

Choosing the Right Sterile Injectable Manufacturing CDMO

How Biotechs Can Reduce Risk
& Accelerate Development

White Paper



Introduction: The High-Stakes Choice of a Sterile CDMO

For small and mid-sized biotech companies, selecting the right sterile injectable manufacturing CDMO (Contract Development & Manufacturing Organisation) is one of the most consequential decisions in the development journey. A poor CDMO fit can slow programs, increase costs, and introduce avoidable risks, whether through limited analytical or manufacturing capacity, misaligned coordination, regulatory challenges, or an inadequate technical fit.

In an environment where timelines drive valuation and funding, CDMO performance can materially influence success.

The Author of this White Paper



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Pre-filled syringes (PFS) packaging at CordenPharma Caponago (IT).



Why This Topic Matters: The True Cost of Choosing Wrong

Drug development is already enormously expensive, with estimates ranging from 1-4B USD for bringing a fully loaded drug to market.¹ For advanced modalities (e.g. peptides, LNPs, oligonucleotides or biologics) manufacturing costs for development material can range from \$100k up to more than half a million per gram,² depending on scale, complexity and purification, making every delay significantly expensive. Hence, for many biotechs, choosing a sterile injectable CDMO with an elevated operational or compliance risk can quickly become one of the company's largest liabilities.

To avoid delays in reaching critical investor milestones, biotechs need a CDMO partner capable of actively reducing exposure to several types of risks, including:

- prioritization issues when CDMOs favor larger clients
- lack of operational flexibility or insufficiently trained resources
- limited equipment or constrained manufacturing slots
- delays in method development, validation, or transfer
- capacity bottlenecks that push out critical milestones

¹ **Schlander, M., Hernandez Villafuerte, K., Cheng, C. Y., Mestre Ferrandiz, J., & Baumann, M. (2021).** *How Much Does It Cost to Research and Develop a New Drug? A Systematic Review and Assessment.* PharmacoEconomics. → [Link](#)

² **Hart, D. (2023).** *The Economics of Synthetic mRNA Capping Strategies.* TriLink BioTechnologies. → [Link](#)

Analytical
scientist
performing
UPLC testing at
CordenPharma
Caponago (IT).





Compounding and formulation area at CordenPharma Caponago (IT).

From a regulatory standpoint, the stakes are even higher. In recent years, inspection findings (e.g. FDA Form 483s, EMA observations, warning letters) have increasingly cited issues such as incomplete batch records, inadequate aseptic technique, data integrity gaps, environmental monitoring failures, and worst-case sterility failures.^{3,4}

For biotechs, the consequences can be severe:

- batches discarded or stuck in release
- unusable clinical material
- delayed IND/CTA submissions
- commercial launch timelines slipping by 12+ months
- unplanned repeat manufacturing costs adding significant extra costs

Avoiding these pitfalls starts with choosing the right partner from the outset.

³ **Ingram, M., Pazhayattil, A., Sagar, P., & Chakraborty, S. (2025).** *2024 Trends in FDA Observations for Sterile Drug Manufacturers.* Pharmaceutical Online. → [Link](#)

⁴ **Atlas Compliance (2025).** *What Are the Top Deviation Trends in FDA 483s and Warning Letters?* → [Link](#)

How to Evaluate a Sterile Manufacturing CDMO: Five Critical Dimensions

Too many biotech programs fail or stall because CDMOs are chosen based on cost or brand reputation rather than proven performance. Quality is not a checkbox – it should be a demonstrated capability. To reduce risk, biotechs should evaluate sterile CDMOs through five core dimensions:

1. Regulatory Credibility

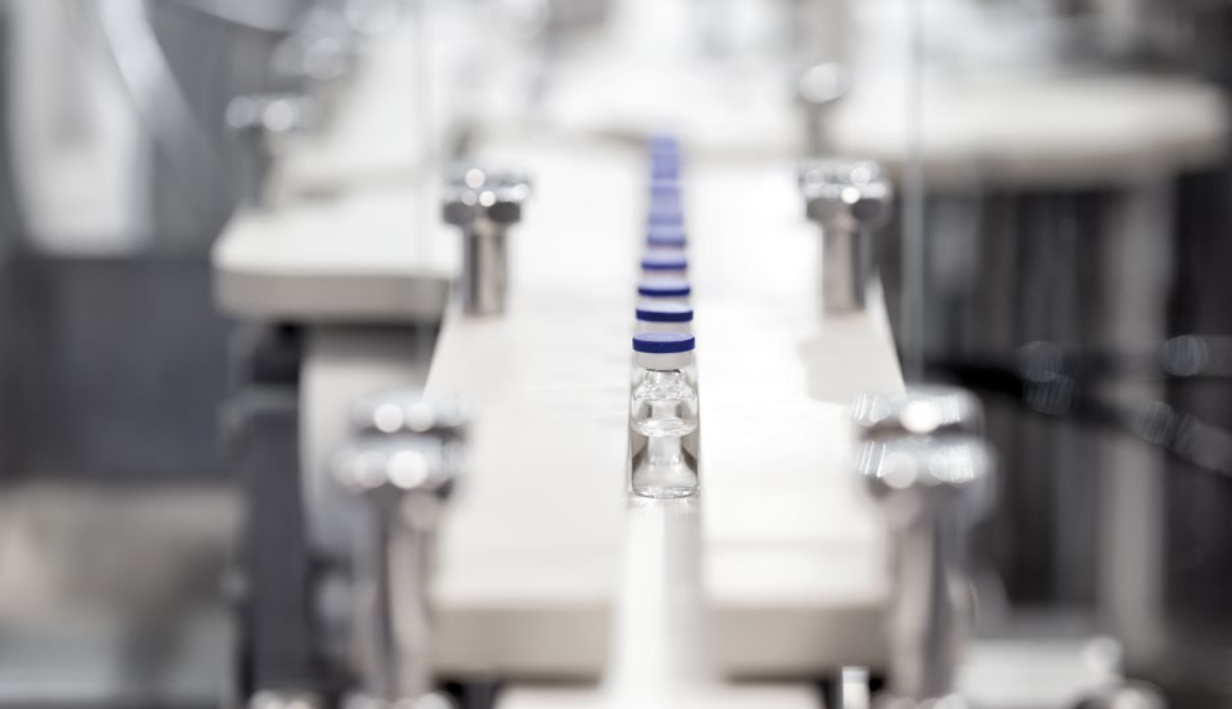
- Track record with FDA, EMA and other authorities
- Recency and outcomes of inspections
- Speed and quality of remediation
- Evidence that products have successfully advanced from the site

2. Operational Reliability

- Schedule adherence and on-time batch release
- Real vs. claimed capacity
- Deviation volume and responsiveness
- Predictability of cycle times
- Persistent rescheduling is often a predictor of future failure

Robotized pre-filled syringe (PFS) filling line at CordenPharma Caponago (IT).





Aseptic vial filling line at CordenPharma Caponago (IT).

3. Technical Fit for Your Molecule

Not just «we do injectables», but:

- experience with your modality, dosage form and process
- evidence to have handled similar formulation, viscosity, stability, shear forces or other complexities and aseptic challenges

4. Program Management & Communication Maturity

- Dedicated project managers
- Transparent reporting and data access
- Clear escalation pathways
- Speed and clarity during investigations. This dimension often determines whether issues stay manageable, or snowball.

5. Business Alignment & Continuity Risk

- CDMO financial stability
- Customer mix and CDMO's earned mindshare
- Turnover in QA/Engineering
- Capital investment plans
- Backup plans if priorities shift
- A CDMO may be technically strong but strategically wrong for your company.

Quality keeps you compliant, but it's operations, technical fit, communication maturity, and business stability that ultimately determine whether your program is delivered on time and on budget. That's why your evaluation shouldn't stop at presentations or capability lists. Go on site, not just as a routine, but to enable true SME-to-SME conversations and deep technical breakout sessions. It's in these discussions that real risks, constraints and opportunities become visible.

CordenPharma's Approach: A Partner Focused on Reducing Risk

Biotechs choosing CordenPharma for [sterile injectable manufacturing](#), including [aseptic fill and finish](#), at both clinical and commercial stages, gain a partner engineered to reduce risk and improve predictability.

Over 30 years of proven sterile expertise

CordenPharma Caponago (IT) supplies commercial sterile injectables to more than 110 countries and has a longstanding record of regulatory success with authorities including the FDA and EMA dating back to 1994.

A manufacturing site built for long-term resilience

An investment program exceeding €100 M is driving major expansion at our Caponago (IT) site:

- state-of-the-art isolator fill-finish lines
- doubled development space for faster project onboarding
- an additional 11,000 m² building to expand late-stage manufacturing

Vials filling and stoppering at CordenPharma Caponago (IT).





Single-use systems for complex formulation & stabilization at CordenPharma Caponago (IT).

This proximity model maintains business continuity by leveraging the same experienced teams across development and commercial phases.

Operational resilience through structured governance

CordenPharma turns complexity into predictable delivery through:

- lean Six Sigma methodologies
- disciplined project governance
- integrated resource planning
- daily visual performance management
- real-time access to project data via digital tools like Smartsheet
- a dedicated site PMO, aligned with corporate/global PMO, ensures standardized processes and clear escalation when needed.

Conclusion

Choosing the right sterile injectable CDMO is no longer just a procurement and cost decision. It is a strategic risk mitigation decision that can determine the speed, cost and success of a biotech program.

Biotechs should evaluate CDMO partners across five critical dimensions: regulatory credibility, operational reliability, technical molecule fit, program management and communication maturity, business stability and long-term alignment.

By partnering with CordenPharma, biotech companies gain a sterile injectable manufacturing partner that scores strongly across all five dimensions, backed by decades of sterile manufacturing expertise, world-class regulatory performance, advanced isolator technologies, expanded development capabilities and a rigorous operational framework that transforms complexity into predictable delivery. The result is a reliable, risk-reduced pathway from early development to commercial supply.

Fully-automated packaging lines offering versatile configurations for vials, PFS, ampoules, and cartridges, at CordenPharma Caponago (IT).

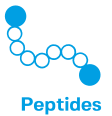


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Peptides



Oligonucleotides



Lipids & LNPs



Injectables



Highly Potent
& Oncology



Small Molecules