1 injectables under contract. By transferring ownership (and technology) of these sites, Novo effectively expedited capacity increases that otherwise might require years to build. However, integrating Catalent and transferring knowledge to these bioreactors and sterile lines was a massive tech-transfer undertaking. Regulatory filings were needed to confirm that Ozempic/Wegovy manufactured in firsthand Catalent vs. company-owned sites were identical in quality. This example demonstrates how acquisition can shortcut capacity growth, but at the cost of a complex transfer and harmonization process.
- *Lilly’s Big Build in Indiana:* Lilly’s Lebanon, IN facility (nicknamed “Project Indiana”) exemplifies a greenfield expansion. Breaking ground in 2023, the site was scheduled to start producing tirzepatide API by end-2026 (apnews.com).
- *Oral GLP-1 Pill Production:* Novo Nordisk’s 2025 annual report identifies Clayton, North Carolina as the manufacturing site for the Wegovy pill’s API and Durham, North Carolina as the site where the tablets are made and packed (Novo Nordisk). The Wegovy prescribing information states that semaglutide’s peptide backbone is produced by yeast fermentation (prescribing information).
- *Generics and Biosimilars:* Novo Nordisk’s 2025 Form 20-F reports 2032 as the U.S. compound-patent expiry for Ozempic, Rybelsus and Wegovy (Novo Nordisk). Other patents and regulatory protections may extend exclusivity beyond an active-ingredient patent’s expiry (patent scope). In India, Dr. Reddy’s announced the launch of its semaglutide injection Obeda on March 21, 2026. The company reports that API development and manufacturing, as well as formulation development, were conducted entirely in-house (launch release).

Implications and Future Directions

The GLP-1 manufacturing ramp-up has profound implications across healthcare and industry:

- **Patient access vs equity:** The FDA's December 2024 and February 2025 decisions resolved the U.S. injection shortages for tirzepatide and semaglutide, respectively (FDA). However, absent policy changes, many payors and patients still struggle with cost – a KFF poll found 55% of GLP-1 users had trouble paying (www.axios.com). Equity concerns remain because those with wealth or insurance get rapid access, while others wait.
- **Supply chain resilience:** The GLP-1 frenzy has underscored the fragility of complex supply chains. Dependencies on key raw materials (e.g. special linkers for semaglutide), hardware (resins, chromatography media), and supply continuity have all become glaring issues. Going forward, companies are likely to diversify supply chains: e.g. qualifying multiple vendors for peptide building blocks, establishing redundant purification capacity, and stockpiling certain inputs. The fact that CDMOs like PolyPeptide are investing in local manufacturing (e.g. restarting a resin plant in Europe) is a direct response. Compounded drugs must meet statutory conditions to qualify for exemptions under sections 503A and 503B of the U.S. Federal Food, Drug, and Cosmetic Act; they are not FDA-approved (FDA).
- **Technological innovation:** The pressure of GLP-1 demand is driving tech innovation. In addition to the green chemistry efforts mentioned, companies are evaluating next-generation peptide assembly methods. Continuous-flow SPPS and enzymatic ligation could eventually become mainstream, reducing waste and cycle times (www.crbgroup.com). Downstream, novel drug delivery (e.g. oral semaglutide already uses SNAC absorption enhancers, which required unique formulation tech) may expand. Orforglipron, marketed as Foundayo, is a once-daily small-molecule, non-peptide oral GLP-1 receptor agonist (Lilly).
- **Regulatory and policy:** Regulators face balancing acts. They must ensure quality in new manufacturing sites (inspections of multi-billion-dollar plants are scheduled), authorizing tech transfers, and approving new dosage forms. They are also mediating legal battles (patents vs generics, compounding vs branded). One future question is whether regulatory guidelines will evolve for streamlined approvals of manufacturing changes given the critical need.
- **Industry structure:** The GLP-1 boom could reshape the CDMO industry long-term. Smaller peptide CMOs may see huge growth, leading to consolidation (e.g. larger CDMOs acquiring niche peptide firms). A historical example of investment in peptide manufacturing is Carlyle's September 2018 acquisition of a significant minority stake in Ambio Holdings, a peptide API CDMO (AmbioPharm announcement). It may also spur new entrants: startups focused on green peptide tech or specialized contract research.
- **Global health:** Finally, the sheer scale raises questions of global health allocation. Currently, Western markets (US, EU, etc.) dominate GLP-1 consumption. As generics emerge and production capacity grows, these therapies could diffuse to Asia, Latin America, and Africa in ways initially unimagined. Already, Indian companies preparing cheap semaglutide formulations (potentially $15/month prices

(cincodias.elpais.com)) point to a future where GLP-1 analogues become widely available globally. For Obeda, Dr. Reddy's reports in-house API development and manufacturing and formulation development (launch release).

Conclusion

The GLP-1 drug manufacturing landscape in 2026 is defined by unprecedented expansion and transformation. Major pharmaceutical companies have embarked on historic capital build-outs (totaling tens of billions) to enlarge production of GLP-1 APIs and formulations (www.axios.com) (apnews.com). Meanwhile, the contract manufacturing sector has mobilized advanced capabilities to meet peptide-specific needs (industrytoday.co.uk). U.S. national shortage status changed as supply expanded: the FDA determined the tirzepatide injection shortage was resolved on December 19, 2024, and the semaglutide injection shortage on February 21, 2025 (FDA). The critical path to delivering new capacity runs through successful technology transfers between R&D, existing plants, and newly built facilities (www.patheon.com). At every step, companies must ensure product quality and regulatory compliance.

Looking ahead, the momentum of GLP-1 innovation continues. Orally available GLP-1 drugs (semaglutide pill, orforglipron) bring new manufacturing models (standard oral dosage production) and may ease pressure on injectables supply. Novel analogues and even dual-agonist/tri-agonist drugs in the pipeline may require further capacity in the next decade. Additionally, as patents expire, a robust pipeline of generics and biosimilar versions of peptides will demand cost-effective manufacturing solutions (green chemistry, continuous processes) and global technology dissemination. The industry's agility in aligning capital projects, CDMO partnerships, and tech transfer will determine whether production can keep pace with demand growth.

In sum, the GLP-1 phenomenon has reshaped pharma manufacturing strategy: it has accelerated vertical integration (Catalent deal), expanded global CDMO networks, and spurred forward-looking plant designs. The lessons learned – about scale-up complexity, supply variability, and talent management – will influence how the industry tackles other therapeutic waves in the future. With 12% of U.S. adults reporting current GLP-1 use in KFF's late-2025 poll (KFF) and much of the world population still unaddressed, the race to manufacture these drugs is not just a business imperative but a major public health endeavor. As capacity comes online, it will ultimately translate into greater availability of life-changing therapies – provided careful, sustained execution over the next several years.

Sources: All data and statements above are based on current industry news, company releases, and expert analyses. Relevant sources include Novo Nordisk and Eli Lilly announcements (www.axios.com) (apnews.com), reputable news reports (apnews.com), and market/technical studies (industrytoday.co.uk) (www.epmscientific.com), as cited throughout.

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