> **This is totally unprecedented...** The developmental installation setup of new manufacturing facilities or new lines is quite tedious, and it takes a long time. So responding to this unprecedented demand is difficult. It is creating stress in the industry.

Scaling for the GLP-1 Revolution

Meeting Global Injectable Demand

Miguel Ángel Ortega Sánchez is Corporate Industrial Director at ROVI, with over 30 years of experience in pharmaceutical manufacturing and supply chain. Holding an ESADE MBA in Operations and a Chemistry degree from the University of Barcelona, he has spent more than a decade at ROVI overseeing industrial operations across sites and strategic projects delivery, with a focus on quality, efficiency and scalable solutions for high value injectable manufacturing.

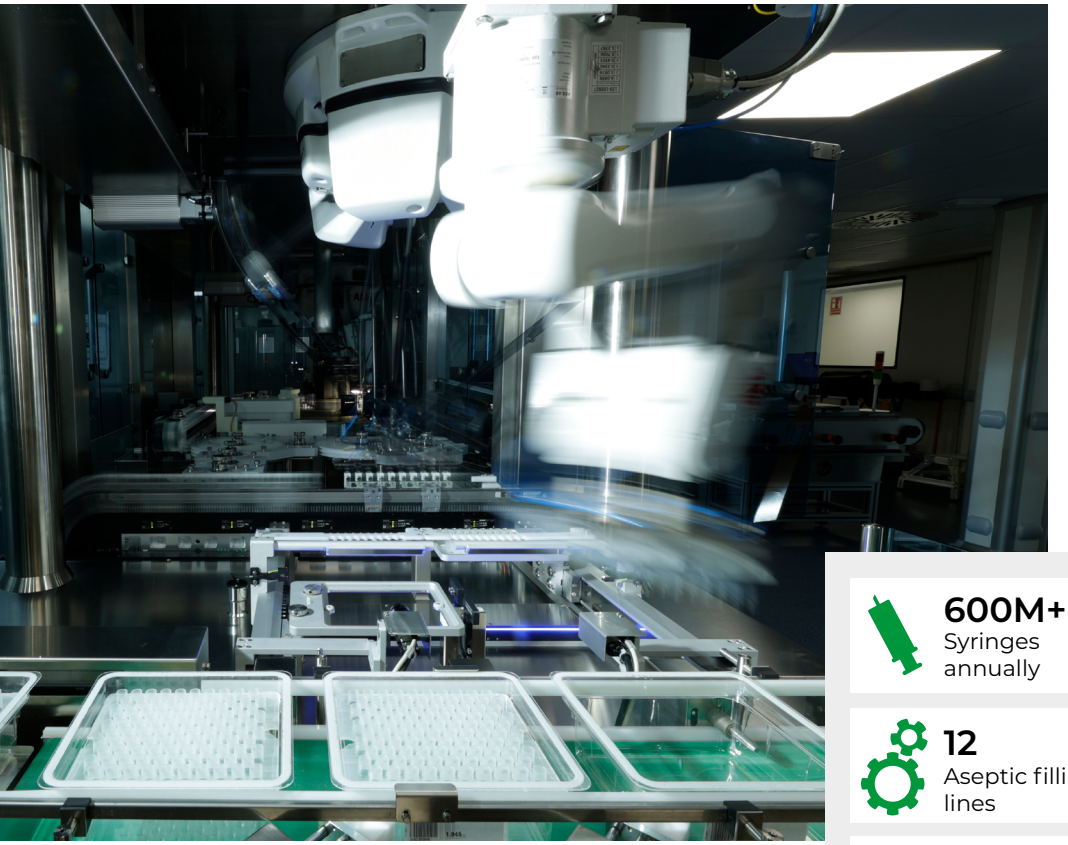
Written By Miguel Ángel Ortega Sánchez

The rise of GLP-1 Receptor Agonists (GLP-1RAs), alongside therapies targeting GIP and Amylin pathways, has triggered a major manufacturing challenge.

Initially developed for type 2 diabetes, these therapies are now being explored for obesity, cardiovascular disease, and neurological conditions. As a result, global demand has surged, rivalling past blockbuster drugs.

Until recently, the industry was moving toward personalised, small-batch therapies. Facility design reflected this, prioritising flexibility and modularity. The renewed demand for high-volume injectables has disrupted that trajectory. With significant R&D resources now concentrated on clinical development, many pharmaceuticals are turning to CDMOs to achieve manufacturing efficiency and cost control at scale, shifting from traditional supplier relationships to long-term strategic partnerships.

CDMOs must now balance two demands: small-batch flexibility and large-scale production under tightening regulations.



Challenges: Responding to a Market That Won't Wait

The rapid rise of GLP-1s has introduced significant operational and strategic challenges across the pharmaceutical manufacturing landscape. From scaling infrastructure and managing delivery device constraints, to maintaining regulatory compliance and reshaping long-standing partnership models, CDMOs are under pressure to adapt on multiple fronts.

One of the most immediate concerns is capacity. The current demand for GLP-1s — particularly in injectable formats — has exposed significant bottlenecks across drug product manufacturing and device supply. Even as many CDMOs and pharmaceutical companies expand internal infrastructure or invest in new lines, the pace of demand continues to outstrip available capacity. This is not limited to formulation and aseptic filling; production of delivery systems such as autoinjectors and prefilled pens is also under pressure.

Scaling infrastructure is only part of the equation — regulatory readiness is proving just as critical.

Compounding this pressure is the need to maintain strict compliance with evolving regulatory standards. The introduction of the revised Annex 1 of the EU GMP guidelines has raised the bar for sterile manufacturing at a time when speed is critical. While some manufacturers have struggled to keep up — with several sites closing or receiving FDA warning letters — others, like ROIS, have taken a more proactive, pre-emptive approach by building new capacity with these standards in mind. This creates a dual burden for CDMOs: scaling fast enough to meet market need, while simultaneously meeting higher expectations from authorities including the FDA, EMA, and others. CDMOs, like ROIS, have approached

600M+
Syringes annually

12
Aseptic filling lines

15
Injectable packaging lines

We are flexible enough to adapt to requirements from different partners. Other CDMOs may try to impose one way of working — we take a different approach.

80M+
Vials per year

40M+
Cartridges per year

3B+
Tablets annually

Pen & autoinjector assembly lines launching
(Manual line in 2025, semi-automatic in 2026 with 7M unit capacity)

75+
Markets served globally

Global Regulatory Approvals
FDA, EMA, PMDA, KFDA, ANVISA, MHRA, and more

ROIS In Numbers

> "The risk of rapid growth is losing control of quality. Facilities that were compliant only a few years ago may no longer meet the requirements of Annex 1. It's essential that expansion goes hand-in-hand with regulatory readiness."

this by combining long-standing experience in aseptic manufacturing with a programme of site modernisation and facility design informed by current regulatory guidance. As a result, ROIS sites have passed multiple inspections post-Annex 1 enforcement, reinforcing their preparedness for today's environment.

Even with the right facilities and approvals, success depends on the ability to adapt.

Beyond infrastructure and compliance, the surge in demand has also revealed an operational truth: flexibility is now a competitive advantage. While some CDMOs rely on rigid, standardised platforms to manage volume, this can limit their ability to accommodate the nuanced needs of different partners and products.

This adaptability is particularly relevant for GLP-1 therapies, where injectables remain the dominant and most effective format — but flexibility to support oral forms when needed adds value for partners. At the same time, pharma companies continue developing lower-volume therapies—making it essential for CDMOs to support both large-scale and niche projects. The ability to support both paths — and adjust based on clinical progress or market shifts — will be essential in the years ahead.

Projected GLP-1 Market Growth

The Future of Manufacturing

The scale of demand for GLP-1s has led some to question whether the current surge is sustainable — or if the industry is at risk of overcorrecting in its efforts to meet it. While growth forecasts vary, few expect demand to stabilise in the near term. Most projections point to continued expansion well into the next decade, with some estimating the market could exceed $125 billion by 2033. (Source: GlobalData, 2024)

"There is absolutely no way that suppliers and manufacturers can keep up with this pace in the short term without better strategy and alignment across the industry. We're talking about a demand curve that will stretch for at least the next 10 to 15 years..." *— Miguel Ángel Ortega Sánchez*

This unprecedented demand has reshaped expectations for what injectables can deliver — not just in terms of volume, but also convenience and patient acceptance. Pens, autoinjectors, and long acting formats have helped reposition injectables as both practical and patient friendly. Far from being a short term solution, injectables are now at the centre of modern drug delivery — particularly for biologics and advanced therapies.

While work continues on solid oral forms of GLP-1s, the timeline and scale of impact remain uncertain. For manufacturers, the focus is less about choosing between formats, and more about building platforms that can scale intelligently, adapt to future modalities, and remain compliant under increasing regulatory scrutiny.

The GLP-1 surge has become a proving ground, one that may influence how CDMOs and pharma companies approach scale, flexibility, and speed of execution well beyond this therapeutic class.

Future-Proofing Through Partnership and Capability

As the GLP-1 market continues to evolve, both pharmaceutical companies and CDMOs must reassess not just how they manufacture, but how they collaborate. Traditional supplier-client models — based on transactional engagements and fixed scopes — are being replaced by long-term strategic partnerships built around shared investment and aligned goals.

"Today's outsourcing models are shifting away from transactional relationships. Leading CDMOs are becoming fully integrated partners — managing complexity from formulation to device." *— News Medical, Why GLP-1 Manufacturing Needs a New Biopharma Approach, 2025*

This shift is especially relevant for high-volume projects, where capacity planning and shared investment are critical to success.

"We are working on forming strategic relationships where both parties would invest in capacity — planning not just for one project, but for a roadmap." *Miguel Ángel Ortega Sánchez*

But effective collaboration also depends on technical strength. In the context of GLP-1, this means having the ability to manage aseptic manufacturing at scale, ensure device compatibility, and execute rapid, reliable tech transfer.

As Vine notes, in her article for The Analytical Scientist, "GLP-1 peptides have challenging solubility and stability profiles, which means tech transfer must be both rapid and highly controlled." (Stephanie Vine, The Analytical Scientist, 2025)

Regulatory readiness remains another point of differentiation. As The Journal of Clinical Investigation notes, "As therapeutic indications expand, regulators will expect greater consistency and more robust quality frameworks across every delivery format." Successful facilities, like those of ROIS, must reflect a mindset that integrates compliance and capability at every stage.

As the GLP-1 market continues to grow in scale and complexity, success will depend on a CDMO's ability to combine compliance excellence, injectable manufacturing expertise, and strategic adaptability. ROIS is already operating from this foundation. With more than 30 years of injectable experience, multiple sites authorised by major global regulators, and a strong track record in tech transfer and aseptic scaling, ROIS is built to support both current demands and future developments. Its recent investment programme — which includes facility expansions aligned with Annex 1 guidance — reinforces a forward-thinking approach. Whether the next challenge is higher volume, faster turnaround, or a new delivery format, ROIS is equipped to help partners meet it with confidence.

> "It's not just about being fast. It's about being reliable — and ready. That's what defines a manufacturing partner you can build around."

ROIS

One of the top three CDMOs for injectables worldwide, ROIS is trusted by over 30 global pharma clients to deliver compliant, high-capacity manufacturing with precision and speed. With approvals from leading regulators — including the FDA, EMA, PMDA, KFDA, ANVISA, and MHRA — we offer end-to-end support across formats. Each of our sites is equipped with a dedicated NPI team, ensuring seamless tech transfer and rapid scale-up. Our recent capacity investments are fully aligned with the revised EU GMP Annex 1 standards, and our facilities have passed multiple inspections post-enforcement — reinforcing our readiness for today's demand and tomorrow's breakthroughs. At ROIS, we're built to support both current needs and future developments.

Ready to scale with confidence? Partner with us — where proven expertise meets future-ready execution.

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