

Three Crucial Reasons for Selecting the Appropriate CDMO

ADRAGOS PHARMA

Table of contents:

Introduction 3

Chapter 1:
Technical Expertise and Capabilities 5

Chapter 2:
Business Partnership 9

Chapter 3:
Regulatory Compliance 11

Conclusion
Why should Adragos be the partner of choice? 13

Introduction

The pharmaceutical industry is known for its complex and rigorous development processes. From research and development to commercialization, numerous steps are involved in bringing a product to market.

When developing a strategy that involves contract development manufacturing organizations (CDMOs) and contract manufacturing organizations (CMOs), it's essential to consider two distinct areas: sourcing CDMO or CMO services.

As such, it's no surprise that pharmaceutical companies often turn to Contract Development and Manufacturing Organizations (CDMOs) to simplify their processes and speed up the launch of products.

CDMOs provide customized solutions to pharmaceutical companies, from drug development to commercial manufacturing and packaging. They offer various services, including formulation development, analytical testing, clinical trial manufacturing, and commercial manufacturing. By partnering with a CDMO, companies can save time, reduce costs, and access specialized expertise that would be difficult to develop in-house.

Conversely, CMOs are crucial in keeping time for pharmaceutical and biotechnology companies.

Moreover, reputable CMOs ensure compliance with quality standards and regulatory requirements, eliminating drug development obstacles.



Outsourcing manufacturing processes allows pharmaceutical and biologic manufacturers to allocate internal resources effectively, prioritize capacities, and enhance process efficiencies.

Adragos Pharma is one such CDMO that offers development and manufacturing services, collaborates with global customers, and offers a comprehensive portfolio. We aim to ensure your product hits the market swiftly and meets the highest quality and regulatory standards.

Our Manufacturing specializes in various pharmaceutical essentials, encompassing suppositories, ampoules, tablets, non-sterile liquids, and semi-solids such as creams, gels, and ointments.

We strictly adhere to applicable regulatory rules, including the Good Manufacturing Practice (cGMP) guidelines and our valued customers' specifications and product requirements.

As a contract manufacturer, we are committed to providing exceptional service in every aspect of our operations.

This e-book explores three approaches— Three Crucial Reasons for Selecting the Appropriate Contract Development and Manufacturing Organization (CDMO)—and their role in the market.

We discuss how the right CDMO can help companies overcome challenges and achieve their goals.

We also provide insights on selecting the best CDMO for your company's needs, considering expertise, capacity, partnership, and regulatory compliance.

Finding a partner, not just a provider, when looking for a CDMO is crucial.

This can help you protect against common issues that may arise. Working closely with your CDMO also ensures better communication and preparedness for any new challenges that may come up.

01. Technical Expertise and Capabilities

02. Business Partnership

03. Regulatory Compliance

Chapter 1: Technical Expertise and Capabilities

One key consideration is the capabilities and expertise that the CDMO can bring to complement the pharmaceutical company's in-house resources.

It is essential to ensure that the CDMO adheres to predetermined quality standards while providing the necessary capacities, capabilities, and expertise that align with the individual requirements of the drug product.

Capacity and flexibility are critical factors that determine the CDMO's ability to meet the demands of the pharmaceutical market. Choosing a CDMO that has state-of-the-art equipment designed for rapid turnover is imperative. The ability to scale operations and adapt to changing project requirements is another crucial factor when selecting a CDMO.

Projects often evolve, and timelines can be subject to unforeseen challenges. A CDMO with scalable manufacturing capabilities and flexible adaptation to project changes can be a strategic partner. Scalability allows for a seamless transition from development to commercial manufacturing, ensuring a smooth and cost-effective progression through the product life cycle.

This ensures higher production capacity and enhanced flexibility, enabling the pharmaceutical company to adapt swiftly to market fluctuations and demands. In a fast-paced industry, time-to-market is crucial, and having a CDMO equipped with advanced technology becomes a strategic advantage.



Selecting the proper Contract Development and Manufacturing Organization (CDMO) is crucial in determining the success of a drug product in the market.

By carefully evaluating various factors, such as the CDMO's capabilities, technical expertise, production capacity, and flexibility, we can ensure the delivery of high-quality, safe, and effective drug products that effectively meet the evolving demands of the pharmaceutical market.

This comprehensive evaluation and selection process not only impacts the immediate success of the product but also contributes to building a strong foundation for long-term market sustainability and growth.

The chosen CDMO's expertise, specialization, and commitment to regulatory compliance, scalability, and cost efficiency are crucial factors that propel projects forward.

By prioritizing these aspects, companies can establish fruitful partnerships, accelerate product development, and succeed in the ever-evolving pharmaceutical landscape.

Technical Expertise and Capabilities

We are a leading Contract Development and Manufacturing Organization (CDMO) with over 220 years of experience and five manufacturing sites in Europe and Japan. Our state-of-the-art facilities and skilled team enable us to provide exceptional quality in every service and product we offer.

Our expertise includes manufacturing and packaging various blister formats designed for solids, liquids, and semi-solids in compliance with the applicable regulatory guidelines, particularly the Good Manufacturing Practice (GMP) guidelines. We prioritize open communication, listen to customer requirements, and implement them accordingly.

We specialize in a diverse range of pharmaceutical essentials, ensuring that our customers receive the highest quality products and services:



Sterile Liquids

- Ampoules (glass and PE)
- Vials (PE)
- IV Bags
- Pre-filled Syringes (PFS)
- Nasal products



Tablets



Semisolids

- Creams
- Ointments
- Gels



Suppositories



Non-sterile liquids

- Suspensions
- Emulsions
- Syrups
- Solutions

Adragos Services

In our services portfolio, we emphasize our end-to-end services as a contract development and manufacturing organization (CDMO), which are tailored to meet the unique requirements of companies aiming to optimize their operations while maintaining high quality and compliance standards.

Our comprehensive services encompass all stages of pharmaceutical development, from planning and supply chain management to regulatory affairs and every step in between.



Supply Chain & Planning - Athens, Greece

Our company's strategic locations enable us to provide efficient supply chain and planning services, ensuring timely delivery across different markets.



Visual Inspection and Packaging Solutions - Kawagoe, Japan

Our Visual Inspection services use advanced technology to meet Japan's strict market standards. We provide secure and compliant packaging solutions tailored to your unique products.



Controlled Drugs Handling - Kawagoe, Japan and Livron, France

Our Kawagoe facility manages controlled drugs with precision, security, and regulatory compliance.



High Potency APIs (HP API) - Athens, Greece

Our Kawagoe facility manages controlled drugs with precision, security, and regulatory compliance.



Stability Studies - All sites

We offer release and recurrent testing, including method establishment, raw material testing, in-process chemistry testing, API and drug product release testing, ICH stability testing, and comparator testing.



Cold Chain Management - All sites

We provide expert cold chain management services to handle temperature-sensitive pharmaceuticals safely.



Regulatory Affairs - Athens, Greece

Our Regulatory Affairs team in Athens can help you navigate pharmaceutical regulations and achieve market authorization.

Chapter 2: Business Partnership

Besides technical capabilities and infrastructure, a customer-centric approach is crucial for a successful partnership with a CDMO. The alignment between the client organization and the CDMO partner is essential for seamless collaboration, as it sets the tone for communication, problem-solving, and strategic planning.

A shared commitment to quality, innovation, and ethical standards ensures a harmonious working relationship and instills trust and mutual respect. This fosters an environment conducive to achieving common goals, driving long-term success, and sustainable partnerships.

A customer-centric approach is a crucial factor influencing the compatibility between the client and the CDMO partner. Customer centricity fosters clear communication, strategic alignment, and proactive problem-solving by focusing on the client's needs and preferences. This approach allows the CDMO to understand the client's objectives better and customize their strategies and services, ultimately leading to a more productive and harmonious partnership.

Creating a welcoming environment for all customers, regardless of their size, is crucial for building strong relationships, encouraging repeat business, and gaining referrals, leading to long-term success.

Efficient and transparent communication channels facilitate the exchange of ideas, expectations, and feedback. It is imperative for both the client organization and the CDMO partner to prioritize open lines of communication to address challenges promptly and share progress seamlessly.

This can include regular updates, milestone reviews, collaborative problem-solving sessions, and establishing a shared sense of accountability. By fostering a culture of open communication and transparency, both parties can ensure that challenges are effectively addressed and progress is effectively managed.

Selecting the right CDMO (Contract Development and Manufacturing Organization) partner is a multifaceted decision beyond technical capabilities. It involves considering various aspects such as organizational culture, a customer-centric approach, effective communication, seamless collaboration, and a commitment to innovation.

These integral elements collectively contribute to the success of the partnership. Additionally, establishing trust during the knowledge transfer phase further solidifies the foundation for a mutually beneficial and enduring relationship, fostering long-term success and growth for both parties involved.

The importance of a customer-centric approach at Adragos



We aim to foster robust relationships with each of our clients, leading to sustained success for our esteemed customers and our organization. We are committed to cultivating valuable connections and providing exceptional customer experiences to achieve this goal.

Strong customer relationships are essential for any CDMO, particularly for a growing entity like Adragos. Therefore, we strive to create an environment where every customer feels valued and respected regardless of their business's size.

We achieve this objective by communicating regularly, responding promptly to inquiries, and delivering superior products or services. At Adragos, strong relationships foster repeat business and referrals, which are crucial to long-term prosperity.

For this reason, we are committed to adopting a customer-centric ethos that involves a thorough understanding of our customers' needs. We carefully address customer requests and concerns, offering customized solutions beyond mere agreement.

Providing exceptional customer service is an integral aspect of our customer-centric philosophy. We understand that prioritizing customers enhances the likelihood of establishing enduring partnerships.

Our primary aim is to exceed customer expectations and cultivate a loyal customer base built on trust and mutual respect. Delivering exceptional customer service involves exceeding expectations to ensure customer satisfaction.

This may include providing supplementary services and solutions or proactively addressing potential issues before they escalate.

Finally, we recognize that continuous improvement is intrinsic to customer-centricity. It is essential to comprehensively understand our customers' needs and leverage their feedback as a guiding influence.

At Adragos, we endorse adaptability, learning from errors, and celebrating achievements as a unified team.

Chapter 3: Regulatory Compliance

The pharmaceutical industry operates in an environment shaped by constantly evolving regulatory standards. Staying abreast of these changes is crucial to ensure product safety, efficacy, and compliance.

The pharmaceutical regulatory environment is characterized by its constant evolution. Regulatory bodies regularly update and refine guidelines to address emerging challenges, technological advancements, and new scientific insights.

These changes encompass a broad spectrum, ranging from manufacturing practices and quality standards to safety and efficacy requirements.

The repercussions of non-compliance with pharmaceutical regulations can be severe, particularly for smaller companies. Regulatory violations can lead to regulatory actions, fines, product recalls, and damage to a company's reputation.

Moreover, the financial burden of rectifying non-compliance issues can be overwhelming, diverting resources from research and development efforts.

Biotech companies often need more resources to maintain in-house regulatory affairs departments capable of keeping pace with the rapid regulatory changes.

Consequently, partnering with a contract development and manufacturing organization (CDMO) is a strategic decision. The CDMO can be responsible for staying informed about the latest regulatory updates and ensuring that the products they manufacture meet the required standards.

Prioritizing regulatory and quality systems is essential when selecting a manufacturing partner. A reliable CDMO should demonstrate a commitment to proactively tracking and implementing regulatory changes, maintaining robust quality control measures, and fostering a culture of compliance within its organization.

The CDMO should have well-established quality management systems (QMS) in place. These systems should encompass every aspect of drug product manufacturing, from raw material sourcing to final product release, ensuring compliance with regulatory standards.

A commitment to continuous improvement is vital. The CDMO should actively seek feedback, analyze performance metrics, and implement enhancements to processes and systems to stay ahead of regulatory requirements.

Adherence to regulatory standards is not merely a legal requirement but a fundamental component of ensuring patient safety and product efficacy in the intricate pharmaceutical development and manufacturing landscape.

Adragos Regulatory Affairs Services

We are dedicated to providing our customers with top-quality products and services. We also coordinate regulatory activities with all internal and external stakeholders and service providers to guide them toward a successful, approved dossier.



Our Regulatory services:

- Regulatory & registration strategy
- Scientific report writing
- Compilation and publishing of data in electronic common technical document (eCTD) format
- Liaising with regulatory authorities
- Registration services and support
- Risk assessment report

Before any development project can be implemented, it must be approved by competent authorities. Our team of experts thoroughly understands current international regulatory changes and is dedicated to offering support in submission and documentation.

Why should Adragos be the partner of choice?

When selecting a partner to cooperate with, evaluating the ability to provide benefits and willingness to contribute and collaborate is essential.

Considering our track record, alignment with your goals and values and commitment to a mutually beneficial partnership are crucial. Taking a comprehensive approach and considering these aspects can ensure a more prosperous and fruitful collaboration that brings value to both parties.

Selecting the proper Contract Development and Manufacturing Organization (CDMO) is crucial for ensuring success in pharmaceutical development.

Adragos is a leading company in this industry, renowned for its unwavering commitment to global collaborations and excellence. We guarantee that your product meets the highest regulatory and quality standards, from initial development to commercial manufacturing, while delivering prompt and compliant results.

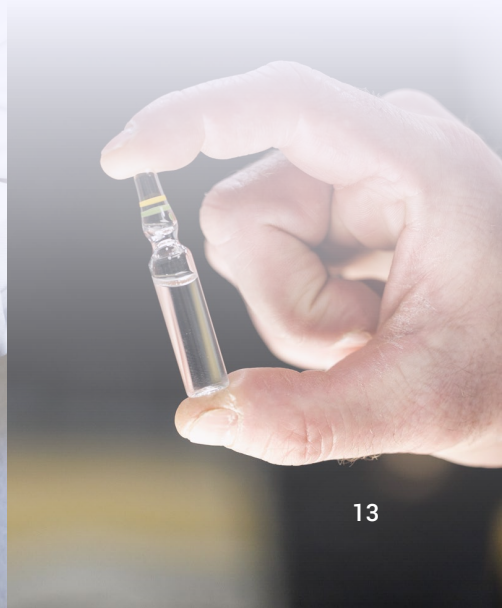
What separates Adragos is our understanding that choosing a CDMO is more than technical expertise and manufacturing capacity. It involves establishing a genuine partnership with our clients.

We go beyond providing a mere service and strive to be strategic allies, offering support and collaboration that surpass the typical client-vendor relationship.

At Adragos, we prioritize regulatory compliance, ensuring your project meets all requirements in today's complex regulatory environment. We stay up-to-date with international regulatory changes and evolving industry standards, minimizing risks and setbacks in your product development journey.

By selecting Adragos Pharma as your CDMO partner, you make a wise decision that aligns perfectly with the pharmaceutical industry's evolving needs. You gain a service provider and a dedicated ally invested in the success of your product from start to finish.





ADRAGOS PHARMA

#WeAreAdragos



Contact us

info@adragos-pharma.com

www.adragos-pharma.com

Sonnenstrasse 17, 80331 Munich, Germany