Third-Party Service or Shared Success: Unraveling the Phenomenon of CMOs in the Pharmaceutical Industry

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Abstract

The integration of Contract Manufacturing Organizations (CMOs) into the pharmaceutical industry has transformed the way companies approach production and innovation. This dissertation investigates the current industry role of CMOs, critical factors for successful partnerships, and explores emerging industry trends.

A qualitative research methodology combined a comprehensive academic literature review with insights from expert interviews. The study was structured around three research questions to integrate theoretical knowledge and practical perspectives. Secondary research provided a robust foundation, while interviews with industry professionals revealed detailed, real-world challenges and opportunities.

The findings indicate that successful CMO partnerships depend on maintaining stringent quality standards, transparent and proactive communication, and alignment of expectations. Challenges such as cultural differences and pricing pressures were identified, highlighting the complexity of cross-cultural collaborations. CMOs are valuable partners for large, established companies. They also serve as critical enablers for smaller firms that lack the resources to invest in full-scale production facilities, helping them bring products to market efficiently. Emerging trends include the increasing adoption of artificial intelligence for supply chain optimization, geographic shifts in manufacturing to China and the Middle East, and market consolidation, with larger CMOs acquiring smaller firms to expand technological capabilities.

These results emphasize the need for pharmaceutical companies to balance technical rigor with relational trust in their partnerships. The study provides recommendations for fostering flexibility and innovation, emphasizing the importance of strategic alignment and technological investment to address the dynamic challenges of the pharmaceutical landscape.

Title: Third-Party Service or Shared Success: Unraveling the Phenomenon of CMOs in the Pharmaceutical Industry

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Key Words: Contract manufacturing organization, pharmaceutical industry, outsourcing, supply chain, biotech, value chain, product lifecycle, innovation, patent lifecycle, strategic partnership, collaboration, regulatory compliance, technology, industry development

Sumário

A integração das Organizações de Fabrico Contratadas (CMO) transformou a forma como a indústria farmacêutica aborda a produção e a inovação. Esta dissertação investiga o papel atual das CMOs na indústria, os fatores críticos para parcerias de sucesso e explora as tendências emergentes do setor.

A metodologia qualitativa combinou uma análise exaustiva da literatura académica com entrevistas a especialistas. O estudo foi estruturado em torno de três questões de investigação, integrando conhecimentos teóricos e perspetivas práticas. A investigação secundária forneceu uma base sólida, enquanto as entrevistas revelaram desafios e oportunidades do mundo real.

Os resultados indicam que parcerias bem-sucedidas com as CMO dependem de normas de qualidade rigorosas, comunicação proativa e alinhamento de expectativas. Os desafios incluem diferenças culturais e pressões sobre preços, destacando a complexidade das colaborações interculturais. As CMOs são parceiras essenciais para grandes empresas e facilitadores para pequenas empresas, permitindo-lhes colocar produtos no mercado de forma eficiente. Tendências emergentes incluem o uso crescente de inteligência artificial para otimizar a cadeia de abastecimento, mudanças na produção para regiões como a China e o Médio Oriente, e consolidação do mercado, com grandes CMO a adquirir empresas menores para expandir capacidades.

Este estudo sublinha a necessidade de equilíbrio entre rigor técnico e confiança relacional nas parcerias. Recomenda-se o alinhamento estratégico e o investimento tecnológico como meios para enfrentar os desafios dinâmicos da indústria farmacêutica.

Title: Serviço a terceiros ou sucesso partilhado: Desvendar o fenómeno dos CMO na indústria farmacêutica

Author: Sven Kühnen

Key Words: Organização de fabrico por contrato, indústria farmacêutica, externalização, cadeia de abastecimento, biotecnologia, cadeia de valor, ciclo de vida do produto, inovação, ciclo de vida da patente, parceria estratégica, colaboração, conformidade regulamentar, tecnologia, desenvolvimento da indústria

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List of Abbreviations

Compound Annual Growth Rate	CAGR
Contract Service Provider	CSP
Contract Development and Manufacturing Organization	CDMO
Contract Manufacturing Organization	CMO
Customer-Driven Manufacturing Organizations	CdMOs
Good Manufacturing Practice	GMP
Key Performance Indicator	KPI
Research and Development	R&D
Research Question	RQ
United States Dollar	USD

1 Introduction

1.1 Research Motivation

This research is driven by a combination of professional experience, personal curiosity, and a desire to contribute to the understanding of an evolving industry. In the past, two years of valuable insights have been gained through full-time roles at two global pharmaceutical manufacturers and within a consultancy branch for Health and Public Services. These experiences, combined with academic studies, have provided a unique perspective and the foundational expertise necessary to explore the chosen subject in depth.

This dissertation adopts an Industry Research approach, to analyze a specific industry and provide strategic insights for its stakeholders. It examines the phenomenon of CMOs and their evolving industry role. Unlike an academic research approach, this research emphasizes a practical viewpoint, delivering actionable insights for industry practitioners.

1.2 Industry Classification and Introduction to CMOs

The pharmaceutical industry is critical in our lives and global healthcare. It drives innovation in drug development and ensures the availability of essential medicines. The path from drug discovery to entering the market is complex, expensive, and time-consuming. One of the critical solutions for overcoming these challenges is the outsourcing of parts of the research, manufacturing, or development process to so-called Contract Development and Manufacturing Organizations (CDMOs) or only Contract Manufacturing Organizations (CMO) (Carter & Brindley, 2022).

This is not a typical outsourcing customer-vendor relationship. CMOs provide specialized services ranging from product development to large-scale manufacturing, allowing pharmaceutical companies to focus on their core strengths and competencies, such as research, marketing, and sales (Carter & Brindley, 2022).

The relationship between pharmaceutical companies and CMOs has become increasingly significant over the past few decades. Beyond the standard customer-vendor interaction, CMOs deliver products or services that directly affect product quality, integrity, supply continuity, and costs. They are also crucial in upholding Good Manufacturing Practice (GMP) and other compliance standards, often operating under supply and quality agreements. These usually long-term relationships can either limit a company's growth or provide substantial value to its business (Lugo, 2009).

As the industry faces growing regulatory scrutiny, global laws, cost pressures, and a demand for innovation, optimizing partnerships with CMOs can be crucial to project success. These partnerships are not without challenges. Poorly managed collaborations often result in unmet project expectations, delays, or even failure (Applebaum, 2006). This highlights the importance of strategic partnership management, with clearly defined guidelines and mutual objectives to fully harness the potential of CMO collaborations.

1.3 Research Overview

This research paper is structured into five chapters. Chapter one, the Introduction, outlines the research problem and objectives of the study. It provides a brief overview of the pharmaceutical industry's reliance on CMOs, and the challenges associated with partnership management. The introduction also sets the stage for the three research questions that guide the analysis and findings of this study.

Second, in the Theoretical Discussion, the theoretical framework surrounding CMO partnerships is explored. Key concepts, including the evolution of CMOs, their role in the pharmaceutical supply chain, the industry's value chain and factors influencing successful partnerships, are reviewed. Secondary research will help illustrate the development of CMOs over the years and their increasing importance in the industry.

Third, the Methodology chapter outlines the research approach, focusing on expert interviews with industry professionals involved in CMO projects from both parties. It details the research design, interview questions, and the process of collecting and analyzing data to answer the research questions.

The fourth chapter, Analysis and Results, presents the main conclusions of this dissertation by addressing the research questions one after another. This chapter synthesizes findings from both the secondary data and the expert interviews, identifying key success factors for managing CMO relationships and highlighting areas where companies can optimize partnerships. It serves as the foundation for understanding how the insights gathered answer the core objectives of the study.

The final chapter focuses on the broader implications of the findings, their limitations, and directions for future research. It emphasizes practical recommendations for stakeholders in the pharmaceutical industry.

1.4 Problem Statement

"Pharma and biopharma companies don't want to work on their relationships. These companies want their relationships to work for *them*" (Shaffer, 2020). This quote highlights the passive approach many companies take toward managing their partnerships, expecting results without actively fostering strong, collaborative relationships. The high complexity of pharmaceutical projects requires more proactive engagement to ensure success. Many companies work with multiple CMO vendors, often without clear guidelines or transparency, which hinders project performance. Poor partnership management can lead to failures, delays, and increased costs, requiring additional resources to realign and meet project objectives.

Moreover, companies in the pharmaceutical industry must stay at the forefront of innovation and implement promising advancements to remain competitive. The industry's future is uncertain, with evolving technologies, shifting regulations, and emerging market demands creating a challenging landscape.

This unpredictability often leads companies to pursue strategies that may not align with future developments, resulting in misdirected efforts and missed opportunities. Hence, companies lack orientation in this uncertainty, making it difficult to effectively manage partnerships and make informed, strategic decisions (Nosal, 2021).

1.5 Research Objective

The research follows the industry research design approach. First, the research aims to provide a comprehensive understanding of the pharmaceutical industry, with a specific focus on CMOs. Second, it involves analyzing success factors related to CMO projects and developing practical guidelines for pharmaceutical companies to implement CMO collaborations effectively. Afterward, the research is closed by designing an outlook on where the industry is heading. Lastly, the research should guide industry experts and decision-makers, from both, CMOs and pharmaceutical companies, with practical recommendations and best practices. To achieve this, the following research questions have been designed.

1.6 Research Questions

- Research Question 1 (RQ 1): What is the role of CMOs in the pharmaceutical industry?
- Research Question 2 (RQ 2): Which factors contribute to successful strategic partnerships between CMOs and pharmaceutical companies?
- Research Question 3 (RQ 3): What are the most relevant developments in the CMO industry?

1.7 Out of Scope

First, the research does not address the initial phase, during which pharmaceutical companies actively search for a partnering CMO. It is assumed that this selection process has already been completed.

Second, the study does not differentiate between partnerships involving pharmaceutical companies and those involving biotechnology companies. The findings are presented in a generalized manner that applies to both types of organizations.

Third, while industry trends are explored and forecasted, their specific impacts on different stakeholders are not analyzed in detail.

2 Theoretical Discussion

2.1 Introduction

This chapter provides a comprehensive review of the relevant literature, keeping it focused on themes critical to addressing the research questions. Beginning with an industry overview, the review narrows down to discuss key areas directly related to the research questions. This approach ensures a focused and systematic examination of the literature.

The research questions served as the guiding framework for organizing and selecting the topics addressed in this chapter. The structure of the literature review is as follows: understanding the pharmaceutical industry and its relevant terminologies, how value is created, followed by an analysis of the CMO segment, an examination of how pharmaceutical companies collaborate, and concluding with an outlook on emerging industry trends.

Google Scholar was utilized as the primary resource for identifying academic literature, complemented by an exploration of pharmaceutical and business journals. Keyword searches played a crucial role in locating relevant sources, using terms such as: pharmaceutical manufacturing, pharmaceutical value chain, contract manufacturing, outsourcing, relationship management, or CMO developments.

2.2 The Pharmaceutical Industry

The pharmaceutical industry is among the most research-driven sectors globally, consistently producing new products that save lives and improve quality of life. Over time, drug discovery has shifted from a largely trial-and-error approach to one that is grounded in core scientific understanding and advancement (Scherer, 2000).

Strong connections have been developed between profit-driven manufacturers and basic research institutions, like universities and national laboratories. In most industrialized countries, new pharmaceutical products are subject to strict regulations concerning their safety and effectiveness, which raise the costs of clinical testing. Due to the significant investments in research, development, and testing and the ease with which proven products can be copied, patent protection plays a crucial role in the industry (Scherer, 2000).

2.2.1 Terminologies

- Diagnostics: Diagnostics are tools, techniques, and procedures used to detect and characterize diseases or health conditions. They include in vitro tests (e.g. blood tests) and

in vivo methods (e.g. imaging), ranging from self-use devices to advanced systems requiring specialized infrastructure and expertise (WHO, n.d.).

- Biopharmaceutical / Pharmaceutical products: Biologics, or biopharmaceuticals, are drugs derived from living organisms and used to treat specific conditions like cancer or autoimmune diseases, often administered via injection or infusion. In contrast, pharmaceutical products are chemically synthesized drugs. These are substances include medicines and vaccines, used to treat, cure, or prevent diseases (WHO, n.d.) (ITA, n.d.).

- Contract Research Organization (CRO): A CRO assists biotechnology and pharmaceutical companies by offering a broad spectrum of early-stage research and development (R&D) services. These services primarily revolve around clinical trials, clinical research, regulatory compliance, site selection, recruitment, monitoring, data management, logistics, biostatistics, medical writing, and project management (Thermo Fisher Scientific, 2023). Such partnerships allow pharmaceutical, biotechnology, and medical device companies to leverage the CRO's expertise, infrastructure, and resources while focusing on other internal priorities (MCPH, n.d.).

- Contract Manufacturing Organization (CMO): A CMO specializes in helping pharmaceutical and biotechnology companies manufacture certain products. Their offerings include large-scale production, stability testing, formulation development, and pre-formulation work. CMOs provide advanced equipment, often cutting-edge technology and skilled personnel, helping their clients manage the complex and expensive task of drug manufacturing. Additionally, CMOs ensure that companies remain compliant with stringent quality and regulatory standards (MCPH, n.d.) (Thermo Fisher Scientific, 2023).

- Contract Development and Manufacturing Organization (CDMO): A contract development and manufacturing organization offers fully integrated solutions, providing both drug development and manufacturing services. CDMOs cover a wide array of services, including formulation development, regulatory assistance, clinical trial support, packaging, supply chain management, quality assurance, and technology transfer (MCPH, n.d.) (Thermo Fisher Scientific, 2023).

2.3 The Pharma Value Chain and the Role of CMOs

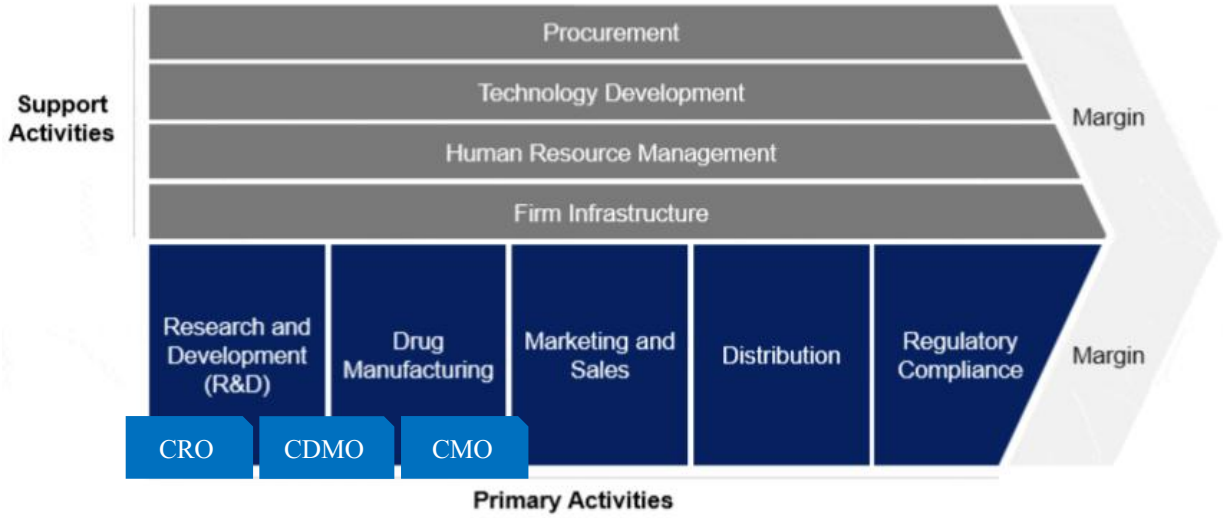

Figure 1 *- The Pharmaceutical Value Chain, adapted from (Bridges, 2024)*

To better understand the role of CMOs, it is crucial to understand the industry's value chain and the areas where CMOs are present. Assessing the Primary Value Chain activities, first, Research and Development (R&D) serves as the foundation, involving the discovery and development of new drug compounds. This stage requires substantial investment in scientific research, specialized expertise, and advanced infrastructure to bring innovative therapies to life. In this stage, pharmaceutical companies can collaborate with CROs to get additional expertise within the research topics (Bridges, 2024).

Following R&D, Drug Manufacturing plays a crucial role in translating discoveries into market-ready products. This process is highly regulated to ensure compliance with safety and quality standards, making it vital to the production of effective and safe medications. As shown in Figure 1, CDMOs are linked between the first two stages, further if a company requires additional manufacturing resources, CMOs can be the right help (Bridges, 2024).

Next, Marketing and Sales come into play once a drug is approved. These activities help promote the product, create market demand, and ensure that healthcare providers and patients are informed about the drug's benefits. Distribution ensures that the drugs reach their intended markets efficiently (Aitken, 2016). Effective distribution channels are necessary to make products accessible to patients around the world, especially in time-sensitive cases where treatments need to reach people quickly. For marketing and sales topics, CMOs are no longer involved (Shaffer, 2020).

Finally, Regulatory Compliance is anchored in the entire value chain. It ensures that pharmaceutical companies adhere to strict regulatory standards in each phase, from development to manufacturing, ultimately guaranteeing the safety and efficacy of the drugs brought to market. Supporting these primary activities are several crucial functions, including Procurement, Technology Development, Human Resource Management, and Firm Infrastructure, which together provide the foundation for operational success, competitive advantage, and an economic margin (Haakonsson, 2009).

2.4 Ecosystem in the Industry – Vertical and Horizontal Integration Models

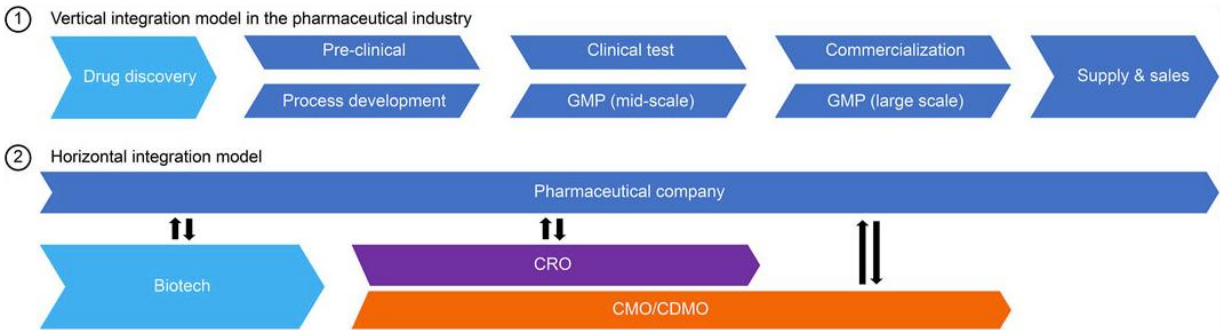

Figure 2 *- Vertical and Horizontal Integration (Kurata, Ishino, Oshima, & Yohda, 2022)*

The upper vertical integration model represents a traditional approach where a single pharmaceutical company owns and controls multiple stages of the drug development and production process. This model encompasses a sequential process starting with drug discovery, followed by process development, pre-clinical tests, and clinical trials. After successful trials, the drug moves into the GMP phase, which is divided into mid-scale production for clinical trials and large-scale production for commercialization. The final steps include commercialization, where the drug is brought to market, with supply and sales, where it is distributed (Kurata, Ishino, Oshima, & Yohda, 2022). Under this model, companies have direct ownership of each phase, which allows for greater control but also requires significant capital investment and resources to maintain operations across the entire value chain (Capo, Brunetta, & Boccardelli, 2014).

With advances in technology and specialization, the horizontal integration model has gained prominence. This model reflects a collaborative approach where various organizations specialize in different parts of the drug development pipeline. Pharmaceutical companies often work with biotech firms, CROs, and CMOs/CDMOs. In this setup, biotech firms primarily

focus on early-stage drug discovery, while CROs handle clinical testing and regulatory tasks (Tcherpakov, 2024).

CMOs and CDMOs manage drug development and large-scale manufacturing. Horizontal integration allows pharmaceutical companies to reduce costs and mitigate risks by outsourcing certain functions to external experts, enabling them to concentrate on core areas such as commercialization and marketing (Kurata, Ishino, Oshima, & Yohda, 2022). This model encourages partnerships, flexibility, and speed to market across the industry.

In the past, the pharmaceutical industry was dominated by the vertical integration model, where companies owned and controlled the entire drug development process. With technological innovations in drug discovery and manufacturing, the industry has shifted toward a more horizontal integration model (Capo, Brunetta, & Boccardelli, 2014). This change allows companies to collaborate with specialized organizations, streamlining the production process and focusing their internal resources on strategic areas. Horizontal integration has become the prevalent model today, reflecting a shift in how pharmaceutical companies approach drug development and commercialization (Kurata, Ishino, Oshima, & Yohda, 2022).

2.5 An Overview of the Global CMO Market

The global pharmaceutical CMO market is projected to reach approximately USD 150 billion by 2024, with North America being the largest regional market. Despite North America's dominance, the Middle East is anticipated to be the fastest-growing region over the next five years. This rapid growth in the Middle East is primarily attributed to more investments in healthcare infrastructure (BRC, 2024).

The pharmaceutical CMO market is experiencing robust growth, with a compound annual growth rate (CAGR) of 7% between 2023 and 2024. This expansion is driven by several key factors, including rising healthcare expenditures, increasing research and development investments, and the growing preference among pharmaceutical companies for outsourcing manufacturing activities to CMOs. Emerging markets are witnessing significant growth as they capitalize on these trends to expand their pharmaceutical manufacturing capacities (BRC, 2024).

By 2028, the pharmaceutical CMO market is expected to nearly double in size, reaching USD 290 billion, with a CAGR of almost 19%. This accelerated growth is attributed to several factors, including additional government support for the pharmaceutical sector, enhanced

access to healthcare, rising investments in the industry, and the expanding role of biopharmaceuticals in the global market (BRC, 2024). The development of biopharmaceutical products is creating new opportunities for CMOs, as these complex products often require specialized manufacturing capabilities (Fortune Business Insights, 2024).

Several emerging trends are expected to shape the pharmaceutical CMO market over the forecast period. Sustainability has become a key focus, with CMOs increasingly incorporating eco-friendly practices into their operations. Additionally, there is a growing emphasis on the integrating artificial intelligence and digitalization to optimize manufacturing processes and improve efficiency. Innovation is also driving the development of more resilient pharmaceutical products and fostering strategic partnerships and collaborations among market players (BRC, 2024).

The leading companies in the pharmaceutical CMO market include Lonza, Thermo Fisher Scientific, Pfizer, Boehringer Ingelheim, Samsung Biologics, WuXi Biologics and Catalent. These companies are at the forefront of the industry, providing a wide range of manufacturing services and actively contributing to the market's growth and innovation (Mikulic, 2023) (Fortune Business Insights, 2024).

The COVID-19 pandemic had a positive impact on the pharmaceutical CMO market, particularly in 2020 and 2021. CMOs played a critical role in manufacturing vaccines and therapeutics for COVID-19, securing significant contracts from pharmaceutical companies and governments. This raised demand for outsourced manufacturing services during the pandemic reinforced the strategic importance of CMOs within the global pharmaceutical supply chain (Fortune Business Insights, 2024).

Concluding, CMOs play a notable role within the industry and value chain by offering end-to-end services that span from drug development to manufacturing. CMOs allow pharmaceutical companies to outsource various phases of the value chain, enabling faster drug development, lower costs, and efficient scaling of manufacturing operations. By collaborating with CMOs, companies can focus more on innovation and marketing while benefiting from the CMO's expertise in regulatory compliance, manufacturing efficiency, and supply chain management. This partnership is critical to accelerating time to market, especially in a highly competitive and regulated industry.

2.6 Working with CMOs – Relationship Management

Managing relationships with CMOs is decisive for pharmaceutical companies to ensure product quality, supply continuity, and regulatory compliance. These relationships evolve through various stages, requiring structured frameworks to optimize both the technical and strategic aspects of partnerships. Two notable approaches offer insights into managing CMOs: Applebaum's seven-step approach (Applebaum, 2006) and the five-stage model described by Nelson Lugo (Lugo, 2009).

Applebaum's seven-step lifecycle model focuses on a structured, comprehensive strategy for CMO relationship management. The stages include:

1. Define Needs and Select: Identify the company's requirements and rigorously select the CMO based on both technical and strategic fit.
2. Align Expectations: Clearly communicate mutual expectations, including key performance indicators (KPIs) and compliance with GMP.
3. Formalize the Partnership: Establishing formal contracts such as supply agreements and quality agreements to clarify roles and responsibilities.
4. Onboard the CMO: Integrating the CMO into the company's operational and quality frameworks.
5. Monitor and Control: Ongoing monitoring of CMO performance using performance metrics, audits, and compliance checks.
6. Adjust and Adapt: Continuously reassess the partnership, allowing flexibility for changes in scope, processes, or requirements.
7. Renew or Transition: Determining whether to extend the relationship or transition to another CMO based on business goals and CMO performance.

Applebaum's approach emphasizes a dynamic process where flexibility and continuous evaluation are critical. These steps promote not only operational efficiency but also strategic alignment with the pharma company's long-term objectives.

On the other hand, Lugo (Lugo, 2009) divides the CMO lifecycle into five stages: Organize, Select, Negotiate, Implement, and Manage. These stages provide a streamlined and process-focused approach. CSP stands for Contract Service Provider, which is a substitute noun for CMO.

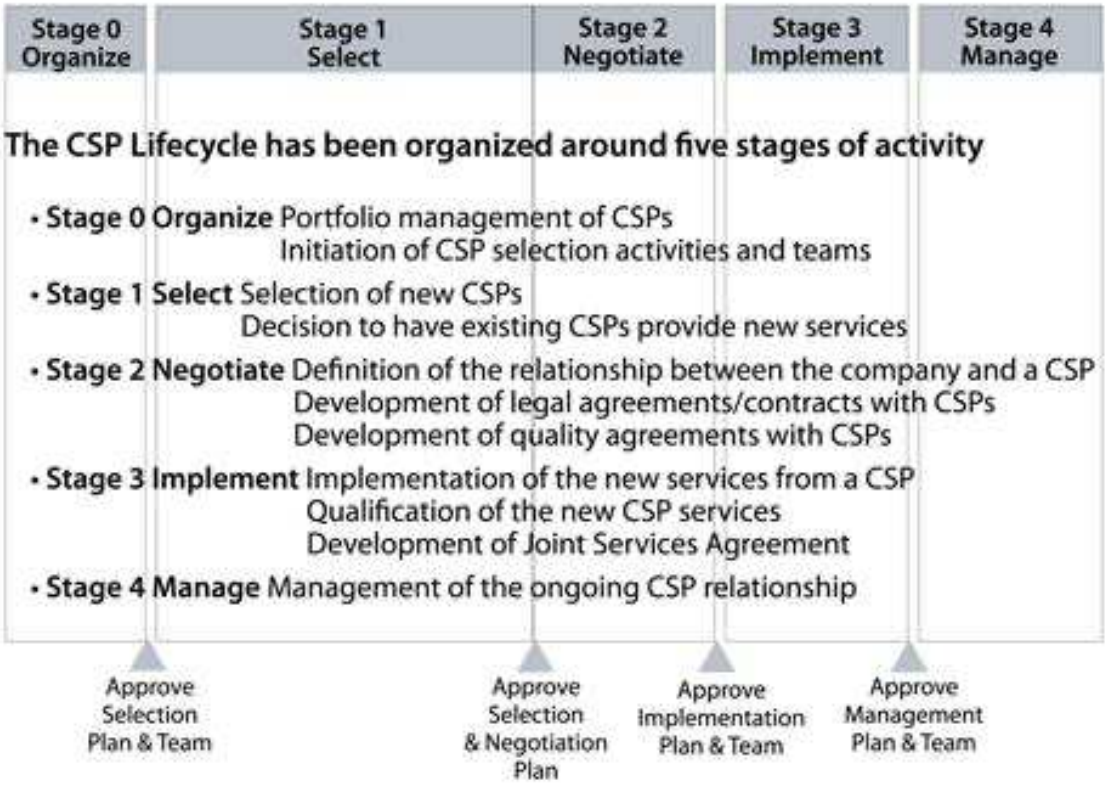

Figure 3 *- The CSP/CMO Approach (Lugo, 2009)*

This five-stage model simplifies the CMO lifecycle into distinct phases and provides a clear linear structure to relationship management. It begins with organizing internal teams and activities to handle portfolio management and partner selection. The second stage involves selecting new or existing CMOs based on pre-defined criteria. In the third stage, the company negotiates contracts and agreements, including legal and quality terms. The implementation stage focuses on integrating and qualifying the services provided by the CMO. Finally, the management stage oversees ongoing performance and relationship management, ensuring that the partnership aligns with business objectives (Lugo, 2009).

While both approaches focus on lifecycle management, Applebaum's model places greater emphasis on long-term strategic adaptation and continuous improvement. Lugo's model, as illustrated in Figure 3, offers a more process-driven method that emphasizes structured decision-making at each phase of the relationship (Lugo, 2009). Applebaum's framework encourages flexibility and dynamic readjustments, such as revisiting performance metrics and adapting the relationship based on evolving business needs (Applebaum, 2006). On the other hand, the five stages offer a more formalized and systematic structure, particularly beneficial for companies looking for rigid guidelines in managing CMO partnerships.

A key difference between the two is in how they address the evaluation and re-evaluation of CMO relationships. Applebaum's "Adjust and Adapt" and "Renew or Transition" stages highlight the importance of regularly re-assessing partnerships, offering a more flexible model for companies in rapidly evolving sectors (Applebaum, 2006).

2.6.1 Traditional versus Customer-Centric Approach

The relationship between pharmaceutical companies and CMOs has shifted from a purely transactional model to a more collaborative, customer-centric approach. Traditionally, pharma companies, acting as customers, engaged CMOs as providers with the primary focus on cost-efficiency and meeting essential contractual obligations, such as production timelines and compliance with regulatory standards (Hotha, 2023).

The traditional model emphasized efficiency and compliance with GMP, where the pharma company outlined production needs, and the CMO's role was to deliver the product with minimal input beyond those operational details. This limited interaction, although functional, often lacked adaptability to handle complexities in drug development or innovation needs, potentially hindering long-term value creation (Voigt, 2016).

Today, the customer-centric model places the pharmaceutical company in the role of an active collaborator rather than a passive client. This approach recognizes the strategic importance of CMOs in the development and production of pharmaceutical products. CMOs are no longer viewed as just service providers, instead, they are seen as integral partners who can contribute innovative solutions and shape the overall business strategy (Rauhut, 2020).

For example, in a customer-centric model, CMOs are involved early in the development process and work alongside the pharma company to address specific challenges related to manufacturing complexity, quality control, and speed to market (Hotha, 2023).

This deeper collaboration is driven by a shared commitment to achieving common goals, such as improving product quality and efficiency while accelerating time to market. A key component of this approach is enhanced communication between the pharma company and the CMO, allowing for greater transparency, flexibility, and adaptability in operations. With advanced digital tools and data-sharing platforms, both parties can jointly monitor performance metrics and make real-time adjustments to processes, ensuring that the partnership remains aligned with evolving business goals and regulatory requirements (Suresh, 2019).

The customer-centric model also fosters innovation, as CMOs are encouraged to introduce new technologies, processes, and expertise that can provide significant value to the pharmaceutical company. This mutual benefit helps not only to improve operational outcomes but also to build long-term relationships that extend beyond simple cost-saving measures (Hotha, 2023). Ultimately, the shift from a traditional to a customer-centric model allows pharmaceutical companies to leverage the full capabilities of CMOs, creating a strategic partnership that drives innovation, quality, and competitive advantage (Lee, 2021).

2.7 Industry Developments

In recent years, the CMO industry has experienced ongoing consolidations between larger companies, for example, significant acquisitions such as Lonza's purchase of Capsugel for USD 5.5 billion and ThermoFisher's acquisition of Patheon for USD 7.2 billion in 2017. In December 2024, Novo Holdings (Novo Nordisk) and Catalent announced they had fulfilled all regulatory conditions for a USD 16.5 billion acquisition of Catalent. The deal, first agreed in February 2024, is expected to close within days. The acquisition includes Novo Holdings' plan to optimize Catalent's manufacturing capabilities to meet growing pharmaceutical demand for its latest blockbuster products Ozempic and Wegovy (Bieri, 2017) (Shah, 2024).

These transactions illustrate a growing trend where larger firms seek to expand their capabilities and market presence amidst increasing demand from smaller pharmaceutical innovators. This consolidation allows CMOs to enhance their service offerings and manage complex technologies, thereby meeting the evolving needs of the pharmaceutical sector (Bieri, 2017).

By integrating multiple services or even companies under one roof, CMOs exemplify the industry's trend toward offering comprehensive, end-to-end services. "Any time a client has to go to multiple vendors, it creates a lot of seams and communication problems", says Richard Shook, director of drug product technical services and business integration at the American CDMO Cambrex (Shook, 2020). He emphasizes that managing various vendors enlarges the risk of miscommunication and overlooked critical knowledge, which can jeopardize the progress of complex projects (Shook, 2020).

Working with a single CMO or owning a CMO's production sites allows for a seamless knowledge transfer across different phases of the drug lifecycle. This holistic approach ensures better coordination, reduces the risk of lost information, and creates a unified knowledge base that can be carried forward throughout the project (Shaffer, 2020).

Moreover, three key manufacturing trends can be observed in the field. First, the CMO industry is transitioning toward more customer-centric models, reflecting a shift from traditional service provider roles to becoming *customer-driven* manufacturing organizations (CdMOs) (Lewis, 2024). This trend emphasizes collaboration, transparency, and flexibility, enabling CMOs to tailor their services to meet pharmaceutical clients' specific needs. By aligning closely with customer goals, CdMOs can offer more personalized, value-added solutions that foster long-term partnerships.

Agile manufacturing is another dominant trend, driven by the need for flexibility in responding to dynamic market demands, particularly in light of increasing product complexity and shorter drug development cycles. This approach allows CMOs to quickly scale up or modify production processes, optimizing efficiency while minimizing time to market (Körber, 2022). The ability to pivot rapidly is essential for pharmaceutical companies navigating regulatory changes and fluctuating demand (Lewis, 2024).

The adoption of digitalization, data management, and automation is transforming the CMO industry. Advanced technologies streamlining operations and improving production precision. Automation in manufacturing processes not only enhances efficiency but also reduces human error, leading to higher-quality outputs in an industry where quality output highly matters (Lewis, 2024).

Furthermore, digital tools enable better data-driven decision-making, helping CMOs manage complex supply chains and improve transparency throughout the production lifecycle. This trend aligns with the broader pharmaceutical industry's push toward innovation and operational excellence (Hole, Hole, & McFalone-Shaw, 2021).

2.8 Preliminary Conclusion

Through the literature review, a status assessment was conducted to determine what current research reveals and to identify commonly used tools and models. This preliminary conclusion section provides initial answers to the research questions defined in section 1.3.

Addressing RQ1 about the industry role of CMOs, the literature highlights a raised strategic contribution across various stages of the pharmaceutical product lifecycle. CMOs serve as substantial partners, supporting pharmaceutical companies during critical stages from R&D to manufacturing. Their involvement bridges the gap between R&D advancements and large-scale production, acting as a connector within the pharmaceutical value chain.

The industry's shift toward a horizontal integration model has further elevated the role of CMOs. Pharmaceutical companies expand collaborations with external partners to achieve cost-effective and faster solutions, leveraging the specialized expertise and flexibility that CMOs provide. Moreover, CMOs contribute to value creation, and their integration into the pharmaceutical value chain raises important questions about dependency, quality assurance, and the long-term sustainability of these partnerships, highlighting areas that require further scrutiny in the following chapters.

In addressing the success factors for collaborating with CMOs (RQ2), the literature presents differing approaches to the process. Applebaum's formal seven-step model outlines a comprehensive framework for collaboration, emphasizing two phases that focus on ensuring long-term partnership success. These phases guide organizations through initial setup and the continuous adjustment of strategies, making them adaptable to changing market dynamics. In contrast, Lugo offers a leaner approach, placing greater emphasis on the final phase of relationship management. Both models highlight the importance of a structured process in fostering collaboration, with attention to long-term development.

Modern CMOs are viewed not only as service providers but as active collaborators in the development and production of pharmaceutical products. This shift requires that CMOs be integrated into the strategic goals of their partners, aligning objectives for mutual success. Communication emerges as a critical success factor in these relationships. Lastly, the literature reveals a gap in clearly identifying the precise success factors that contribute to a successful CMO collaboration, which remains a subject for further investigation in the following chapters.

In conclusion, RQ3's industry developments and trends show that the CMO industry is experiencing significant growth, particularly in emerging markets, with the Middle East projected to be the fastest-growing region over the next five years. The global CMO market is expected to grow by 7% in 2024, nearly doubling in size from $150 billion to $290 billion until 2028. This expansion is driven by more extensive healthcare access, advancements in manufacturing technologies, and a growing demand for more efficient production methods.

Key industry developments include a shift towards more customer-oriented, agile manufacturing, as well as the integration of digitized and automated processes. Companies are extending investments in AI and other technologies to optimize production. Additionally, larger pharmaceutical companies are making strategic investments and acquisitions, incorporating CMO production sites into their portfolios, reflecting ongoing market dynamics and the need

for innovation in the sector. It remains to be seen whether these developments are truly reflected in the practices of current industry players.

3 Methodology

3.1 Introduction

This chapter describes the research methodology used to address the primary research gap: identifying critical factors to enhance relationship management between CMOs and pharmaceutical companies and exploring the future direction of the CMO industry. The aim is to establish a structured approach that provides insights for both academic study and practical application.

A qualitative research approach was chosen because it aligns with the study's focus on capturing detailed insights and diverse perspectives from industry professionals. Individual expert interviews were selected as the primary method for data collection because they allow for in-depth discussions and provide participants with the opportunity to share their experiences and viewpoints in a focused manner (White & Rayner, 2014).

This research required much effort to find qualified interview participants who met the necessary high criteria and qualifications. In total, 42 experts were contacted during November and December 2024, of whom four gratefully accepted the interview request.

The data collected through these interviews is analyzed using an inductive coding approach with a thematic analysis to uncover patterns and key themes relevant to the research objectives (Fereday & Muir-Cochrane, 2006) (Glaser & Strauss, 1967). The chapter concludes by addressing the challenges encountered during the research process and explaining the measures taken to overcome these difficulties and biases, to ensure the reliability of the findings.

3.2 Secondary Research

Secondary research was undertaken to build a foundational understanding of the subject. This involved reviewing relevant literature sourced from a variety of academic databases, to digest a comprehensive perception of the current and historical academic view on the topic.

The research primarily relied on articles from established academic journals, e.g. the Academy of Management Journal, Journal of International Business Studies, Biotechnology Journal, and the Journal of Pharmaceutics. These journals were selected for their relevance and focus on crucial themes, such as the pharmaceutical and biotechnology industries, outsourcing practices, and strategic partnership management.

The literature search was guided by specific keywords, including: pharmaceutical industry, contract manufacturing, outsourcing, CMO industry, biotech, healthcare, pharmaceutical

manufacturing, strategic partnership, and relationship management. These terms were used individually and in combination to ensure a thorough exploration of relevant topics. Google Scholar functioned as the central database.

3.3 Qualitative Analysis

This study adopts a qualitative research approach, as it aligns with the nature of the research questions, which focus on understanding the role of CMOs, the dynamics of strategic partnerships, and the development of the industry. A qualitative approach is best suited to address these questions, allowing for in-depth exploration and providing differentiated insights that quantitative methods could not capture. The aim of interviewing industry experts is to obtain rich and contextually informed responses (White & Rayner, 2014).

Not without its limitations, qualitative research can be prone to biased interpretations and presents challenges in generalizing findings. To address these potential issues, careful attention was given to the design of the research process, including the selection of participants, the development of a comprehensive, structured interview guide (see Appendix 1), and the use of systematic thematic analysis to ensure objectivity and consistency in data interpretation (Fereday & Muir-Cochrane, 2006).

Within the qualitative framework, interviews were identified as the most suitable method for data collection. While other methods, such as observations or diary studies, were considered, interviews offered distinct advantages. The interactive nature of face-to-face interviews (conducted virtually via Microsoft Teams in this study) allows for immediate clarification of misunderstandings. It enables the researcher to ask for deeper follow-ups. Furthermore, the flexibility of interviews allows for rewording or reordering of questions if unexpected issues arise, ensuring a more natural and effective dialogue (White & Rayner, 2014).

Semi-structured interviews were chosen for their balance of structure and adaptability. With a clear set of open-ended questions to guide the process, this format ensures that key topics are covered. Additionally, it allows for spontaneous adaptations and deeper exploration when necessary. On the other hand, interviews come with certain disadvantages. They are time-consuming, require careful preparation, the identification of suitable participants, and the coordination of virtual sessions (White & Rayner, 2014).

3.4 Research Structure

3.4.1 Data Collection

Data for this study was collected through interviews with four industry experts, representing a range of roles and experiences. The participants were selected based on their professional backgrounds, ensuring they had either direct experience working for a pharmaceutical company and collaborating with a CMO in their daily work, or vice versa. In addition, experts needed to have more than five years of industry experience.

In total, 42 people were contacted, of whom 24 were via LinkedIn direct messaging, nine via WhatsApp and nine via E-mail. From the total of 42, 22 did not respond at all, 16 declined due to lack of time, and four accepted the interview request. To increase the response rate where it was possible, a follow-up message has been sent. On LinkedIn, this was mostly not possible due to a Premium feature, which restricts sending multiple messages to people outside one's network. Additionally, at the end of each interview, participants were asked to recommend colleagues who might contribute valuable insights to the study.

To maintain confidentiality, all participant names are anonymized. A detailed overview of the interview participants is provided below:

ID*	Current Position	Background & Experience	Company Business	Country
1	Senior Business Development Manager	MSc.* Pharmaceutical Sciences & MBA, > 10 years industry experience	Pharmaceutical Launching	Spain
2	Global Process Engineer	MSc. Pharmaceutical Biotechnology, > 10 years industry experience	Diagnostics & Pharmaceuticals	Switzerland
3	Global Supply Chain Planner	MSc. Industrial Engineering, > 8 years industry experience	Diagnostics & Pharmaceuticals	Germany

4	Founder CMO Consultancy	Apprenticeship at CMO, BSc.* Business Chemistry, > 10 years industry experience	Consultancy for Pharmaceutical Industry	Switzerland

**ID = Identification, MSc. = Master of Science, BSc. = Bachelor of Science*

***Table 1** - Overview of Interview Partners and their Characteristics (own illustration)*

The interviews were conducted during the months November and December 2024, with each session lasting from 40 to 60 minutes. To facilitate meaningful discussions, an interview guide was developed and shared with participants in advance (see Appendix 1).

The interview guide is structured into five parts, beginning with an introduction to gather participants' profiles and contextualize their roles and experiences with CMOs. The following three sections align with the study's research questions, exploring the role of CMOs, factors for successful partnerships, and anticipated industry trends. Open-ended questions include questions on personal examples to encourage detailed responses. The guide concludes by inviting participants to share additional thoughts and suggest colleagues for further interviews.

Before the main interviews, the guideline was tested in three pilot sessions. These pilot interviews were conducted with peers to assess the clarity and relevance of the questions, remove any ambiguities, and evaluate whether the planned time frame was sufficient.

3.4.2 Data Analysis

The data analysis for this study is based on the principles of thematic analysis employing an inductive coding approach to derive codes directly from the data (Fereday & Muir-Cochrane, 2006). This method ensures the emergence of new insights and theories in an organic manner, rendering it particularly suitable for exploring expert knowledge and future industry perspectives without being constrained by predetermined frameworks (Glaser & Strauss, 1967).

By remaining open to new ideas and leveraging broad, open-ended expert insights, this approach minimizes the risk of overlooking significant themes, thereby supporting a comprehensive and detailed analysis (White & Rayner, 2014).

The analysis process consisted of five key steps:

1. Familiarization: The first step involved thoroughly re-reading the interview material to develop a comprehensive understanding of the content and to gain an initial sense of the data's depth and diversity.

2. Reflection: In this stage, the researcher posed critical questions about the data, such as whether it aligns with or challenges existing knowledge and theories.
3. Conceptualization: Patterns and concepts emerging from the data were identified and assigned unique codes, represented by letters and numbers, to ensure systematic tracking and organization.
4. Cataloguing Concepts: The identified concepts were documented and grouped, which provided a detailed record of where each concept occurred within the dataset (see Table 2).
5. Linking and Theory Building: Finally, the researcher revisited the original material to identify gaps and refine the emerging theory. Due to time constraints, no additional data collection was undertaken at this stage.

Throughout the coding process, description-focused coding was applied. This method involved extracting relevant statements from the data, tagging responses to open-ended questions, and focusing on understanding participants' answers. Unlike interpretation-focused coding, which prioritizes subjective interpretation (Adu, 2019). Notably, coding was guided by the study's research questions rather than the specific interview questions.

The researcher conducted the coding process manually without any software tools, as personal involvement in all interviews ensured an in-depth awareness of the data and its context. The automated Microsoft Teams tool was applied for the interview transcription.

3.5 Challenges and Justifications

This research encountered several challenges, particularly in recruiting suitable interview participants and ensuring methodological accuracy within a limited timeframe. These challenges were carefully addressed to uphold the study's credibility and validity.

The primary obstacle was the recruitment of appropriate interview participants. Identifying and securing interviews with industry experts, many of whom had demanding schedules. To overcome this, the recruitment process was initiated as early as possible, in early November 2024.

Another critical consideration was ensuring research's neutrality and reliability. To minimize bias, the interview guide was carefully designed with open-ended, neutral questions. Efforts were also made to recruit participants with diverse roles, ensuring a wide range of perspectives

and reducing the risk of bias. A strict analysis framework was applied to maintain consistency in data interpretation and to minimize subjective influence.

4 Analysis and Results

4.1 Introduction

This chapter presents the analysis and results of the qualitative research conducted for the study. The primary objective is to present the methods of analysis and the findings transparently and systematically. Once the interviews had been completed, the transcripts were reviewed and cleaned to guarantee accuracy and familiarity with the data. After that, an inductive thematic coding approach was employed, enabling the identification of recurring themes and key points emphasized by the participants.

The results of this process are summarized in Table 2, which categorizes the overarching concepts, corresponding codes, and their appearance across the four interviews. This table provides a structured overview of the themes that emerged from the data, forming the foundation for the subsequent analysis. Excerpts of the interview transcripts can be found in Appendix 2.

4.2 Qualitative Analysis - Conceptualization

Theme	Code	ID 1	ID 2	ID 3	ID 4
Industry role	Partnering at the end of product lifecycle		X		
	Differentiation based on technology	X	X	X	X
	Knowledge transfer to CMOs		X	X	X
	Opportunity for instant volume increase	X	X		X
	Patent lifecycle procedure	X	X		X
	Growing industry importance	X	X	X	X
	Production opportunity for small companies				X
	Solution for risk management			X	
Advantages of collaboration	Offering production volume flexibility	X	X	X	X
	Bringing in new technologies – tackling new challenges	X	X	X	X
	Continuous manufacturing	X		X	
	Quick solutions in slow industry environment		X	X	X
	Each part can focus on core business			X	
	Patent regulation as a key driver for time pressure	X	X		X
	Added value through smart manufacturing				X
Challenges in collaborating	Managing process control loss	X	X		
	Dependency on supplier	X	X		X
	Cultural differences between global teams		X	X	X
	Different ways of working		X	X	
	Compliance with GMP		X	X	

Critical success factors	Quality as a main driver	X	X	X	X
	Proactive communication		X	X	
	Transparency is extremely important	X	X	X	X
	Alignment and expectation management		X	X	
	Individual balancing act of working together				X
	More about relationship building versus fixed standards	X			X
Pricing Pressure	Pharmaceutical industry needs to save costs	X	X	X	
	Golden times from the past have ended	X	X	X	
	Pressure on leaner and cheaper innovation		X	X	X
Industry Developments	AI in the starting position	X	X	X	X
	Many potential future use cases for AI	X	X		X
	Middle East with growing presence	X			
	US to China shift with extended manufacturing	X		X	X
	More specialized manufactures – small scale	X	X		
	High-volume manufacturers to address potential global demand peaks		X		X
	Consolidated manufacturers with an expansion on production sites		X		X

Table 2 *- Inductive Coding Results (own illustration)*

4.2.1 Industry Role

The role of CMOs within the pharmaceutical industry has evolved, with all interviewees agreeing on their growing importance in recent years. CMOs have emerged as critical partners in addressing the challenges facing pharmaceutical companies. The CMO Consultancy Founder underscored the central role of CMOs in also enabling the growth of small companies and startups, particularly those lacking the resources or infrastructure to produce in-house. This perspective situates CMOs not merely as service providers but as strategic facilitators of industry access for emerging market participants. Such a role is particularly relevant in an industry where barriers to entry remain high.

It is noteworthy that this broader view contrasts with the application described by the Global Process Engineer, who observed that in his company, CMOs are frequently engaged during the later stages of a product's lifecycle. This difference shows the varying ways in which CMOs are perceived and utilized, depending on organizational strategy and operational priorities. While larger companies may see CMOs as a solution for patent-expiring products, smaller enterprises can view them as a crucial element in the early stages of production and market entry.

All participants reached a consensus regarding the role of CMOs as drivers of innovation. Their capacity to differentiate through advanced technology and expertise is aligned with the code of "knowledge transfer." By leveraging and integrating insights from multiple pharmaceutical companies, CMOs act as hubs of technical knowledge, fostering innovative production processes that can benefit the broader industry. This collaborative model positions CMOs as key contributors to technological advancement within the field of pharmaceutical manufacturing.

In addition, three interviewees highlighted the unique role of CMOs in meeting sudden spikes in demand, a capability that underscores their operational flexibility. For example, Novo Nordisk's response to the rapid elevation in demand for their products Ozempic and Wegovy illustrates how CMOs can help pharmaceutical companies manage unexpected market dynamics. This ability to efficiently scale production and meet time-sensitive needs further shows the strategic importance of CMOs in the modern pharmaceutical supply chain.

4.2.2 Advantages of Collaboration

The second theme examines the advantages of collaboration with CMOs, with flexibility identified as a primary benefit. All participants highlighted the CMOs' ability to rapidly scale production volumes in response to demand surges. This flexibility is particularly valuable in an industry where production processes are often rigid and time-intensive.

For instance, ID2 illustrated that "new technologies can lead to the situation where the pharmaceutical company is not yet equipped with it, whereas the CMO is already." This capability to leverage advanced manufacturing capabilities guarantees that companies remain agile in an ongoing competitive market.

Another benefit is the speed at which CMOs can facilitate both production and market entry. Three participants emphasized that CMOs are uniquely positioned to accelerate these processes, which is otherwise challenging in an industry where building new production lines can take multiple years. The Global Process Engineer explained, "if you need a quick volume increase, which is hardly possible in the pharmaceutical industry, where it takes years to build a new production line, the quicker solution is approaching a suitable CMO." This advantage is particularly significant considering the pharmaceutical industry's dependence on timely market entry to maximize returns within the limitations of patent terms.

The patent landscape further highlights the importance of speed in CMO collaborations. As ID4 explained, pharmaceutical companies must adhere to strict patent limits of 20 years, with each day of delay resulting in financial inefficiencies. CMOs' capacity to accelerate production and facilitate market entry enables companies to capitalize on their monopoly position more effectively, driving higher turnover and profitability.

4.2.3 Challenges in Collaborating

The third theme addresses the challenges associated with collaborating with third-party suppliers. During the analysis, five distinct codes were identified.

Two codes stood out as particularly significant, each mentioned three times: the sudden dependency on the supplier and the cultural differences that arise in such partnerships. These challenges are relevant as they require adaptation to different working styles, which can lead to conflicts. For example, ID3, the Global Demand Planner, described their experience working with CMOs from Eastern Asia, noting that "cultural differences, as well as significant variations in communication, are recognizable." These discrepancies underline the complexity of cross-cultural collaboration, where differences in expectations and communication styles can be a burden for the partnership.

Transparency and communication were cited as critical for mitigating these challenges. The Process Engineer noted that transparency does not require sharing every detail but focusing on critical aspects to ensure alignment and avoid misunderstandings.

4.2.4 Critical Success Factors

The fourth theme focuses on the critical success factors identified in the interviews and highlights the key components that contribute to effective collaboration with CMOs. All participants agreed on the importance of maintaining quality standards, with the Senior Business Development Manager emphasizing, "Quality is paramount." This underlines the non-negotiable nature of quality assurance in partnerships with CMOs, as regulatory compliance and product integrity are critical in pharmaceutical manufacturing.

Transparency in communication was another factor all four respondents highly valued. While this was generally acknowledged, ID2 and ID3 specifically expressed a desire for a more proactive approach to communication from CMOs. This proactive stance ensures that potential issues are addressed before they escalate and that both parties gain a clear understanding of

project progress and challenges. The emphasis on transparency highlights the need for CMOs to create open lines of communication to build trust and foster a collaborative environment.

The CMO consultant held an opposing view. He described it as “more about building relationships than about fixed standards,” a feeling shared by the business development manager, who acknowledged the importance of a balance between flexibility and structure. This perspective adds to the discussion, suggesting that while quality and transparency are fundamental, building a strong, adaptable relationship is equally important for long-term success.

For the Process Engineer and the Global Demand Planner, "alignment and expectation management" were identified as additional key factors. To prevent conflicts, it is essential to ensure that both parties have a shared understanding of objectives, timelines, and deliverables.

The importance of expectation management underscores the broader issue of strategic alignment, where both CMOs and their partners must clearly define and adhere to their shared goals to maintain operational efficiency.

4.2.5 Pricing Pressure

The fifth topic, pricing pressure, came up unexpectedly during the interviews as it was not initially asked in the interview guide. Nevertheless, all participants addressed the topic, underlining its relevance in the current pharmaceutical landscape. Within this theme, three different codes were identified that reflect the challenges and opportunities associated with cost management in the industry.

Participants ID1, ID2 and ID3, who all work in pharmaceutical companies, emphasized the growing need for cost savings. All three noted that the pharmaceutical industry’s “golden age” is over, and an era of increased financial control and tighter cost management has arrived. This shift puts pressure on companies to pursue leaner and more cost-efficient innovation.

All participants except ID1 emphasized the role of CMOs in addressing this pricing pressure. CMOs are seen as key players in enabling cost-effective solutions, as they can innovate within limited budgets. Their operational efficiency, advanced technologies and flexible manufacturing capabilities make them valuable partners in addressing the economic challenges facing the pharmaceutical sector. By outsourcing production and utilizing the expertise of CMOs, pharmaceutical companies can reduce their overhead costs while maintaining their competitive advantage in the market.

4.2.6 Industry Developments

The last theme deals with developments and trends in the CMO sector, with seven codes identified in the analysis. An important topic in all interviews was the role of artificial intelligence. All participants agreed that AI holds significant potential for the industry, with numerous use cases in areas such as drug development, supply chain optimization and personalized medicine. All interviewees also emphasized that AI is still in its infancy, describing it as a "starting position" with limited immediate impact.

Geographically, the discussion focused on the changing dynamics of manufacturing locations. Three out of four participants noted a shift from the US to China due to an increase in manufacturing activity in China. This trend gave rise to critical reflections. The Global Process Engineer questioned whether China's growth is supported by a robust infrastructure or only fueled by government funding. The Business Development Manager noted an additional shift to the Middle East and pointed to a rise in manufacturing facilities in that region.

From a long-term perspective, the Global Process Engineer outlined two significant trends anticipated over the next decade. The first is a focus on high-volume production to address global diseases and respond to sudden surges in demand, as seen during the COVID-19 pandemic. The second trend is a move toward highly specialized production tailored to personalized healthcare solutions. ID4 confirmed these thoughts.

Another significant development identified by ID2 and ID4 is the consolidation of manufacturers. Both participants highlighted a trend toward fewer but larger CMOs dominating the industry. The CMO Consultant elaborated on this trend, explaining that consolidation often occurs for two key reasons: to acquire long-term contracts in a company's pipeline or to gain access to specialized technologies. These insights underline the strategic motives driving mergers and acquisitions within the sector, as larger CMOs seek to expand their capabilities and strengthen their market positions.

4.3 Main Conclusion

The main conclusions of this study are drawn from the previous analysis of the key themes derived from the interviews. This chapter provides answers to the three research questions posed in 1.3, integrating insights from the qualitative findings to address each question separately. Furthermore, the conclusions are critically connected back to the preliminary findings outlined in Section 2.7, ensuring a link between the theoretical framework, secondary research, and empirical results.

4.3.1 Answering RQ1

The role of CMOs in the pharmaceutical industry has evolved significantly, positioning them as critical strategic partners rather than mere service providers. The analysis builds on section 2.7, which highlights CMOs' contribution across various stages of the pharmaceutical product lifecycle. Experts emphasize that CMOs not only facilitate large-scale production but also enable market access for small companies lacking the infrastructure for internal manufacturing. This role helps address the industry's high barriers to entry, supporting smaller players in achieving market participation.

A key finding from the interviews is the flexibility offered by CMOs, which allows pharmaceutical companies to scale production volumes rapidly in response to fluctuating demand. This operational adaptability contrasts with the rigidity of in-house production processes and is particularly valuable in an industry characterized by time-intensive infrastructure development.

For instance, as one participant explained, "if a pharmaceutical company lacks the capacity or the latest technology for quick scaling, the CMO can step in with pre-established infrastructure and advanced tools to bridge the gap." Participants noted that CMOs' access to advanced technologies often places them ahead of pharmaceutical companies, enabling faster production capabilities and maintaining competitive agility.

Moreover, the interviews highlighted CMOs' ability to accelerate market entry, a critical factor in an industry constrained by the finite timelines of patent lifecycles. In the pharmaceutical industry, patents typically provide 20 years of exclusivity from the date of filing, but this period includes the lengthy time required for research, clinical trials, and regulatory approval. As a result, the effective commercial window to maximize returns is often much shorter.

Building new production infrastructure can take years, but CMOs provide a faster alternative. They ensure pharmaceutical companies optimize their market presence during the patent-protected period. This speed-to-market advantage translates into higher profitability and efficient utilization of the patent's economic potential.

Innovation emerged as another defining aspect of CMOs' role. By acting as hubs of knowledge transfer, CMOs integrate expertise from multiple pharmaceutical clients, fostering advancements in manufacturing processes. This collaborative model enables CMOs to drive

technological innovation and deliver specialized production solutions, contributing to the overall progress of pharmaceutical manufacturing.

Ultimately, CMOs have become essential actors within the pharmaceutical industry. Their ability to deliver flexibility, advanced expertise, and accelerated production positions them as strategic partners across the entire product lifecycle. Beyond operational support, CMOs facilitate innovation and market agility, strengthening their role as key contributors to the pharmaceutical value chain's efficiency.

4.3.2 Answering RQ2

The analysis of expert interviews, combined with theoretical insights, reveals several key factors that contribute to successful strategic partnerships. These factors include quality standards, transparent communication, and the alignment of expectations. While the literature presents structured models, such as Applebaum's seven-step framework and Lugo's leaner 5-stage approach, the reality of collaboration is more complex. In practice, there is no rigid step-by-step process for ensuring success. Instead, it requires a continuous balancing act between the parties, where flexibility and adaptability are essential to overcome challenges.

The theoretical models emphasize structure and adaptability, but they often overlook the practical complexities of cross-cultural collaboration, a recurring challenge highlighted in the interviews. Differences in working styles, communication approaches, and cultural expectations are common obstacles that complicate the process. Clear communication, focusing on critical issues rather than exhaustive detail, emerges as an essential factor for maintaining alignment and avoiding misunderstandings.

The expert interviews also emphasized the importance of relationship building in successful partnerships. While quality standards and regulatory compliance remain essential, there is a growing recognition that trust, mutual respect, and alignment of goals are equally crucial. CMOs are increasingly seen not just as service providers but as active partners integral to pharmaceutical companies' strategic objectives. This shift reflects a more dynamic, collaborative approach, where both technical and relational factors must be carefully managed.

Finally, the success of CMO partnerships is not determined by rigid frameworks or standardized procedures. Instead, it relies on a continuous process of managing technical requirements, fostering open communication, and aligning strategic objectives. The real challenge lies in navigating the practical complexities of collaboration, including cultural differences and

expectation management, to ensure long-term success. The theoretical models provide helpful guidance, but they fail to capture the dynamic and evolving nature of these relationships in practice.

4.3.3 Answering RQ3

The CMO industry is facing significant developments driven by pricing pressure, technological advancements, and shifting geographical dynamics. Pharmaceutical companies are under pressure to manage costs, and CMOs are seen as key enablers of cost-effective solutions through innovation and operational efficiency. This shift highlights the growing reliance on CMOs to provide flexible manufacturing solutions while reducing overhead costs.

AI is emerging as a major trend with potential applications in drug development, supply chain optimization, and personalized medicine. While still in its early stages, AI's role is expected to grow, offering the opportunity to optimize production and improve precision in manufacturing.

Geographically, there is a noticeable shift in manufacturing from the US to China, with the Middle East also gaining importance as a hub for pharmaceutical production. This diversification reflects the industry's efforts to balance supply chains and reduce dependency on specific regions.

Long-term trends include a focus on high-volume production to address global health crises and a shift toward specialized production for personalized healthcare. Additionally, the industry is seeing a trend of consolidation, with larger CMOs dominating the market through mergers and acquisitions, driven by the need for technological capabilities and long-term contracts.

In conclusion, the CMO industry is evolving through technological innovation, geographical shifts, and consolidation, all of which will shape the sector's future. CMOs' ability to adapt to these changes will be crucial for maintaining competitiveness in an evolving market.

5 General Discussion

5.1 Academic and Practical Implications

This study provides a comprehensive exploration of the dynamics of strategic partnerships between pharmaceutical companies and Contract Manufacturing Organizations (CMOs), focusing on critical success factors, challenges, and industry developments. By combining theoretical insights with practical findings from expert interviews, the research makes significant contributions to both academic knowledge and industry practices. Specifically, it offers a framework for understanding and improving collaboration models, bridging the gap between theoretical constructs and real-world applications.

The contribution to academic literature is defined as:

- Expanding academic discourse on strategic partnerships in the pharmaceutical industry by critically evaluating existing collaboration models.
- Underscoring the balance between technical factors, such as quality standards and regulatory compliance, and relational elements like trust, alignment, and cultural understanding.
- Highlighting the evolving role of CMOs as strategic partners integrated into the long-term objectives of pharmaceutical companies rather than merely service providers.
- Comparing Applebaum's structured seven-step framework with Lugo's relationship-oriented approach reveals a gap in practice due to the absence of definitive, step-by-step guidelines in real-world partnerships.

Building on the academic contributions, the practical implications are:

- Emphasizing the importance of transparent and proactive communication, expectation management, and aligning strategic goals for successful partnerships.
- Highlighting the need for a flexible, relationship-oriented approach to address challenges such as cultural differences and pricing pressures.
- The findings stress that outsourcing to CMOs can reduce overhead costs and improve operational efficiency for pharmaceutical companies, if partners are carefully selected, and trust and collaboration are actively fostered.
- For CMOs, the study underscores the necessity of positioning themselves as strategic partners by demonstrating their ability to innovate, manage costs effectively, and align with their clients' long-term goals.

Additionally, the study addresses broader industry trends, such as the adoption of artificial intelligence, geographical shifts in manufacturing, and market consolidation. These findings offer actionable insights into operational and strategic adjustments required to navigate these developments, strengthening the competitive positions of both pharmaceutical companies and CMOs in the evolving global healthcare landscape.

5.2 Limitations and Future Research

While this study provides valuable insights into the dynamics of partnerships between pharmaceutical companies and CMOs, several limitations must be acknowledged. First, the research has only scratched the surface of how CMOs are integrated into the broader pharmaceutical landscape. A deeper investigation is necessary to fully capture the complexities of these partnerships, particularly in relation to their strategic and operational roles.

Data limitations posed a significant challenge, as reliable information on specific aspects of the industry, such as precise cost metrics on services or long-term performance outcomes, was unavailable.

It is acknowledged that another limitation is the size of expert interviews, which may not fully represent the diversity of perspectives within the industry. Significant effort was made to secure as many expert interviews as possible. A broader range of interviews encompassing different geographical regions and organizational levels would enhance the generalizability of the findings.

Additionally, the interview data is subjective, as participants' perspectives were shaped by their individual experiences and the organizational contexts. While this subjectivity provides valuable real-world insights, it also introduces potential bias.

Finally, the study's exploration of future market developments relied on hypothetical predictions and remains uncertain due to the evolving nature of the pharmaceutical sector. Also, the individual impact of specific trends is not defined.

Future studies could build on this research by conducting larger-scale, longitudinal analyses to examine the long-term impact of CMO collaborations on pharmaceutical companies' performance and innovation. Expanding the scope to include perspectives from smaller, emerging CMOs as well as additional regions such as Asia, Africa and Latin America could provide a more comprehensive view of the global industry.

Another promising idea for research is the application of artificial intelligence and digitalization within CMO partnerships. Investigating how these technologies influence production efficiency, communication, and strategic alignment would provide valuable insights into their potential to reshape the industry.

Coming to an end, further exploration into the cultural and relational dimensions of these partnerships could help develop practical frameworks for managing cross-cultural challenges and fostering trust. By addressing these areas, future research can provide additional actionable recommendations for optimizing collaboration and advancing the strategic integration of CMOs into the pharmaceutical value chain.

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Appendices

Appendix 1 – Interview Guide

Part 1*: Introduction and profile*

- Could you briefly describe the main business of your company?
- What are the primary products or services your company offers?
- What is your role and your responsibilities within the organization?
- How does your organization typically collaborate with CMOs?

Part 2*: Research Question 1: CMO's industry role*

- How do you see the role of CMOs in the pharmaceutical industry? Contribution to success?
- What are the main advantages for pharmaceutical companies in partnering with CMOs?
- Are there any challenges or limitations you have observed in the role of CMOs?
- Could you provide an example of how a CMO has significantly impacted a pharmaceutical project or strategy?

Part 3*: Research Question 2: Factors for strategic partnerships*

- In your experience, what are the critical factors that ensure a successful partnership between CMOs and pharmaceutical companies?
- Can you describe a specific instance where a strategic partnership with a CMO was particularly successful? What made it so?
- What do you consider to be the main barriers to forming strong partnerships?

Part 4*: Research Question 3: Industry outlook & developments*

- What are the most relevant developments/ trends shaping the CMO industry?
- What technological advancements/ innovations have had the greatest impact lately?
- How do you see the CMO industry developing over the next five to ten years?
- Are there any regulatory or market changes that you believe will significantly influence the CMO industry in the future?

Part 5*: Rounding off*

- Is there anything else you would like to add that we haven't covered in this discussion?
- Can you suggest a colleague who would be suitable for the study?

Appendix 2 – Excerpts from the Interview Transcripts

Excerpt ID1 – Senior Business Development Manager

6:27 Interviewer:

Since my thesis is focusing on the pharma industry and also the role of CMOS, how they how they work together. So in your opinion, from your experience, how do you see the CMO role? Do you think it's important?

7:01 Interviewee:

Definitely. Over the past 10-12 years that I've been in the industry, I've observed significant changes. These changes have compelled CMOs to differentiate themselves, adopt new technologies, and address evolving challenges. The world is changing rapidly, and CMOs are adapting to these shifts.

For instance, we've seen much of the volume-based manufacturing migrate to Chinese and Indian manufacturers. Meanwhile, companies in Europe and the United States are increasingly focusing on specialized, differentiated technologies. Examples include advancements in genetic technologies, such as CAR-T therapy, long-acting injectables, and mRNA technology, which gained prominence during the COVID-19 pandemic. Another key development is continuous manufacturing, which is now gaining significant traction, particularly with leadership from organizations like the FDA and EMA.

These CMOs often manufacture both for themselves and for others, but they understand the necessity of specialization to stand out. Without differentiation, they risk becoming just another manufacturer of standard products, competing solely on price. And given the intense price pressures in the market, technological differentiation is no longer optional, it's essential for survival and recognition.

14:24 Interviewer:

So you are clearly seeing a shift toward more specialty manufacturing and innovation-driven strategies within the CMO space. CMOs are recognizing that competing solely on price is no longer sufficient, they need to differentiate themselves by offering unique and specialized solutions, do you have an example at hand?

14:45 Interviewee:

Let us say a major Canadian company, traditionally focused on manufacturing standard products, has recently expanded its portfolio to include differentiated offerings, such as long-acting injectables targeting neurological conditions and vitamins. Notably, they are not developing or manufacturing these products independently. Instead, they rely on a CMO specializing in these advanced technologies to both develop and manufacture the products for them.

This particular CMO operates purely as a service provider for third parties, rather than developing its own products. Without such partnerships, the Canadian company would likely not have access to these specialized technologies. This illustrates the critical role CMOs play in bridging gaps in capability and providing access to cutting-edge solutions. They also enable clients to enter the market competitively by aggregating expertise and offering cost-effective solutions.

19:16 Interviewer:

Sounds interesting, let us imagine now you are starting a new relationship with a CMO, when building this relationship, in your opinion, what is most important?

19:43 Interviewee:

That's a tricky question because things have evolved significantly over the years. One constant in all collaborations and in the way we operate is that quality remains paramount, t's non-negotiable. Quality is always a 'yes or yes' discussion.

The second critical aspect is supply chain reliability. In recent years, supply chains have faced substantial disruptions, such as shortages of APIs, excipients, and other materials. The situation is further complicated by the increasing technological complexity of products, such as pre-filled syringes and auto-injectors. It's no longer just about sourcing APIs and excipients; now, we also have to consider the components of the devices used to deliver the products. With more players entering the market, the supply chain has struggled to adapt to these new demands, creating significant challenges for buyers.

For example, in our case, we often participate in public tenders. If we fail to deliver due to supply chain disruptions, the consequences can be severe. In some countries, particularly in Latin America, failure to deliver can result in heavy penalties, including being blacklisted. While we sometimes negotiate with suppliers to address these issues, highlighting their role in the problem and working toward a solution this remains a recurring challenge.

The third key factor is flexibility. Markets are constantly changing. Today, a particular product might be highly significant and heavily promoted, but tomorrow, an innovative competitor could shift the market entirely, reducing volumes and altering demand dynamics. In such scenarios, flexibility becomes crucial to adapt to these changes and address market needs effectively.

In summary, the three most relevant factors are quality, supply chain reliability, and flexibility. Each is critical to managing the complexities of the modern pharmaceutical landscape.

27:39 Interviewer:

Let's assume problems are appearing in the partnership and a CMO can no deliver as you have it on contract, then what?

28:59 Interviewee:

There are multiple consequences when these issues arise. Contractually, we have mechanisms to address such situations. For instance, if the fault lies entirely with the supplier, they are liable to assume certain responsibilities, while challenges persist. As mentioned, these can include financial penalties and repercussions for future tenders.

If we fail to deliver on a tender, it doesn't just affect the current contract it impacts our standing in future opportunities. For the next tender, instead of starting on equal footing, we begin at a disadvantage, essentially starting from a negative position. This creates significant challenges in maintaining our competitiveness.

Another crucial consideration when selecting a CMO is price. The pharmaceutical market is under immense pressure globally, including in Europe, Latin America, Southeast Asia, and even the U.S., which was traditionally seen as a highly lucrative market. The dynamics have shifted; pharma is no longer the business where profits flowed effortlessly. While it remains an attractive industry, the need to consider cost has become increasingly critical in this evolving landscape

36:31 Interviewer:

And when we were talking about industry developments, in your opinion, do you see other major impacts shaping the industry in the upcoming 5-10 years? We were talking about price pressure, do you see other developments?

37:12 Interviewee:

Today, one of the key developments we cannot overlook is artificial intelligence. We are now discussing innovations like 3D-printed drugs and AI-driven drug development, where a multitude of molecules can be analyzed and narrowed down to identify one or two strong candidates for developing innovative medicines. This technology has the potential to transform the pharmaceutical market. A significant question remains: how will regulatory agencies address these advancements? There's considerable responsibility associated with using AI, yet the mechanisms behind it are not fully understood, raising many unresolved questions.

In terms of adoption, I see two main groups leading the way. Firstly, large innovator companies are investing in AI to explore its potential applications. Secondly, there are smaller, early-adopter companies, often startups, experimenting with how they can capitalize on this emerging technology. From my perspective, as someone working for a mid-sized, relatively conservative company, the direct impact of AI on the industry still feels minimal. While it is a common topic of conversation within business circles, there aren't yet many tangible, material outcomes directly attributed to AI.

One application of AI that is being discussed though not specifically within CMOs is software tools that help companies identify products of interest in particular territories based on a predefined wish list. For instance, these tools might work effectively in established markets like Europe and the U.S. but often struggle to address the complexities of regions like Latin America. While promising, these applications are still in their early stages, and much of their potential remains to be realized.

Excerpt ID2 – Global Process Engineer

11:02 Interviewer:

After mentioning your current responsibilities, you mentioned you are also visiting CMOs on a regular basis, overall, in your team, would you say the work with CMOs increased or decreased in the past years?

12:08 Interviewee:

Our general strategy is as follows: we start with small-scale development, and as the product grows, it typically moves to one of our internal sites. Currently, we have three drug product manufacturing sites. These are our three main DP sites at the moment. This might change in the future as we aim to build and retain expertise within the company.

As a product progresses through its lifecycle, the later it is in the lifecycle, the higher the likelihood that production will be transferred to a CMO. Our strategy is that once we stop producing a product internally or it's no longer a priority for our market, it should be handled by a CMO. This approach helps us manage internal capacity fluctuations and provides greater flexibility, especially since volumes typically decrease toward the end of a product's lifecycle.

That said, our decision always depends on our internal capacity and infrastructure. For example, if a new product comes along, we assess whether we have the necessary facilities to produce it in-house. If not, we might directly outsource production to a CMO. Similarly, if older production lines are no longer suitable for new products, they may continue to handle older products for longer, delaying the transition to a CMO. In essence, the transfer to a CMO usually occurs later in the product's lifecycle. As for whether this trend will increase or decrease over time it really depends on these factors.

16:53 Interviewer:

So I mean it is quite individual isn't it? Anything to add?

17:33 Interviewee:

In recent years, there have been several developments that point toward significant changes in the industry. For example, with the impact of COVID-19 and the recent hype around weight-loss injectables like those from Novo Nordisk and Eli Lilly, we're seeing new dynamics. Novo Nordisk, for instance, even acquired a CMO to secure production capacity. This highlights how, when volumes increase dramatically, internal manufacturing might not be sufficient, making CMOs critical in such scenarios.

When we talk specifically about these new weight-loss injectables, they involve a different technology. Typically, we work with biologics that are frozen, thaw them at our site, and then fill them. Sometimes, we mix components, but these are generally liquids. Products like these often come in powdered form, requiring additional steps like reconstitution with water. This

shift introduces technological requirements that may not exist internally. When there's a need for rapid production of a new product using unfamiliar technology, it's almost impossible to manage internally, especially in the pharmaceutical sector. Building, qualifying, and gaining regulatory approval for a new production line can take three to four years a timeline that risks losing significant revenue due to patent and market constraints.

In such cases, CMOs that are better prepared or have already built capacity for specific products or technologies become the preferred option. For instance, a CMO working with Novo Nordisk or Eli Lilly may already have the necessary capacity and expertise, allowing quicker market entry compared to building in-house capabilities. CMOs may even possess greater know-how about the product and production processes, offering a competitive advantage.

The variety of technologies has also expanded significantly over the years. When I started working, the focus was largely on solids like tablets and antibodies. Today, the landscape includes innovations like radioligands radioactive compounds bound to antibodies which require completely different facilities, cell therapies involving personalized medicine for individual patients, and much more. With such diversification, it's increasingly difficult for pharmaceutical companies to have the equipment and facilities to handle every new technology.

This challenge is compounded by cost and risk. For instance, companies must prepare for production as early as Phase II of clinical trials, but the likelihood of a drug reaching the market is still relatively low. Investing heavily in new facilities for every candidate is unsustainable and carries a high risk of financial loss if the product doesn't succeed. Therefore, these specialized technologies and their associated challenges often make it more practical to turn to CMOs, sometimes even from the very beginning of the process.

24:10 Interviewer:

Considering you mentioned the key advantages namely flexibility and speed to market, anything else you would like to add here?

24:38 Interviewee:

When you need capacity quickly, it's often challenging to manage internally because most production lines are fully utilized. Idle machines represent tied-up capital that generates no value, so companies aim to minimize downtime. As a result, we rarely have free or flexible capacity available. While planned capacity can be organized internally, unplanned needs are much harder to address, which is where external options like CMOs come in.

Another factor is the evolving economic environment in the pharmaceutical industry. When I started in pharma, it was during the so-called golden years. Back then, there were blockbuster drugs generating billions of dollars in revenue, even if they were approaching the end of their patent lifecycles. You could feel that there was plenty of money to invest. Today the situation has changed. At these companies, many of the largest blockbusters have since lost patent protection, and cost considerations now play a much bigger role.

Whenever a new product is launched, a sourcing process is conducted to evaluate where and how it can be manufactured. This involves not just technical and logistical considerations but also cost. CMOs are often cheaper, at least on paper, compared to in-house production costs per unit.

That said, whether CMOs are genuinely more cost-effective depends on how you calculate and compare costs. For example, internal production costs often include significant overhead and resource expenses, whereas these might not be fully accounted for in the price per unit from a CMO. So, while CMOs might appear cheaper initially, the comparison isn't always straightforward or one-to-one. It depends on the specifics of how the costs are calculated and what's included in the analysis.

28:41 Interviewer:

Ok so on the first view, but you need to consider the whole picture.

28:53 Interviewee:

Yes, exactly. And this is also why we tend to outsource production toward the end of a product's lifecycle. At that stage, competition typically emerges, whether from other companies producing biosimilars or generics.

This naturally creates cost pressure, and we try to address this by seeking more cost-effective production options, often through outsourcing.

35:02 Interviewer:

Lets move on, we covered the first to parts mainly, what would you say are the biggest challenges when it comes to working with a CMO?

35:21 Interviewee:

For us it is about quality, this is actually one of the biggest challenges, I would say. Every company has its own quality standards. I would say that we are a company with high to very high standards, and we often have higher standards than some CMOs. The question then becomes: Can they meet our standard or not? If not, we need to evaluate whether we can accept it or not. These are the discussions we have when there are significant differences in standards.

At times, CMOs also violate basic regulations, like Annex I in Europe, which is our most important regulatory document. If they breach it, we must decide how to handle it. Can we accept it or not? These are major issues.

Transparency is another critical factor. We've experienced situations where CMOs were not transparent. For instance, when they only mention problems right before the product release when we urgently need the product and say, 'By the way, we had this issue.' This puts us in a difficult position where we have to decide whether to accept the issue and still release the product or not.

This timing pressure puts us in a tough spot. If they had told us a month earlier, we could have made a more informed decision. But with the tight deadlines, especially for products closely tied to supply, it really creates a lot of pressure.

39:33 Interviewer:

Does this happen on a regular basis?

39:41 Interviewee:

I would say this is very individual for each CMO. There are some CMOs that are very proactive; they communicate everything to us, always seeking our approval early on, and they are very customer-oriented. Then there are other CMOs that are the complete opposite. In those cases, it tends to be more systematic.

It happens repeatedly, and I would say that, in some instances, this is politically motivated. It's not necessarily the employees but more of a company-wide approach, where the premise seems to be to solve as much internally as possible and only share the essential information with us.

42:12 Interviewer:

That is a good transition for the next part, here I would like to talk a bit about partnering up, you mentioned you would welcome communication and transparency, and critical things to be communicated as soon as possible, is that correct?

43:29 Interviewee:

I mean, it obviously depends. Production is incredibly complex, and there are many details that can be shared. We don’t want to know every single detail, but we do want to be informed about the critical things. Specifically, those things that impact approvals or are relevant for transfers. For example, if we have a major issue on the production line, and they don’t tell us about it, but we only find out later during the transfer process, it can be extremely frustrating. It wastes a lot of time at a point when we have timelines to meet and want to complete the transfer as quickly as possible.

47:02 Interviewer:

Ok, talking about partnerships, could you give an example of a very positive partnership and what made it so?

47:49 Interviewee:

I think I’ve already covered most of the points. But I do have an example, and these companies are really very proactive. They address issues early, anticipating problems. One thing is that we demand certain things, saying 'this is needed,' but they usually come back with 'yes, but we foresee this and that problem.' This obviously saves us a lot of trouble later on. When we are in production, they are very transparent, communicating problems early. They are also quite transparent with pricing and invoices, letting us know well in advance, so we don’t get hit with the bill unexpectedly.

Also, in general, it's not cheap, but it's transparent. That's something important to note. Essentially, there is a price per unit, but for projects, they also charge extra. Right now, we are relatively dependent on these CMOs because switching a CMO would cost us four to five years. So they know very well that if we want to carry out a project with them, we pretty much have to do it with them. And that gives them the leverage to set project prices, which sometimes seem outrageous. This might also be a general issue in pharma because the mindset is still there: Big Pharma has money, right?

51:35 Interviewer:

Ok, all right, moving on to the last part, we already touched upon industry developments, anything from your side you would like to add? What are the key trends you are witnessing?

52:31 Interviewee:

So, there's a clear specialization in certain areas. Also, I would say without being able to fully prove it that there's a certain consolidation happening. There are now very large CMOs, such as Vetter, who are expanding a lot, and we've noticed a lot of activity with Catalent and, I don't know, these US companies that also produce for Novo Nordisk and others. Thermo Fisher is also buying up a lot. Right now, in Switzerland, Thermo has taken over quite a bit, especially from the large Big Pharma companies that no longer wanted them, so they were sold off.

I have the feeling that these companies are expanding quite strongly, particularly the big ones, who are doing acquisitions. It's hard to generalize, but I've observed that, for example, Lonza is building a huge new filling facility. Then, I know that Thermo Fisher bought the facility from CSL and is now using it for contract manufacturing. So, I would say they're focusing on expanding their internal resources by strategically making acquisitions.

In Copenhagen, I believe Thermo or Fuji bought something as well. All in all, I would say that Pharma companies are sometimes reducing their resources or refocusing, and these buildings are often taken over by CMOs. I have the feeling they're expanding their capacities. As for acquiring smaller companies, I can't really speak to that because I don't know many small ones and don't collaborate with them.

So, I would say this trend will continue. There are two poles, in my view. On one hand, you have these huge-volume products like weight-loss injections, Covid vaccines, or maybe in the future, something for Alzheimer's or Parkinson's. These will be massive volumes that companies will have to handle, and that's where capacity expansion is crucial. On the other hand, there's a market for very small products, and this market is becoming more and more personalized. That means we'll have smaller-volume products, and often these involve technologies that pharma companies don't have, so they'll be outsourced to CMOs.

Excerpt ID3 – Global Supply Chain Planner

4:50 Interviewer:

Since my topic focuses on scrutinizing the role and impact of CMOs in the pharmaceutical industry, we're now moving to the second part of our discussion. You've had experience in your current role as well as in your previous role working with CMOs. From your perspective, how do you see the role of CMOs in the industry? Would you say they play an important role? Do they drive innovation?

5:39 Interviewee:

Yes, I believe CMOs play a very important role in the pharmaceutical industry, and they contribute to innovation in two key ways.

First, outsourcing production allows companies to concentrate on their core competencies primarily research. For instance, we have always been research-focused as that's how the company originally established itself. By relying on CMOs for manufacturing, these companies can channel their resources and expertise into developing new medicines and advancing scientific discovery.

Second, CMOs specialize in manufacturing, and their expertise enables them to continuously optimize and innovate in production processes. They are often motivated to adopt the most efficient and advanced technologies to stay competitive and improve their operations. This specialization ensures that the manufacturing side benefits from state-of-the-art processes, ultimately driving innovation in how medicines are produced. So, I'd say CMOs support innovation by freeing pharmaceutical companies to focus on research while simultaneously advancing manufacturing processes.

8:30 Interviewer:

How much are you in touch with externals, and do you encounter challenges or limitations when collaborating with CMOs?

9:02 Interviewee:

I am in touch with CMOs depending on the demand and supply situation sometimes almost daily. During periods when everything runs smoothly, communication might occur less frequently, perhaps once a week or even less. In urgent situations, daily communication is required, primarily via email, with occasional calls for time-sensitive matters. Regular meetings with suppliers are crucial, and in my opinion, there should be at least one meeting per month as a baseline. Depending on the situation or demand fluctuations, more frequent meetings weekly or biweekly may be necessary.

One significant challenge I have observed is cultural differences. I collaborate with two CMOs within the EU, where minor differences exist, but these are manageable. Working with a CMO based in Eastern Asia highlights stark contrasts in culture, communication styles, and ways of

working. These differences can lead to misunderstandings and present barriers to effective collaboration.

15:14 Interviewer:

We'll be discussing strategic partnerships, which are quite common in the industry today. Regarding the partnerships you have with CMOs, what makes them successful?

15:49 Interviewee:

For me, a good partnership is based on transparency. One of the main challenges we face is balancing the significant fluctuations in both demand and supply over time. Achieving this balance requires a high degree of transparency, which can be difficult to ensure when working with external suppliers.

Since we rely on information provided by the CMOs whether through calls or emails we lack direct visibility into their IT systems or processes. This reliance makes the accuracy and openness of their communication critical. Ensuring good visibility and transparency is, therefore, a key factor in building a successful partnership. Additionally, effective communication plays a crucial role in maintaining strong and reliable collaborations with CMOs.

23:02 Interviewer:

From your industry perspective, are you seeing similar trends or any notable changes shaping the CMO sector?

24:13 Interviewee:

Well, I'm not particularly aware of significant merger activities, but there are other notable trends. One key focus in the industry is on cost efficiency, which applies to both internal and external processes. CMOs are increasingly prioritizing the adoption of new technologies and automation to enhance efficiency. This shift is especially relevant given the labor shortage in Europe and much of the Western world. Automation isn't about replacing labor but about improving productivity in the face of these challenges.

Another significant trend is digitalization. CMOs are focusing on digitalizing their processes to ensure they can manufacture pharmaceutical products, be it drug products, diagnostic instruments, or devices in the most cost-efficient way. Digitalization is becoming essential for staying competitive in the industry.

36:33 Interviewer:

With all the current discussions around AI, are you seeing any touchpoints with artificial intelligence in your industry?

37:50 Interviewee:

Let me think. In terms of manufacturing, I can't pinpoint any concrete examples of AI applications yet it might still be too early. AI is a rapidly growing technology, but it doesn't seem to have one specific, fully established application in this space at the moment.

I see potential in areas like demand forecasting. AI could be used to improve projections and create more stable demand and supply forecasts. Beyond that, AI could help streamline day-to-day activities for demand planners, global planners, manufacturing planners, and other supply chain personnel. Its primary value might lie in making these processes faster and more efficient while increasing overall productivity.

Excerpt ID4 – Founder CMO Consultancy

9:26 Interviewer:

Let's move on to the second part now. You've worked in the pharmaceutical industry and are now engaging with CMOs as well as the space in between. How would you generally describe the role of CMOs in the industry?

10:08 Interviewee:

I believe the trend is that the CMO business will continue to strengthen and grow in the long term. That's my overall impression, and it's primarily driven by two factors: speed and flexibility.

This is what makes CMOs successful because, in the end, anyone can build facilities. The real question is how quickly, how efficiently, and how well you can do it and whether you even want to operate those facilities yourself in the long term.

Take Lonza as an example. They are experts at setting up, qualifying, and getting facilities ready for use. Even with their expertise, it can take two to three years to complete a facility. If you're starting from scratch without that knowledge, it might take five to six years to build, qualify, and make a facility operational.

The driver here isn't necessarily cost but rather how long a customer can keep their drug on the market as a monopoly before generics enter. Patents usually last about 15 years, starting from when they're filed, often after the first clinical trial. Once the patent is filed, the clock starts ticking.

Every month or year you can extend your exclusivity and sell your product without competition from generics represents a multi-million-dollar business. That's why speed and readiness are so critical it's all about maximizing the patent-protected time to capitalize on your investment

15:12 Interviewer:

Perhaps as a follow-up to the previous discussion about CMOs and CDMOs, where do you see the greatest challenges in this area? In collaborating?

16:31 Interviewee:

In the pharmaceutical industry, challenges are inherent, whether you produce in-house or outsource. For example, even with CMOs that specialize in contract manufacturing, the core challenges around quality, GMP compliance, and regulatory requirements remain constant.

Especially in the pharmaceutical sector, the increasing complexity of regulatory requirements is a continuous hurdle. For CMOs, their selling points often include highly automated, fully integrated, and digitalized systems. But all these advanced systems must be qualified and validated, which can be a significant challenge.

Nowadays, with more IT and digital components being introduced in pharma processes, everything must meet strict qualifications. These digital systems must comply with evolving regulations, and oftentimes, the expertise or established processes to manage them effectively are still lacking in certain areas.

This creates a delicate balancing act for CMOs. On one hand, they must rigorously meet regulatory standards, which are frequently updated, particularly in the area of digitalization. On the other hand, they face immense time pressure due to pipeline demands or contracts with customers, where they commit to having facilities operational within a specific timeframe often two years.

During this time, they must also ensure that their systems meet the inspection and approval standards of regulatory bodies like Swissmedic or the FDA. It's a tricky balance to strike between adhering to stringent quality and compliance requirements and meeting tight deadlines.

That said, while compliance and quality are undoubtedly challenges, they are also well-known and expected obstacles in the pharmaceutical industry, whether you're a CMO or operating in-house.

21:46 Interviewer:

While talking to other interviewees, often an argument was that pharmaceutical companies maintain a very high standard of quality. How can it be ensured that the same level of quality is upheld at the CMO level?

22:09 Interviewee:

That's a critical point. As I mentioned before, if the facility doesn't even obtain a license be it from the EMA, FDA or Swissmedic then production cannot proceed. This is particularly relevant in cases where facilities are located in third countries, like India or China, where quality standards may not yet align with those in Europe.

In such cases, everything gets delayed. Sure, it might be cheaper, but at the end of the day, production can't start until the processes and the facility receive the necessary licensing. That's

also why companies like Lonza, Siegfried, or Bachem succeed they operate within Switzerland, where they can meet these high regulatory standards.

Quality is always a key factor. Customers ultimately care most about whether production is viable and licensed. As long as the facility meets these requirements and operations run smoothly, the specifics of quality beyond this benchmark become less of a concern for clients.

But it's not just about regulatory compliance. Operational quality also plays a massive role, especially in areas like fermentation, which involves lengthy, complex, and costly processes. Each batch can be worth millions, so ensuring that processes work reliably achieving, for example, a 90% success rate, is critical.

In essence, there are two major quality challenges: Regulatory compliance, ensuring the facility and processes meet all qualifications and standards to obtain licensing. And second operational quality, making sure the production processes themselves function as intended, particularly with the growing complexity of biological processes that are highly sensitive and time intensive. Mistakes in these areas can be incredibly costly, given the complexity and value of modern production processes.

27:22 Interviewer:

Let's touch on collaboration specifically. What I've often heard from the pharma side is that transparency is crucial. For instance, if anything deviates or doesn't go as planned, pharma companies value immediate communication. How would you rank the critical success factors for collaboration?

28:01 Interviewee:

I think this is less about us within the CMO but more about the CMO's relationship with a customer if I understand correctly. And that's always a balancing act, how much do you communicate, and how much do you hold back?

It's also about how issues are presented, whether it's about non-compliance, problems, or anything else. There are different philosophies here, and it heavily depends on the client's background. A customer from Japan, China, the USA, or Europe will each have a unique approach, and understanding these cultural nuances is essential.

This is where the role of a program manager, or a client partner, becomes critical. They must decide how much to reveal, how transparent to be. It's more a matter of philosophy than right or wrong. This balancing act revolves around trust and risk management, which makes it more about relationship building than following a fixed standard.

32:49 Interviewer:

Would you say there's no concrete handbook for this, and it's more case by case depending on the customer?

33:20 Interviewee:

Yes, I think it's always based on reciprocity. For instance, as a program manager or client partner, the more a customer is transparent with me, be it about budgets, payments, future orders, competition, or their plans to build their own facility, the more aligned we can be. Discussions range from qualification of facilities, production schedules, supply chain considerations, and raw material availability to reserving production capacities.

It's really a bit of a 'game,' so to speak, that's rooted in trust. And the degree of transparency often shapes the dynamics of the relationship.

To go back to another point you touched on earlier, advantages of pharma companies working with CMOs, one thing that shouldn't be overlooked is the role of startups. Unlike big pharma, startups often develop new drugs, have completed Phase 1 clinical trials, secured promising results, and received investment. But they lack production facilities entirely. For these companies, working with a CMO is essential.

It's also a form of risk management. Startups often choose not to build their own facilities early on because they're unsure whether their product will survive all clinical phases. Collaborating with a CMO allows them to remain flexible and avoid heavy capital expenditures on building a facility, even though it's more expensive in the short term.

This is a major use case. Small to medium sized companies with high risk drugs still need regulatory compliant production for Phases 2 and 3. I think it's important to highlight this perspective, especially if most of your interviews so far have focused on pharma companies. It's a reminder of the diverse needs within the industry.

39:41 Interviewer:

Would you say you're seeing trends in the market where larger CMOs are consolidating their positions by acquiring smaller companies or facilities?

40:04 Interviewee:

Yes, but it's happening to a minimal extent. For example, Lonza has acquired capsule production capabilities, which wasn't about acquiring other CMOs but rather expanding their value chain into new technologies. Traditionally, Lonza has focused on manufacturing APIs, but now they've also moved into areas like liquid filling, which they previously didn't cover. By acquiring capsule manufacturing capabilities, they added a new dimension to their offerings.

In contrast, what Lonza has done more frequently is to purchase production sites from companies like Novartis or Roche. For example, they've acquired facilities in Stein and Visp, as well as a site in the U.S., where I believe they recently bought a Roche facility. Lonza currently has very full order books and significant CAPEX budgets, which enables them to invest heavily in acquiring facilities rather than smaller CMOs.

On the other hand, there are examples of CMO consolidation in the market. For instance, in Visp, there used to be a smaller fill and finish facility called Swissfillon, which was acquired by another CMO. Such acquisitions typically happen for two reasons. First, the smaller

company might have attractive customer contracts, and second, it offers a quicker way to expand capacity. A third reason could be to acquire specific technologies or expertise that align with the buyer's business model, as was the case with Lonza's move into capsule manufacturing.

43:24 Interviewer:

Do you currently see any particular technologies emerging in the industry that are likely to dominate the market in the coming years?

43:50 Interviewee:

Yes, this is closely linked to the unique selling points of CMOs and how they differentiate themselves in such a competitive market. It is not just about reliable production for customers anymore, it is about providing added value.

One significant trend is the rise of digitalization, smart manufacturing, and AI. CMOs are now generating vast amounts of data from their production processes, and this data allows them to make informed decisions and provide strong performance metrics to their clients. But more importantly, it enables them to offer process optimizations.

Typically, when a customer approaches a CMO, they bring their process and say, 'Here is the recipe, produce this product for us.' A CMO then takes on the tech transfer, implements the process, and starts production. By leveraging these new technologies, CMOs can go a step further, they might identify ways to improve the process, making it more efficient, cost effective, or scalable for the client.

This ability to combine production with process innovation is becoming a key differentiator. Smart manufacturing allows CMOs to optimize processes, improve yields, reduce costs, and offer greater flexibility. I think this trend will continue to shape the market and could be one of the defining factors of the industry's future.

47:39 Interviewer:

Do you think the industry is moving in a direction where CMOs could also act as service providers or consultants, using their expertise to benefit their customers?

48:03 Interviewee:

Yes, exactly, though more on a process-oriented level. This is particularly relevant in the interaction between the CMO and the customer. For CMOs themselves, it is about how they can become more efficient. Take Lonza, for example while they are highly effective in delivering within tight deadlines and adhering to compliance, the processes are often very inefficient. This inefficiency is somewhat tolerated because of the high margins in the pharmaceutical industry. As long as projects are completed on time, cost considerations often take a back seat.

There is increasing focus on improving efficiency. This includes qualifying equipment more quickly, creating modular systems, and reusing existing solutions to avoid starting from scratch. Companies like Roche or Novartis, as well as Lonza, are heavily involved in discussions about outsourcing to save costs. For instance, this could involve reducing reliance on internal resources by leveraging external services or tapping into global resources, such as staff or services in India.

This trend of optimizing processes is slowly making its way into CMOs as well. Though much of the work is still done on-site with a focus on reliability, there is growing interest in innovative solutions like augmented reality or virtual reality tools. These technologies enable remote expert support and training, making operations more flexible and efficient.

Another critical development is the shift from paper-based processes to electronic systems, which ties into the broader themes of digitalization and automation. This involves digitizing everything from batch records to protocols and qualification documents, ultimately streamlining workflows and reducing inefficiencies.

52:55 Interviewer:

I have read about an increasing collaboration with CMOs from the Middle East, as more companies are emerging there, often supported by government funding. Have you observed this or formed an opinion on it?

53:29 Interviewee:

Not here, of course, not in Switzerland or anywhere nearby, but I can definitely imagine it, especially with China and similar regions. They are clearly aiming to catch up and integrate themselves more into the global value chain.

In Europe, I do not think this is a major trend. For instance, there was an initiative in Spain to establish a government-funded chip manufacturing factory, but these kinds of projects have not really taken off in Europe because the environment here is already attractive enough for companies to invest.

I do think it is plausible that Chinese or Middle Eastern companies, which are often partially funded by their governments, are pursuing such strategies. It seems to be a way of strengthening their standing in the global market and advancing their capabilities.

55:40 Interviewer:

Yes, and in principle, if the quality, pricing, and regulatory standards in these countries were on par with ours, then essentially there would be nothing stopping big pharma from producing there. But until then, there is still a long way to go.

56:08 Interviewee:

Absolutely. As mentioned, the processes are becoming increasingly complex. It is true that for simpler industries like chemicals or food, production can often be outsourced easily to other

locations. But when it comes to high-end pharmaceutical products, the stakes are entirely different.

The main driver here is the value per batch. For high-end pharma products, a single batch can be worth millions. If a batch is ruined, the losses are enormous. This is why it often makes more sense to accept slightly higher production costs in exchange for ensuring reliability and minimizing the risk of failure.

The cost of failure is a critical factor. It is not just about how much it costs to produce the product but also the financial impact of mistakes. For high-value products, this consideration is decisive.