ROIS

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CDMO Partnerships

Why Speed and Flexibility Matter Now More Than Ever

Miguel Ángel Ortega Sánchez is Corporate Industrial Director at ROIS, 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 ROIS overseeing industrial operations across sites and strategic projects delivery, with a focus on quality, efficiency and scalable solutions for high value injectable manufacturing.

A serious challenge.

Increasingly stringent regulatory frameworks, evolving patient preferences and demanding project time-scales present a serious challenge for conventional pharmaceutical manufacturing structures.

Before the GLP-1 boom of recent years, the pharmaceutical industry had begun to shift away from blockbuster drugs towards specialized, personalized therapies, such as Cell & Gene Therapies (CGT's) and Advanced Therapies for Medicinal Products (ATMPs). While this fuelled demand for facilities geared to small-batch production, GLP-1s, biosimilars and vaccines have rejuvenated the need for manufacturing at scale – especially for the fast-growing injectables segment. Consequently, many pharma companies are now looking to outsource large-scale projects to CDMOs again to keep pace with demand.

The difficulty, lies in finding a CDMO capable of combining speed and scalability without compromising on quality or compliance. Rigorous new regulations further restrict the pool of viable contract manufacturers, as previously compliant manufacturing facilities may not necessarily meet updated standards.

This adds up to an ambitious shopping list: CDMOs should have the expertise needed to expedite technology transfer, a proven track record of regulatory compliance, and the agility and capacity to minimise time-to-market.

What used to be acceptable in 18 months, clients now want in 9 – with particular urgency for GLP-1s and biologics.

This expectation has become the norm, not the exception.

The Challenge of Adapting to Shifting Requirements

Meeting tighter regulatory requirements presents major challenges for CDMOs. The revision of Annex 1 to the EU GMP Guidelines, for instance, has markedly increased regulatory expectations of sterile manufacturing.

In this context, CDMOs need to demonstrate unwavering compliance, ideally across multiple regulatory regimes, in order to secure contracts. A track record of success with similar products offers reliability and predictability for pharma companies looking to derisk their manufacturing operations whilst focusing on developing new biologic injectable products.

Yet, the combination of strict regulatory requirements and dynamically evolving market demands has created a perfect storm for pharmaceutical manufacturing. In addition, the explosive growth of GLP-1s has placed additional strain on finite capacity. Project timelines are also increasingly aggressive. This is due in part to far greater urgency, a prime example being the drive to develop and manufacture COVID-19 vaccines. However, intensifying competition – especially for speciality injectables – is another contributing factor.

> A CDMO can't trade speed for compliance. This is where experience truly pays off.

Conventional CDMO Structures Lack the Flexibility to Adapt to Fast-Moving Developments

In the face of tighter requirements and a dynamic market, conventional structures and procedures curb CDMOs' ability to adjust to new realities. Rigid manufacturing operations often lack the scalability needed for novel products and complex molecules, which can soon lead to bottlenecks. Inflexible organisational structures are also prone to slow decision-making. These soon pose fundamental problems when speed and agility are the order of the day.

The importance of transparent communication cannot be overstated, especially in international and multilingual partnerships. Pharma companies are increasingly extending their sights beyond traditional project management, instead looking for CDMOs capable of assisting throughout the product lifecycle. For this model to succeed, the CDMO must align expectations across all stakeholders and map out a swift route to first batch production – capabilities inherently reliant on deep industry experience.

Most CDMOs are positioned for either high-volume production or clinical agility – but few combine both aspects. Ultimately, this requires flexibility and lean decision-making processes, which prove extremely difficult to retrofit into entrenched structures. And, at the same time, CDMOs cannot afford to sacrifice their laser focus on quality in pursuit of a shorter time to market.

ROIS IN NUMBERS

Facility highlights: Expanded isolator lines, enhanced PFS capabilities, and upgraded QC labs

- **600M+** Syringes annually
- **15** Injectable packaging lines
- **12** Aseptic filling lines
- **75+** Markets served globally

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.

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

- **80M+** Vials per year
- **40M+** Cartridges per year
- **3B+** Tablets annually

Rising to the Challenge: How CDMOs Can Meet Dynamic Expectations

The current landscape calls for a radically different approach. While conventional CDMO structures are characterised by inflexibility, adaptive and rapid response systems are the order of the day.

Take ROIS, for example: following an ambitious expansion programme, the Spanish CDMO's new manufacturing plants have ample capacity to facilitate rapid scaling. Adaptable facility layouts mean production lines can be reconfigured as needed, with cross-trained teams ready to be deployed in line with project-specific requirements. Supply chain redundancies and close relationships with key suppliers ensure business continuity and reliability for its partners.

This enables ROIS to pivot smoothly between batch-size clinical development and commercial-scale manufacturing – without sacrificing timeline integrity.

Accelerating the Technology Transfer is Vital for Minimising Time to Market

Minimising friction during technology transfer is vital for CDMOs to advance projects swiftly to first GMP batch production. Robust and agile documentation, meticulous validation and effective communication serve to eliminate potential obstacles.

At ROIS, extensive internal expertise and experience from past projects lay solid foundations for swift progress. What's more, with concurrent work-streams for quality assurance, validation and technology transfer, the company's operating model is geared towards advancing projects at pace. In some circumstances, first GMP batch production is feasible in as little as nine months from project initiation

Building on its strong specialism in liquid aseptic filling injectables and biologics, ROIS has expanded and modernised its four EU manufacturing facilities in line with regulatory requirements, including GMP Annex 1. With flexible production capacity in excess of 500 million PFS per year, ROIS can respond quickly to its clients' needs without the risk of operational bottlenecks.

Early Focus on Compliance Minimises the Risk of Surprises

CDMOs seeking to keep development cycles to a minimum cannot afford to postpone regulatory considerations as requirements grow increasingly complex, especially for biologics and combination products.

A clear focus on regulatory compliance from the outset reduces the risk of backtracking later in projects. This way, ROIS maintains a clear-eyed overview of project status and secures progress towards initial marketing.

CASE STUDY

Challenge

We received an enquiry from a client developing an emergency-use injectable, with a fixed target of starting GMP supply within seven months.

Timeline

Under 7 months

Outcome

Despite the ambitious time-scale, we completed technology transfer, validation and first GMP batch production in record time – enabling our client to reach their IND milestone three weeks early.

What's more, the project included both PFS and vial formats, which demonstrates the value of our hybrid model.

> **"At ROIS, we've invested in modularity, batch-size agility and internal governance processes that prioritise client needs without operational bottlenecks. We've expanded high-speed isolator lines, enhanced PFS capabilities and upgraded our QC labs for biologics diagnostics. Few CDMOs can move this fast and stay this compliant."**

From One-Off Contracts to Long-Term Collaboration: The Evolving Role of CDMOs

In the face of shifting requirements, and following the fast-moving events of recent years, pharma companies are now rethinking their entire manufacturing approach. Instead of keeping operations in house or placing one-off manufacturing contracts, growing numbers of pharma companies are embarking on long-term strategic partnerships with CDMOs.

This makes CDMO selection all the more vital. By choosing a provider with the requisite expertise and the ability to meet stringent new demands, pharma companies can chart a course for sustained success. Let's recap some of the key criteria:

Five Must-Haves for a Future-Ready CDMO

Experience

Find a CDMO with a track record of successful on-time delivery, rapid scaling and regulatory compliance.

Flexible Capacity

The ability to accommodate everything from small-batch to commercial manufacturing is now a non-negotiable.

Regulatory Ready

As requirements intensify, close relationships with regulators are essential for CDMOs to guarantee compliance moving forward.

Certification

Make sure your chosen CDMO holds relevant accreditations – for your target markets and beyond to provide scope for expansion.

Partners

Don't look for a supplier; find a partner. Beyond purely transactional arrangements, holistic partnerships pave the way for shared, long-term success.

ROIS

Over 30 global pharma clients trust ROIS to deliver compliant, high-capacity manufacturing with precision and speed. As one of the top three CDMOs for injectables worldwide, we offer end-to-end, cross-format support with approvals from major regulators. A dedicated NPI team at each of our sites ensures seamless tech transfer and rapid scale-up. Recent capacity investments align fully with the revised EU GMP Annex 1 standards, as confirmed by multiple post-enforcement inspections. At ROIS, we're ready to meet today's demand and support tomorrow's developments.

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