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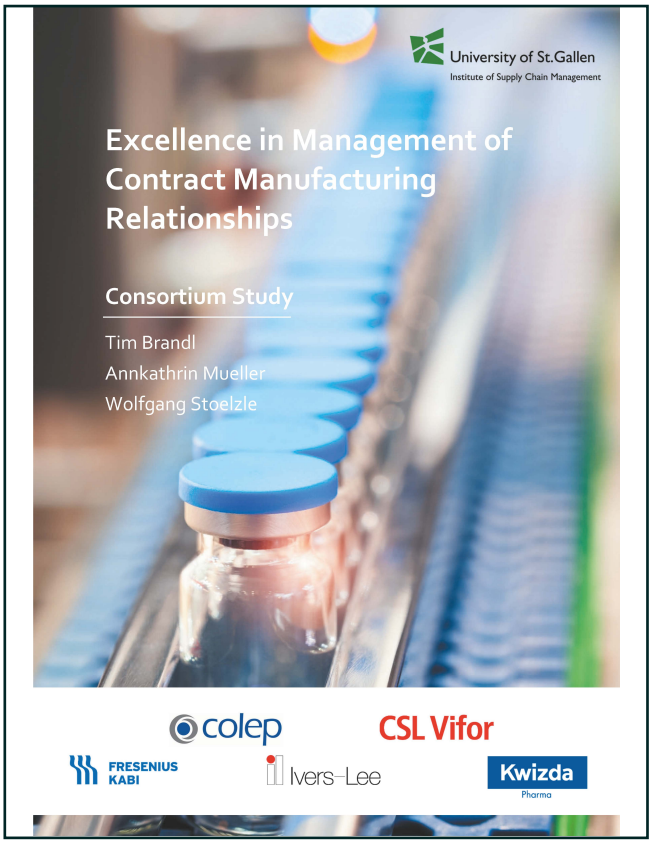
Excellence in Management of Contract Manufacturing Relationships



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Introduction

Since contract manufacturing gained popularity in the second half of the 20th century, the cooperation between pharmaceutical companies and contract manufacturing organizations (CMOs) has developed significantly. Initially characterized by an arms-length mentality, contract manufacturing relationships (CMRs) have become integral to pharmaceutical companies' supply chains. Thus, pharmaceutical companies and CMOs, move toward a more substantial alignment of business strategies and expectations to achieve mutual benefit. This study takes a two-sided approach, including the client company and CMO perspective, to identify relevant issues, success factors, and appropriate practices for excellent CMR management.

Relevance and Motivation

When contract manufacturing was introduced in the pharmaceutical industry about three decades ago, CMOs primarily operated as extended workbenches, producing clients' products invisible to the end consumer. Fittingly, the Los Angeles Times called this type of production «stealth manufacturing» in 1999 (Peltz, 1999). CMOs had little strategic relevance to pharmaceutical companies at the time, and the relationships were typically opportunistic.

The industry has proliferated, and the CMOs have become more specialized and professional. At the same time, the costs for pharmaceutical research and development have increased significantly. By cooperating with CMOs, pharmaceutical companies can expand their production capacities flexibly and cost-efficiently, allowing them to utilize their resources for research and development. Furthermore, they can benefit from the contract manufacturer's production-related knowledge and access to new technologies and geographies. Due to the advantages of contract manufacturing for pharmaceutical companies, the share of subcontracted production has risen sharply in recent years. According to the European Pharmaceutical Review (2021), the global market value of pharmaceutical CMOs was estimated at USD 89.91 billion in 2020. It is expected to increase at a growth rate of 1.33 to USD 120.00 billion by 2027.

Moreover, pharmaceutical companies plan to collaborate further with CMOs and subcontract significant business activities and volumes. Likewise, CMOs continue to extend capacities, invest in manufacturing technologies, and offer further value-added services. Thus, CMRs have become increasingly crucial for the success of pharmaceutical companies. Therefore, excellence in CMR management is becoming a competitive factor for pharmaceutical companies to balance the need for cost efficiency, quality, flexibility, and innovative technologies in the supply chain.

However, previous studies, and the dialogue with practitioners, reveal room for improvement in the targeted identification and exploitation of joint business opportunities through more effective relationship management.

Study Focus and Objectives

The pharmaceutical industry is characterized by demanding quality, technical and legal requirements that restrict and hamper business relationships. Therefore, relationship managers must establish a delicate balance between control and trusted self-governance to enable flexible, compliant, efficient, and effective CMRs. In this context, three primary fields of action can be identified:

Developing CMRs: CMRs are complex relationships constantly affected by internal and external dynamics. Partnering companies must be aware of those dynamics despite the difficulty of accurately predicting and quantifying them. Whether the effects are disruptive or gradual, partners must constantly adapt management to guide the relationship in following the business objectives. Thus, a solid trust basis and open exchange on future paths and business opportunities must be embedded in CMR management.

Tailoring CMRs: As each relationship differs, management approaches must be tailored individually to the partnership and its development path. Therefore, a thorough understanding and systematic analysis of relationship criteria and differentiators affecting the management requirements of the CMR is paramount.

Aligning CMRs: Relationship alignment enables flexible and trusted cooperation outside contractual agreements. Since the partners' unspoken expectations and perceptions can differ significantly, engaging with the other side's perspective is essential to foster commitment. Therefore, active and systematic alignment represents a recurring task along the CMR's lifespan.

Against this background, the study examines the fundamental aspects of excellent relationship management of pharmaceutical CMRs. Excellent CMR management is based on systematically addressing the underlying success factors and challenges to meet the expectations of both partners. By integrating client companies' and CMOs' perspectives, the study reveals levers for excellence in CMR management. In this capacity, the study covers the management challenges of dynamic CMRs and shares insights into how to approach challenges in daily operations. Finally, it identifies tangible concepts and management practices for pharmaceutical CMRs.

All in all, the study addresses the following research question:

RQ 1)

How can pharmaceutical companies achieve excellence in the management of CMRs?

More precisely, the three following topics are considered to address the previously mentioned challenges in more detail:

RQ 1a)

How can pharmaceutical companies purposefully develop CMRs and react to changes?

RQ 1b)

How can pharmaceutical companies differentiate CMRs to tailor management?

RQ 1c)

How can pharmaceutical companies align the partner expectations in CMRs?

This study aims to promote discussion about excellent CMR management in the business community by answering the presented questions. In addition, the study's results are intended to inspire client companies and CMOs to design their relationship management activities.

Study Structure and Design

The study contains the following chapters to answer the previously stated research questions:

- Chapter 2 outlines the methodical approach of the study and explains the applied research methods.
- Chapter 3 gives an overview of the current state of knowledge on CMR management. It briefly introduces CMRs in the pharmaceutical context and focuses on industry-specific challenges.
- Chapter 4 addresses practices for the purposeful development of CMRs. It examines CMR trajectories and dynamics and presents approaches for the systematic progression of CMRs.
- Chapter 5 focuses on practices for tailoring management to CMRs. It critically discusses prevalent partner differentiation approaches and provides tools for enhancing the tailoring of CMR management.
- Chapter 6 features practices for aligning partners beyond contracts. Therefore, the relevance of expectation management in CMRs is highlighted, and the «Relationship Gap» concept is introduced.
- Chapter 7 integrates the presented findings and practices into a framework to provide impulses for excellent CMR management.
- Chapter 8 finally summarises the managerial implications. In addition, limitations and further needs for research are presented.

Figure 1 visualizes the connection between the study structure and the before-mentioned research questions, which are addressed in Chapters 4 to 7.

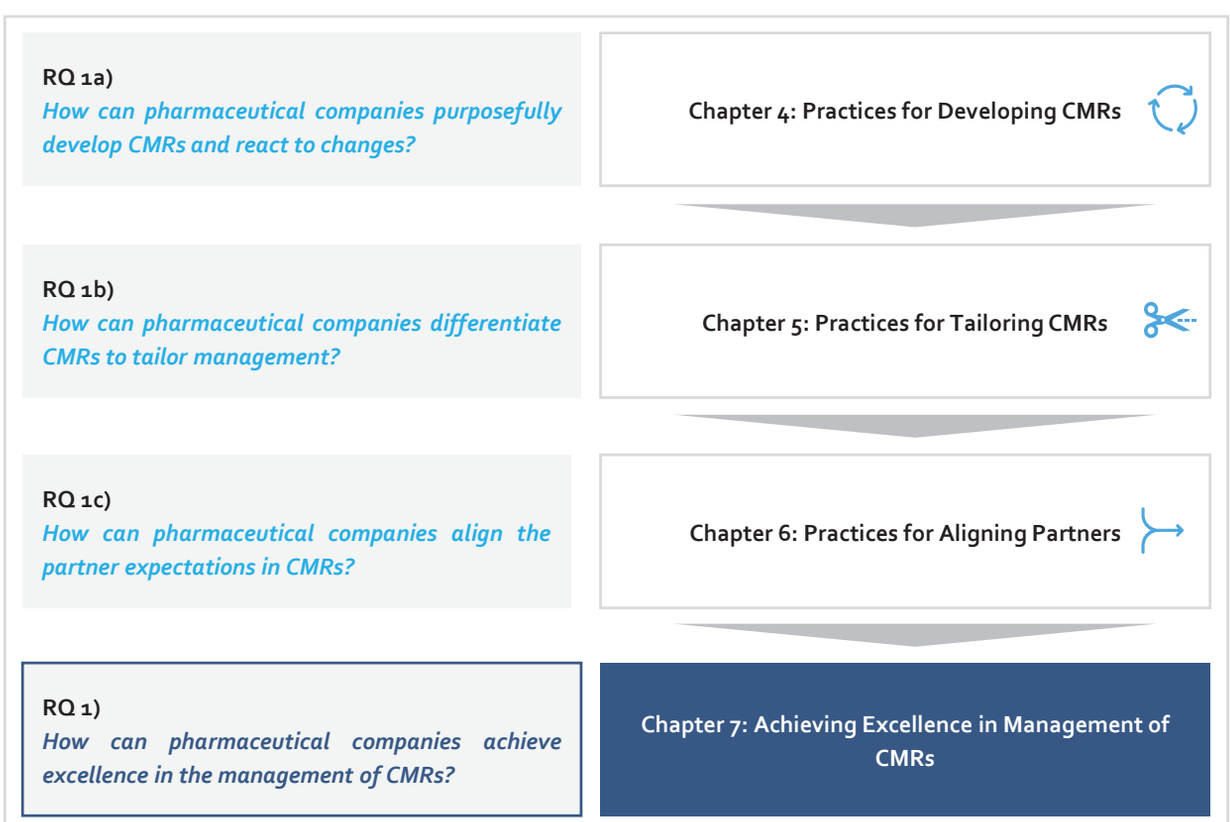

Figure 1: Study structure

Methodical Approach

The study applies a Design Science Research (DSR) approach to identify appropriate practices to support CMR management. DSR is a research methodology that enables close collaboration with practitioners to develop real-world solutions. To this aim, literature reviews, expert interviews, and focus groups were conducted to gain insights from practice and literature. The approach and methods for data collection are described in this chapter.

Overview

The DSR methodology has been developed in information science to generate valuable scientific results in a fast-paced practical environment. For this purpose, the research process continuously compares the research objective against changing practice requirements and existing knowledge to design solutions as outcomes, which DSR calls «artifacts». The designed artifacts can be either frameworks or tangible methods and physical objects. Considering the complex and dynamic environment of pharmaceutical CMRs, the DSR methodology supports the identification of substantial success factors, guidelines, and practices to enable excellent CMR management.

Hevner (2007) presents DSR as an iterative process composed of three intertwined cycles, illustrated in Figure 2. The relevance, rigor, and design cycles connect practice and theory to deliver valuable, tangible solutions.

Relevance Cycle: The relevance cycle represents the research process' interface with practice. It captures the problem situation and identifies possible opportunities for solving it. Therefore, five pharmaceutical client companies and CMOs are iteratively consulted in the relevance cycle to derive requirements for the artifact design. Lastly, the artifact developed to solve the problem can be evaluated and tested with the users to ensure its validity and value in the business environment.

Rigor Cycle: Simultaneously, the researcher analyses the knowledge base of established literature, frameworks, and methods to identify insight and impulses that can be incorporated into CMR management to address the defined challenges. Finally, the validated solutions to CMR management are added to the scientific knowledge base through the rigor cycle to serve as an orientation for future researchers and practitioners.

Design Cycle: The design cycle integrates the relevance and rigor cycle results to develop solutions based on the business needs and the available knowledge. The design process goes through several iterations in which the artifact is repeatedly evaluated by practice experts, compared with existing knowledge, and improved. The design cycle ends when the user has confirmed the artifact's usefulness and applicability.

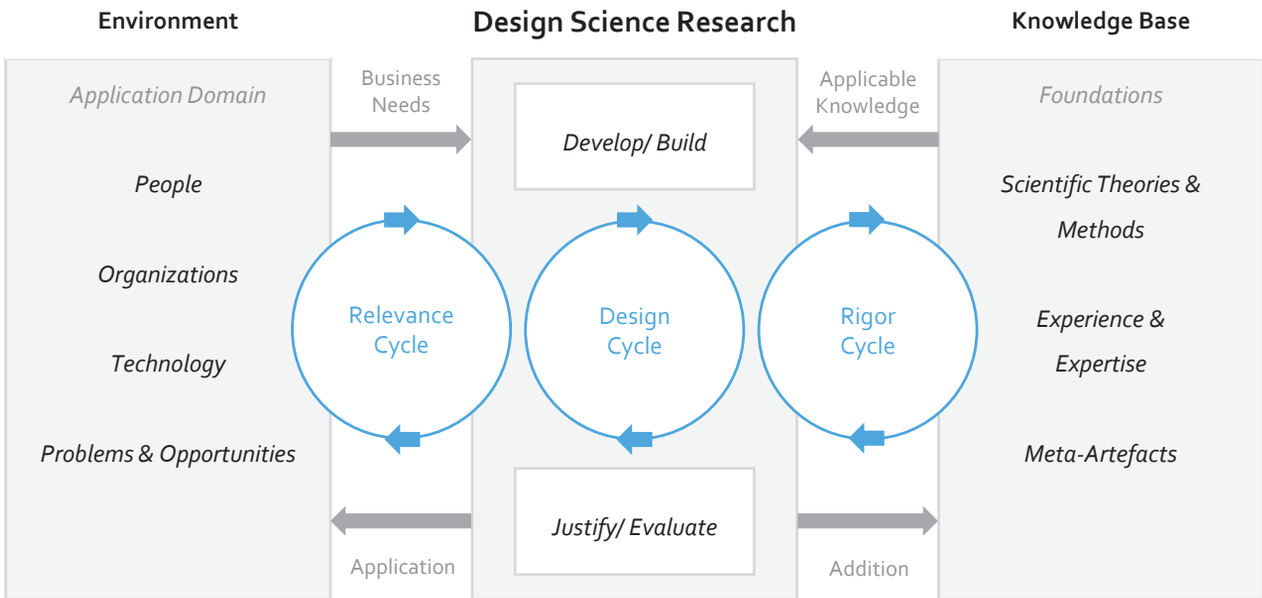

Figure 2: The Design Science Research framework

The DSR process is repeated until a finished, helpful artifact is obtained to contribute to CMR management excellence. Such an artifact can then be applied in the environment and, at the same time, represents a generation of new knowledge contributing to science.

In this study, the DSR methodology guides the research process and is supported by empirical research methods to gain insights from practice and theory. The study employs expert interviews and focus groups as part of the relevance cycle to understand the problem and evaluate the developed solutions. In the rigor cycle, literature reviews are conducted to identify existing concepts and impulses from other research fields. Finally, DSR integrates the practitioner's expertise and knowledge base insights through a continuous exchange to develop concrete solutions in the design cycle.

Expert Interviews

Expert interviews are a research method used to collect knowledge, experience, and opinions from experts who deeply understand the research topic. Along the guidelines by Saunders, Lewis & Thornhill (2020), expert interviews with representatives from pharmaceutical client companies and CMOs were conducted in the study. The interviews followed a semi-structured agenda to allow experts to present a holistic picture of the challenges of joint value creation in CMRs.

In the context of CMRs, the research method provided valuable insights since it allowed the client companies and CMOs to anonymously disclose their point of view and comment on those of the other parties. Furthermore, the interviews captured the industry experts' experiences and perceptions of current CMR management practices. Thus, the study could focus on the most pressing and promising fields for action in CMR management.

The expert interviews belonged to the DSR relevance cycle. They were conducted in the study's early stages to lay the groundwork for artifact development.

Exploratory Literature Review

Exploratory literature reviews provide an overview of the current state of knowledge on a research topic. They are used to compile all relevant information. Concerning the management of CMRs, exploratory literature reviews play a crucial role. The knowledge that can help achieve excellent CMR management is widely scattered. On the one hand, the study drew on the literature on supplier management, supply chain management, strategic alliances, and joint ventures. On the other hand, grey literature in the form of best practices in different industries was also studied to gather impulses.

Therefore, the literature review is applied as part of the rigor cycle to consider existing knowledge in solution development and to generate innovative insights into CMR management.

Focus Groups

Focus groups gained popularity as a research method in the 1980s. Like expert interviews, focus groups gather rich insights by questioning industry experts in the research field. Furthermore, focus groups can create additional added insights by interviewing several people together who are allowed to interact. For this purpose, the experts are invited to a group discussion, which is led by a researcher who serves as a moderator.

Unlike in an individual interview, the experts not only describe their opinion but also have to substantiate it to the other participants and are simultaneously confronted with their statements. Thus, new perspectives emerge through the encounter of different views and the exchange and discussion of them. Focus groups are, therefore, particularly suitable for research situations in which interpersonal relationships and diverging perspectives are relevant. As part of the study, focus groups were used to shed light on the challenges, demands, and success factors of excellent CMR management from the perspective of pharmaceutical clients and CMOs. Thus, conflicting views could be uncovered through mixed focus groups, and mutually relevant solutions could be developed and evaluated. In addition, because CMRs increasingly rely on strategic and social alignment among partners due to their high complexity, focus groups significantly contribute to the study findings.

Focus groups are part of the relevance cycle as they help understand the environment and stakeholder requirements and are used to test and evaluate the designed artifacts.

Empirical Sample

The empirical sample of this study consists of the consortium partners, which includes two typical pharmaceutical client companies, two CMOs, and one company that fills both roles. The partner companies with representatives from the D-A-CH region represent different company structures and sizes in the pharmaceutical industry. The focused empirical sample allowed for intensive interaction with partners to develop valuable contributions to the excellent management of CMRs that can be applied in practice. To this end, the study conducted 14 expert interviews and five focus groups iteratively in line with the DSR methodology. In addition, the Institute of Supply Chain Management (ISCM-HSG) contributed experience from comparable industries in contract manufacturing to stimulate new perspectives.

Within the framework of the DSR approach and methods presented, the study provides impulses to excellent CMR management based on practical requirements and scientific findings. Those impulses were subsequently evaluated for their usefulness by the focus groups. In this way, the research questions posed in advance are answered.

Knowledge Base

The knowledge base includes the established knowledge of pharmaceutical CMRs as the foundation on which the study develops solutions for excellent CMR management. Therefore, the chapter highlights the unique characteristics, importance, and challenges of CMR management in the pharmaceutical industry.

Principles of Contract Manufacturing in the Pharmaceutical Industry

Contract manufacturing is a supply chain management arrangement in which a company subcontracts one or more stages of manufacturing activity to external parties (Han, Porterfield, & Li, 2012, p. 159). Accordingly, the activities subcontracted in CMRs can include individual production steps or the entire manufacturing process. In addition, CMOs increasingly take on manufacturing-related activities such as product development, warehousing, and shipping, establishing themselves as comprehensive value-added partners.

In this context, CMRs differ from conventional outsourcing arrangements because the CMO offers comprehensive and specialized services. Therefore, the subcontracted activities are no longer isolated activities but significant parts of the value chain which the CMO administers to some extent autonomously.

Consequently, CMOs are embedded in the client company's supply chain due to the scope and relevance of the outsourced tasks, which are business critical. Furthermore, CMOs contribute significantly to the client's value creation through specialization by offering knowledge, technologies, and capacities that the client cannot reproduce easily. As a result, the formal relationship between clients and CMOs as customers and service providers is misleading. In practice, CMRs are characterized by very often intense co-dependency and high switching barriers to a different partner. As a result, a power balance emerges, which often resembles eye-level collaboration more than a buyer-supplier relationship. For example, clients have limited control over day-to-day manufacturing operations requiring trusted collaboration and are bound to the relationship for a significant time, especially after the start of the commercial phase.

In this context, the need for relationship management of CMRs is emphasized. Due to the interconnectivity of the supply chain and close collaboration, the CMO cannot be managed as a service provider or extended workbench. Instead, the CMR must be organized jointly, considering both parties' specific capabilities and perspectives. CMR management refers to all business and social aspects of relationships between clients and CMOs across all activities and products.

In addition, the pharmaceutical industry poses particular challenges to CMR management due to its industry specifics. On the one hand, the long development timelines for new products, the attrition of potential drug candidates, and the high investment needs for product development and production facilities favor cooperation with partners to share investment risks. On the other hand, broad innovation and technological advancement require access to specific capabilities, where CMOs in specific product fields, manufacturing steps, and technologies come into play. As a result, pharmaceutical CMRs bring together partners' complementary capabilities to deliver high-end medicines.

In this sense, pharmaceutical CMRs often entail much longer collaboration than CMRs in other industries. Food CMRs, for example, are often subject to more opportunistic targets, as recipes and technologies for staple foods have limited protection under competition law. Apparel and electronics CMRs face extremely short product life cycles enabling frequent partner changes. Due to their comparably high commitment intensity and longevity, pharmaceutical CMRs require particularly excellent relationship management.

Consequently, production phases must be optimally utilized to amortize the high investment costs on both sides, adjust to the growth trajectory of the product and assure uninterrupted supply to patients. First, after obtaining a patent, it is essential to quickly place the product on the market using established manufacturing and fulfillment networks. Later, transitioning from patent protection to generics entry requires a complete review of the manufacturing strategy for successful competition by focusing on supply chain efficiency.

Thus, pharmaceutical CMRs operate in an environment characterized by high-cost intensity, lengthy, highly regulated transition processes, and dynamically evolving production technologies and market needs

Benefits and Challenges of CMRs

Working with CMOs allows pharmaceutical companies to reduce capital expenditures for production technologies, equipment, facilities, and personnel in this environment. Contract manufacturing benefits client companies as the industry increasingly manufactures unique and personalized products that are often only in demand in small batches. Working with CMOs, client companies have no obligation to invest in equipment specifically for low production volumes or when the viability of a new product or technology is not yet proven. CMOs can better balance demand fluctuations and ensure high plant utilization by offering their capacity to different customers.

Similarly, CMOs provide development and manufacturing capacities and capabilities in the development and approval phases, allowing clients to scale production after registration rapidly. In addition, they can adjust production volumes flexibly to respond to market trends and legal regulations, access specific geographies, or provide business continuity as a second source. Thus, client companies and CMOs can effectively share the investment risk of pharmaceutical products through CMRs. With client companies focusing on research, product development, and marketing, CMOs focus on managing production systems and networks. Furthermore, CMOs hold operational expertise for various manufacturing technologies and materials through experience working with multiple clients. Therefore, CMRs are platforms for accessing new technologies and sharing manufacturing experiences.

However, close entanglement also poses challenges for operating CMRs. First, the technology transfer to a CMO site is a complex process prone to mismatches that can put start-up timelines at risk. Second, subcontracting manufacturing to CMOs naturally limits the client company's influence on scheduling, processing, and production quality control. In particular, access to capacity must be coordinated with the CMO as demand changes dynamically since the capacity is also offered to other customers. Third, both partners rely on each other to recoup their investments in innovative products and cutting-edge manufacturing sites.

Consequently, the complexity and scope of collaborative activities in CMRs pose challenges to efficient management by the client. Furthermore, pharmaceutical companies and CMOs maintain many CMRs simultaneously, all of