



Global MBA

Research Methods and Consulting Project (BMBA5007)

Assessment 2 Consulting Report

**Exploring and Evaluating Strategic Partnership Opportunities
for a Europe-Based API Pharmaceutical Company**

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Declaration of Originality and Independent Work

I hereby declare that this thesis is my original work and has been completed solely by me. I have not used any AI tools for the generation of content, analysis, or writing of this thesis. All ideas, analysis, and interpretations presented are entirely my own.

List of Abbreviations

- AI – Artificial Intelligence
- AMR – Antimicrobial Resistance
- API – Active Pharmaceutical Ingredient
- CDMO – Contract Development and Manufacturing Organization
- CEP – Certificate of Suitability (to the Monographs of the European Pharmacopoeia)
- CGMP / cGMP – Current Good Manufacturing Practices
- CMS – Contract Manufacturing Services
- CNS – Central Nervous System
- CRAM – Contract Research and Manufacturing
- CSR – Corporate Social Responsibility
- CVS – Cardiovascular System
- EDQM – European Directorate for the Quality of Medicines & HealthCare
- EUGMP – European Union Good Manufacturing Practice
- FDI – Foreign Direct Investment
- FDF – Finished Dosage Form
- GARDP – Global Antibiotic Research & Development Partnership
- GMP – Good Manufacturing Practice
- GSK – GlaxoSmithKline
- HPAPI – Highly Potent Active Pharmaceutical Ingredient
- IP – Intellectual Property
- KSM – Key Starting Material
- MCDM – Multi-Criteria Decision Making
- NCE – New Chemical Entity
- NPNC – Non-Penicillin, Non-Cephalosporin
- R&D – Research and Development
- SAF – Suitability, Acceptability, Feasibility (Business Analysis Framework)
- SWOT – Strengths, Weaknesses, Opportunities and Threats
- USDMF – United States Drug Master File
- USFDA / FDA – United States Food and Drug Administration
- WHO – World Health Organization

Executive Summary

The global pharmaceutical industry is a dynamic and rapidly growing sector, driven by rising healthcare demand, technological advancements, and increasing investments in research and development. India has emerged as a strategic hub for pharmaceutical production, supported by a broad domestic base of approximately 3,000 pharmaceutical firms and more than 10,500 manufacturing units, alongside large-scale companies, cost-efficient manufacturing, strong R&D capabilities, and high regulatory approvals, making it an attractive destination for cross-border collaborations. Within this context, X Company, a Europe-based mid-sized API manufacturer specializing in anti-infective APIs, faces challenges including a narrow product pipeline, limited innovation and R&D capabilities, high manufacturing costs compared to Asian competitors, and financial constraints. These constraints have emerged largely as a result of deliberate strategic reorientation decisions, through which X has refocused its operations on strengthening core API manufacturing capabilities for global B2B markets. To address the resulting limitations in growth and diversification, strategic partnerships with Indian pharmaceutical companies were explored, drawing on existing literature on cross-border alliances and collaborative frameworks.

This study adopts a mixed-methods case study approach, integrating secondary data from industry databases, company reports, and academic literature. A structured Partner Evaluation Framework was developed based on insights from the literature assessing strategic, operational, relational, and financial dimensions, while the SAF model, Partner Scorecard, and SWOT analysis were applied as tools to evaluate partners. From an initial pool of 386 Indian firms, 44 were shortlisted based on the evaluation framework, with five ultimately evaluated for partnership suitability using the Partner Scorecard evaluating through dimensions supported by prior research, including Regulatory Strength & Reputation, Manufacturing Capability & Operational Reliability, Market Expansion Potential & Global Reach, Strategic Fit, R&D Capabilities, Financial Stability, Cultural Compatibility, Risk-sharing, and Sustainability & Ethical Practices, and SAF analysis.

The findings identify Orchid Pharma, Concord Biotech, and Alivus Life Sciences as the most strategically aligned partners. Among them, Orchid Pharma ranks first, offering a strong fit through its anti-infective API portfolio and broader therapeutic coverage, robust regulatory

approvals, established R&D capabilities, under-commercialized assets with significant growth potential for Orchid, and clear revenue enhancement opportunities for both parties. Concord Biotech provides fermentation-based APIs and broader therapy areas, with co-development opportunities, while Alivus Life Sciences offers a diversified API portfolio encompassing anti-infectives and exhibits strong operational stability as a CDMO player. Partnerships with these firms address X Company's pipeline gaps, high production costs, and the partnering companies' limited market reach, enabling commercialization, co-development. Additionally, aligned CSR initiatives enhance social impact and support sustainability objectives.

Strategically, the study recommends prioritizing partnership with Orchid Pharma for maximum operational and strategic synergy, while maintaining engagement with Concord and Alivus to broaden portfolio coverage and innovation potential. Structured evaluation and monitoring frameworks are advised to ensure ongoing alignment and partnership success. This research demonstrates that cross-border alliances with Indian pharmaceutical firms provide a viable pathway for X Company to enhance growth, diversify its portfolio, and strengthen its global competitiveness.

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01. Introduction

The global pharmaceutical industry is one of the most dynamic and growing sectors, playing a crucial role in safeguarding public health, driving innovation, and generating long-term economic value. The sector is geographically diverse, with major clusters across North America, Europe, Asia, and Africa, and continues to grow as a result of rising healthcare needs, technological advancements, and increasing investments in R&D. The pharmaceutical industry will expand from US\$16.81 billion in 2025 to US\$55.16 billion by 2032, reflecting a compound annual growth rate (CAGR) of 18.5% (Coherent Market Insights, 2025). The United States leads the global pharmaceutical industry, while Switzerland, the United Kingdom, and France are major European players (Rathore et al., 2023). Major multinational companies such as Pfizer, AbbVie, Johnson & Johnson, and Novartis retain substantial influence in shaping industry trends and competitive frameworks (Statista, 2025). With Europe's life sciences sector growing steadily, this research project offers an opportunity to apply academic and analytical skills to a real-world strategic management challenge within the pharmaceutical domain.

India has emerged as one of the world's most significant pharmaceutical hubs. Its industry is forecast to reach a market size of approximately US\$450 billion by 2047 (Statista, 2024), driven by strong demand, cost-competitive manufacturing, and increasing investments in biotechnology and innovation. The sector is further strengthened by a broad domestic base of roughly 3,000 pharmaceutical firms and more than 10,500 manufacturing units (Orchid Pharma Limited, 2025). Indian companies have adopted collaborations, contract manufacturing, and strategic partnerships as key growth strategies, enabling them to expand global presence and build capabilities in generics, biosimilars, and Active Pharmaceutical Ingredients (APIs). Leading Indian players such as Sun Pharma, Divi's Laboratories, Cipla, and Dr. Reddy's Laboratories continue to shape global supply chains and reinforce India's position as a major hub for high-quality drug manufacturing (Statista, 2025). Thus, as global pharmaceutical production activities gradually shift toward Asia, India presents promising opportunities for cross-border partnerships.

Within this global context, the present report focuses on a Europe-based API manufacturer, referred to as X Company, which specializes in anti-infective APIs. With decades of expertise,

X is a mid-sized company recognized as a leader in critical care anti-infective APIs. X has taken firm business decisions to reorient the company towards strengthening its core API capabilities for global B2B markets. However, these decisions have also resulted in a significantly reduced product pipeline, limited innovation, and long-term growth challenges. The central issue emerging for X is how to expand its revenue streams and product offerings beyond historical anti-infective APIs to remain competitive in a rapidly evolving market. This forms the basis of the research problem addressed in this study.

Business decisions reveal X's strong capabilities as well as critical constraints. The company's capabilities include a large B2B customer base with a strong global presence, supported by manufacturing sites, as well as an FDF facility and an R&D center. X faces substantial challenges: a narrow pipeline, high manufacturing costs relative to Asian competitors, heavy dependence on mature low-margin products, limited differentiation in a highly competitive market, and financial constraints (X Company, 2024). Additionally, constrained internal R&D capacity restricts innovation and pipeline renewal. Opportunities exist in rising global demand for anti-infectives under the antimicrobial resistance (AMR) agenda, in forming partnerships with Indian manufacturers, and in expanding into adjacent critical care therapeutic areas. Nonetheless, X must also navigate threats such as intensified Asian competition, regulatory complexities, market volatility for products and global supply chain vulnerabilities.

Management of X company has identified external alliances as a strategic pathway to address these challenges. Literature highlights that international partnerships allow firms to gain access to new technologies, manufacturing capabilities, patents, and foreign markets, thereby enhancing global competitiveness (Hagedoorn, 2002) Emerging markets, including India are especially attractive due to their advanced manufacturing capacity, cost efficiency, and rapidly evolving biotech ecosystem (Feller, 2003). For X, strategic collaboration with Indian pharmaceutical or biotechnology companies presents a viable route to diversify its portfolio, lower production costs, expand market reach, and strengthen long-term sustainability.

Accordingly, this research presents the research aim, objectives, and questions developed to address X's strategic growth challenge. It outlines a structured methodology for identifying and evaluating potential Indian partners, applying strategic frameworks, defined evaluation criteria, and analytical tools. The report concludes with key findings, discussion, and

recommendations to support managerial decision-making regarding optimal partnership opportunities for X Company.

Research Aim

To explore and evaluate potential partnership opportunities with Indian pharmaceutical and biotechnology companies for a Europe-based API pharmaceutical company X to support growth and diversification strategies.

Research Objectives

1. To analyze the external and internal factors influencing partnership opportunities between Europe-based API company X and Indian pharmaceutical companies.
2. To develop and apply an evaluation framework for assessing potential Indian companies.
3. To identify and recommend the most suitable Indian companies to align with the Europe-based API company X's strategic goals.

Research Questions

1. What external and internal factors influence partnership opportunities between the European API company X and Indian pharmaceutical companies?
2. What criteria and tools are most suitable for assessing potential Indian partners?
3. Which Indian companies present the strongest strategic fit for partnership, and why are they suitable?

02.Literature Review

The strategic formation of partnerships in the pharmaceutical sector has been extensively analyzed across empirical research, case studies, and theoretical frameworks. This review synthesizes literature relevant to a Europe-based API manufacturer seeking collaborations in India, focusing on four key areas: External and internal factors affecting partnerships, frameworks and evaluation tools for Partner Assessment, factors for partner evaluation, and methodological insights. The aim is to provide an academic foundation for assessing partnership opportunities between X Company and Indian pharmaceutical firms.

2.1 Partnership Definition

Partnerships are intentional strategic collaborations between separate organizations that pursue aligned objectives, seek shared value, and recognize that their success depends significantly on each other (Wu, Shih and Chan, 2009). While partnerships are widely studied, empirical research on international, cross-border collaborations, particularly in the pharmaceutical sector, remains limited (Esmaelnezhad *et al.*, 2023). This underscores the need to systematically explore cross-border alliances to identify success factors and potential risks, rather than assuming that domestic partnership dynamics automatically translate to international contexts.

2.2 Factors Influencing Partnerships

2.2.1. External Factors

The growth of the Indian pharmaceutical industry has attracted significant global attention due to its scale, competitiveness, and expanding scientific capabilities. It is recognized as one of the fastest-growing industries worldwide, ranking third globally by volume and demonstrating strong science-based development (Khanna, 2025). External factors shaping this growth include rising demand for generics, consolidation of global supply chains, and increasing outsourcing by Western firms (Feller, 2003). These factors make India an attractive destination for international companies seeking collaborations in drug discovery, contract research and manufacturing, joint ventures, and strategic partnerships (Feller, 2003).

2.2.2 Internal (Firm-Level) Factors

Partnership decisions are influenced by internal capabilities such as regulatory compliance, specialized technologies, global customer reach, and operational resources (Festel *et al.*, 2014; Mindruta *et al.*, 2016). Conversely, firms with resource constraints, including high costs and limited R&D capacity, are motivated to seek alliances to address these gaps and achieve pipeline diversification (Hagedoorn, 2002; PricewaterhouseCoopers, 2025). This dual nature of internal strengths and weaknesses highlights that alliances are driven both by opportunity and necessity, a point often overlooked in studies that emphasize only strategic complementarity.

2.3 Strategic Importance of International Alliances

International partnerships are increasingly central to pharmaceutical strategies, enabling firms to access technological expertise, enhance core competencies, and enter new markets. Case studies highlight alliances such as ICON-LEO Pharma in dermatology clinical trials and Eli Lilly-Evotec in metabolic diseases, illustrating the strategic importance of international collaborations (McKinsey & Company, 2025). European firms, particularly in the UK and Scandinavia, dominate alliances, while companies like Novartis and Roche maintain extensive global partnerships (Gottinger and Umali, 2008). Around 14 of the 55 blockbuster drugs were obtained through partnerships, highlighting the direct contribution of alliances to product pipelines (McKinsey & Company, 2025).

As India continues to expand its API and biotechnology capabilities, these combined internal and external factors make it a strategically attractive destination for international companies seeking cost efficiencies, portfolio diversification, and broader market access, providing a strong rationale for X Company to explore partnerships within the Indian pharmaceutical ecosystem.

2.4 Critical Factors for Partner Evaluation

Across the literature, several critical factors emerge as determinants of partner suitability in pharmaceutical alliances. Selecting the right partner is essential for forming successful strategic alliances as alliance outcomes depend heavily on partner choice (Esen and Alpay, 2017).

Regulatory strength is emphasized, with firms favoring partners compliant with EUGMP and CGMP standards and free from legal or compliance issues (Festel *et al.*, 2014; Khanna, 2025). Technological capability is also a key determinant (Zhang *et al.*, 2013; Mindruta *et al.*, 2016; Cummings *et al.*, 2012; Papadopoulou and Hecht, 2021) encompassing horizontal R&D capacity for rapid product development and vertical integration in supply chains, including manufacturing of active ingredients, formulation, and specialized packaging (Festel *et al.*, 2014), which accelerates product development while complementing existing capabilities. Studies indicate that partners with these capabilities accelerate time-to-market, reduce costs, and enhance innovation potential (Festel *et al.*, 2014).

Strategic intent and collaborative willingness are essential as misaligned goals or low commitment can undermine even technically capable partnerships, particularly in high-risk, R&D-intensive biopharmaceutical contexts (Cummings *et al.*, 2012; Papadopoulou and Hecht, 2021). Alongside these, reputation and credibility serve as intangible assets that signal reliability and professional conduct (Cummings *et al.*, 2012; Papadopoulou and Hecht, 2021; Khanna, 2025). Financial and operational stability further support partnership feasibility, although evidence suggests that complementary operational capabilities may offset weaker financial positions in certain biotech alliances (Papadopoulou and Hecht, 2021; Khanna, 2025).

Cultural compatibility is recognized as determinants of cross-border alliance success, with shared values and management practices reducing conflict and the risk of earlier termination (Cummings *et al.*, 2012; Zhang *et al.*, 2013). Strategic synergy emerges from complementary resources, knowledge, and capabilities, thereby enabling partners to generate greater joint value than individually possible (Wu *et al.*, 2009; Zhang *et al.*, 2013; Mindruta *et al.*, 2016; Sadovnikova *et al.*, 2016) In this sense, strategic fit not only underpins why firms seek cooperative agreements but also explains how alliances enable access to missing capabilities (Esen and Alpay, 2017).

Ethical considerations, through CSR and responsible practices, enhance stakeholder acceptance and safeguard the partnership's public image (Festel *et al.*, 2014). Finally, focus on risk factors-performance, relational, quality, market, and regulatory risks enable proactive mitigation strategies, emphasizing that successful alliances are not only built on opportunity but also on the capacity to manage potential vulnerabilities (Cummings *et al.*, 2012; Festel *et al.*, 2014).

While the literature provides substantial insight into these factors, notable gaps remain. Most empirical studies focus on operational, technological, or strategic dimensions, with limited attention to cultural, trust (Esmaelnezhad *et al.*, 2023; Esen and Alpay, 2017) risk and CSR aspects. Collectively, the literature emphasizes that successful cross-border pharmaceutical partnerships require a multidimensional evaluation approach, balancing tangible resources with relational, ethical, and risk considerations. This approach ensures that collaborations generate sustainable mutual value while mitigating potential vulnerabilities, providing a precise foundation for evaluating partnerships between X Company and Indian pharmaceutical firms.

Table 1 Factors and Sub-factors for Partner Evaluation

Factor	Sub-factor	Author(s)	Importance for the Study
Regulatory Strength	Compliance with EUGMP, cGMP	(Festel <i>et al.</i> , 2014; Khanna, 2025)	Ensures legal and regulatory compliance for global operations
Complementarity-Technological	R&D, manufacturing technologies	(Zhang <i>et al.</i> , 2013; Mindruta <i>et al.</i> , 2016; Cummings <i>et al.</i> , 2012; Festel <i>et al.</i> , 2014; Papadopoulou and Hecht, 2021; Esen and Alpay, 2017)	Enhances potential for joint innovation and rapid product development
	horizontal and Vertical integration	(Festel <i>et al.</i> , 2014)	
Complementarity-Operational	Resource and capability complementarity, pipeline, supply chain management, production capacity, global reach, size	(Wu <i>et al.</i> , 2009; Zhang <i>et al.</i> , 2013; Mindruta <i>et al.</i> , 2016; Sadovnikova <i>et al.</i> , 2016; Festel <i>et al.</i> , 2014)	Provides assurance of operational continuity, cost reduction, and operational synergy

Complementarity- Financial	Financial resources, investment capacity	(Zhang <i>et al.</i> , 2013; Festel <i>et al.</i> , 2014; Khanna, 2025)	Ensures partners can support joint initiatives, though strong pipelines can offset weaker financials
Strategic Intent / Collaborative Willingness	Alignment of goals, openness to joint innovation	(Cummings <i>et al.</i> , 2012; Papadopoulou and Hecht, 2021)	Ensures strategic alignment and mutual benefit in partnerships
Reputation & Credibility	Professionalism, past alliance experience	(Papadopoulou and Hecht, 2021; Khanna, 2025; Cummings <i>et al.</i> , 2012)	Builds trust and reliability between partners
Cultural Compatibility	Shared values, management styles	(Zhang <i>et al.</i> , 2013; Cummings <i>et al.</i> , 2012)	Minimizes conflicts, facilitates communication, and supports smooth collaboration
CSR & Ethical Practices	Ethical operations, corporate social responsibility	(Festel <i>et al.</i> , 2014)	Supports reputational integrity and stakeholder acceptance
Risk	Performance Risk, Relational Risk, Quality Risk, Market Risk	(Cummings <i>et al.</i> , 2012)	Identifies potential partnership vulnerabilities and enables proactive risk management to enhance alliance success
	Regulatory risk	(Festel <i>et al.</i> , 2014)	

2.5 Data collection

The academic literature provides multiple frameworks for systematically assessing collaboration partners. Scholars emphasize that effective assessment must integrate quantitative indicators such as regulatory compliance, financial stability, and operational capacity with qualitative factors like cultural alignment (Esmaelnezhad *et al.*, 2023), strategic alignment, partner compatibility, strategic intent, and willingness to collaborate.

Empirical studies support triangulated methodological designs, combining secondary data with interviews or surveys. Festel *et al.* (2014) demonstrates how semi-structured interviews, paired with secondary data, enable holistic evaluation of outsourcing partners in the pharmaceutical supply chain. Interviews reveal implicit knowledge such as organizational culture, responsiveness, and partner attitude, while secondary sources validate objective attributes like GMP compliance, production capabilities, and past regulatory performance. Similarly, Zhang *et al* (2013) applied a case study approach to evaluate contract research and manufacturing organizations in India and China for a European pharmaceutical firm highlighting the analytical value of combining internet-based secondary data (e.g. portfolio disclosures, annual reports) with qualitative evidence from interviews. Zhang's methodology further reinforces the value of semi-structured interviews with open-ended questions grounded in prior literature, ensuring both consistency and flexibility.

Research involving Leo Pharma in Europe, also employs semi-structured interviews (Papadopoulou and Hecht, 2021) to assess partner suitability. These studies highlight that strategic alignment, mutual expectations are best understood through qualitative engagement rather than purely numerical indicators.

A particularly relevant methodological precedent is the Indian pharmaceutical industry case study conducted by Khanna (2025), which combined secondary data with a survey emailed to firms, followed by personal interviews with respondents who filled out the survey. The questionnaire explored existing collaboration types, the success of those alliances, and partnership drivers, enabling standardized comparison across firms. The supplementary interviews added depth and mitigated common issues in B2B research such as low response rates and limited disclosure.

Similarly, the Indonesian pharmaceutical case study by Prayogi and Wandebori (2020) demonstrates how researchers may rely predominantly on secondary data when access to confidential information is restricted.

Together, these studies reveal both strengths and limitations. While interviews and mixed-method case studies capture depth and context-specific insights, they are resource-intensive and often constrained by access to senior decision-makers. Surveys enable extensive data collection but may suffer from low participation due to confidentiality concerns in pharmaceutical settings. Researchers therefore advocate structured, multi-method evaluation to enhance reliability, reduce bias, and strengthen the validity of partner assessments.

Aligned with this literature, the present study adopts a mixed-method case study approach, combining secondary data with a structured survey and optional semi-structured interviews. This design reflects established methodological practice and responds to practical constraints such as geographically dispersed firms and limited access to senior managers while supporting an evidence-based evaluation of potential Indian partners.

2.6 Frameworks and Evaluation Tools for Partner Assessment

The methodological approach presented by Prayogi and Wandebori (2020) also illustrates the value of combining strategic analysis tools such as PESTEL, SWOT and Porter's Five Forces to evaluate environmental and organizational conditions for a real-world problem which also involve diversifications as the solution to business problem.

Tools such as SWOT, Delphi, logic methods have been applied to evaluate potential partners across operational, technological, financial, and regulatory dimensions (Akhavan *et al.*, 2015). While formal Partner Scorecard models and the SAF framework are not widely used in published alliance-selection research, related studies support their academic and practical relevance. For example, Chang, *et al* (2019) applied a hybrid MCDM model to evaluate strategic alliance partners in the green biopharmaceutical sector, showing the value of structured, multi-dimensional evaluation. Similarly, Puzović *et al.* (2023) used a fuzzy MCDM approach for open-innovation partner assessment, integrating qualitative and quantitative criteria. SAF has also been applied with MCDM methods, for strategic option evaluation, demonstrating its practical credibility for alliance partner assessment (Zolfani *et al.*, 2021).

Furthermore, Thanaraksakul and Phruksaphanrat's (2009) supplier evaluation framework demonstrates how criteria-based scorecards can structure assessments across operational, financial and CSR-related indicators. Although applied in supplier selection rather than cross-border alliance evaluation, the logic of integrating multiple dimensions into a scoring model offers a credible conceptual foundation for adopting a Partner Scorecard in this study. Their findings support the argument that structured tools can mitigate subjective bias and complement qualitative judgement.

Critically integrating these studies strengthens the methodological foundation of the present research by demonstrating that combining qualitative analytical tools with structured scorecard methods provides a more precise and balanced basis for partner evaluation, particularly in data-constrained environments.

03.Methodology

3.1 Research Design

This study adopts a case study approach within a mixed-methods framework to evaluate partnership opportunities between a Europe-based API manufacturer, X company and selected Indian pharmaceutical firms. A case study approach was appropriate because it enables a holistic assessment of how potential partners align with X Company's strategic, operational, and technological priorities. The initial plan to integrate primary data had to be scaled back due to extremely low company engagement, a common limitation in confidential B2B pharmaceutical settings. In such contexts, applied business research prioritizes strategic relevance over statistical representativeness, making a mixed-methods case study both relevant.

The research began with macro- and micro-environment analyses of India from X Company's perspective using PESTEL and Porter's Five Forces. These tools identified regulatory, economic, technological, and competitive conditions shaping partnership feasibility and contextualized India's relevance as a strategic market. A SWOT analysis of X Company

assessed its internal strengths, weaknesses, and opportunities. Integrating these frameworks ensured partner evaluation was grounded in X Company's long-term positioning.

Partner identification was guided by criteria defined by X Company's management, including regulatory certifications, business type, financial scale, product portfolio and alignment with X, manufacturing scope, market model, therapeutic focus, capabilities and strengths, operations, human resources, pipeline status, geographic presence, export capability, strategic fit and limitations, collaboration readiness, and alignment with the defined Partner Personas. The focus on India was justified by its strong manufacturing capacity, cost advantages, and a well-established base of EU-GMP-compliant firms.

3.2 Questionnaire Development

Primary data collection was carried out through a structured online survey (Appendix 01) administered via Microsoft Forms, which ensured secure submission, accessibility, and automatic data collation for respondents across different locations. The survey targeted senior professionals in business development, strategy, and operations involved in decision-making, and invitations were distributed via LinkedIn, official emails, and corporate website contact forms. Survey items were designed based on the literature (Table 1) and used 5-point Likert scales to assess strategic fit, operational readiness, and collaboration willingness, while open-ended items captured qualitative insights. A pilot test involving four individuals (including an industry expert and the research supervisor) assessed content validity, while readability was tested using Radhakrishna's (2007) Flesch-Kincaid method, achieving a Grade 11 score suitable for professional respondents.

3.3 Data Collection

A purposive sampling strategy was adopted to identify firms most likely to generate meaningful strategic insights. Purposive sampling is appropriate for small, specialized B2B populations where probability sampling is neither feasible nor necessary. The sampling frame comprised 386 firms drawn from the EudraGMP database, as non-European manufacturers must hold EU-GMP approval to supply APIs or finished dosage forms (FDFs) to the European market. Data cleaning was undertaken to validate firm-level entries and consolidate duplicate site listings,

ensuring that each firm was represented only once. Following this process, the sampling frame comprised 386 unique firms.

A sequential filtering process was then applied based on criteria specified by Company X's management. The first filter retained firms aligned with Company X's predefined partner personas, reducing the sample from 386 to 341 firms. This filter classified firms according to their business models, identifying companies whose business models aligned with at least one persona type. At this stage, personas were used to indicate potential strategic fit rather than confirmed performance outcomes. Persona Type Ia comprised companies producing anti-infective APIs. Persona Type Ib included similar firms with broader therapeutic portfolios beyond anti-infectives. Persona Type II represented API-focused businesses separated from large generic manufacturers transitioning towards innovation-led strategies, while Persona Type III included firms developing late-stage novel antibiotics or seeking to combine Company X's molecules with other agents.

In the second filter, firms were assessed against company X's management criteria, including product portfolio, manufacturing scope, therapeutic focus, and collaboration readiness, to evaluate their potential to engage in a strategic partnership with a company like X. This reduced the sample to 271 firms. The third filter excluded companies of very small scale, with limited capabilities, or lacking recognized regulatory approvals such as USDMFs or CEPs within their overall portfolios, resulting in a final analytical sample of 44 firms. No upper firm-size or revenue threshold was applied at the screening stage; firms were excluded only if they were very small-scale or lacked the regulatory and operational capabilities required for a strategic partnership with Company X. This approach aligns with guidance emphasizing that small-scale strategic research prioritizes relevance over statistical size (Denscombe, 2010) and mirrors pharmaceutical case studies such as Khanna (2025), which examined a limited number of firms.

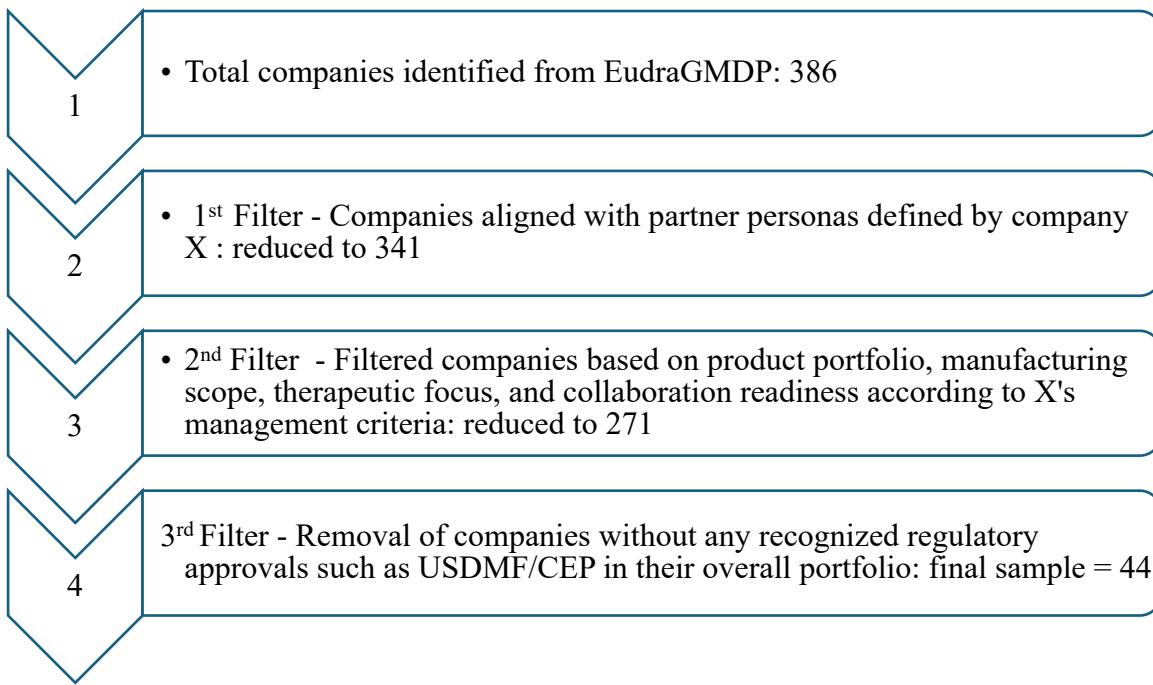


Figure 1 Final Sample Selection

Despite structured outreach, follow-up reminders, and a shorter set of interview-style questions (Appendix 01) sent to encourage participation, engagement remained minimal. Three companies responded initially, but none completed the survey, and no interviews were obtained. Shamrock Pharmachemi Pvt Ltd (Director - Global Operations, Alliances & Lead Strategist, BD) expressed interest via LinkedIn and shared an email address; the survey was sent and followed up through both LinkedIn and email, but no further response was received. Maithri Drugs Pvt Ltd (General Manager - Business Development) acknowledged contact on LinkedIn but indicated unavailability due to travel; follow-up reminders were sent, yet the survey was not completed. Macchem Pvt. Ltd (Assistant General Manager - EU & SEA, Business Development) requested the questionnaire via a specified email address; despite sending the survey and multiple follow-ups through LinkedIn and email, no response or completion occurred.

This outcome reflects well-documented challenges of B2B pharmaceutical research, where confidentiality and the limited availability of senior executives restrict primary participation (Khanna, 2025). Semi-structured interviews were considered but were not feasible due to low response rate combined with geographic dispersion, and time constraints.

Thus, secondary data formed the core dataset due to limited primary engagement. Quantitative and qualitative data were collected from PharmaCompass and EudraGMP for company profiles, regulatory compliance, and product portfolios. Corporate strategies, R&D activity, and collaboration history were sourced from annual reports and company websites, while peer-reviewed literature from Emerald Insight, EBSCOhost, PubMed, and ScienceDirect informed the development of evaluation criteria. Market insights were supplemented using recognized industry reports such as Statista, enabling triangulation across technical, strategic, and financial dimensions.

3.4 Data Analysis

For analyzing the 44 selected companies, a multi-framework approach was employed, integrating both quantitative and qualitative aspects. A structured Partner Evaluation Framework based on the literature summarized in Table 1, was used to assess companies. The framework, presented in Table 2, evaluated firms across four dimensions: Strategic Fit, Operational Fit, Relational Fit, and Financial and Risk Profile.

Table 2 Partner Evaluation Framework for Potential Partner Selection

Dimension	Key Indicators
Strategic Fit	Market alignment, capabilities, portfolio alignment
Operational Fit	Technology, regulatory compliance
Relational Fit	Reputation, collaboration willingness, cultural fit
Financial Profile	Financial Stability, risk profile

From the final sample of 44 companies, five firms were shortlisted using the Partner Evaluation Framework. The evaluation was conducted in two sequential stages: an initial screening for eligibility and strategic relevance, followed by a detailed comparative assessment.

Stage One:

In Stage One, all 44 firms were screened for baseline eligibility and strategic relevance, resulting in the exclusion of 29 firms. Details of all 44 firms, including those excluded at this stage, are provided in Appendix 02. Specifically, ten firms were excluded as FDF-only

manufacturers either due to the absence of injectable manufacturing or the lack of compliant injectable facilities. A further four firms were removed due to insufficient regulatory filings, reflecting weak regulatory depth and limited global market readiness. Three firms were excluded due to regulatory compliance issues, including suspended CEPs, EU-GMP non-compliance, or formal warning letters. Additionally, eight firms were excluded where anti-infectives were present but predominantly antiviral or antiparasitic or otherwise misaligned with Company X's anti-infective strategy. Finally, four firms were excluded due to capability-related misalignment, including firms operating through EU subsidiaries. Following this screening, 15 firms remained eligible for detailed comparative evaluation.

Stage Two:

In Stage Two, the remaining 15 firms were subjected to an in-depth comparative assessment using the Partner Evaluation Framework (Table 2). Although all firms met the minimum eligibility requirements established in earlier filters, comparative analysis revealed meaningful differences in the depth and strength of performance across evaluation dimensions.

Of the 15 firms, ten were excluded due to relative underperformance in one or more critical areas. Four firms (Harman Finochem, Cohance Life Sciences, Lee Pharma, and Innovare Labs) demonstrated lower anti-infective specialization, reducing their strategic relevance to Company X. Two firms (Kopran Limited and FDC Limited) were excluded due to comparatively weaker regulatory depth, reflected in a lower number of active USDMFs relative to peer candidates. Three firms (Maithri Drugs, Chromo Laboratories, and Sekhmet Pharmaventures) exhibited constraints related to financial transparency, operational scale, and ownership structure, including private ownership and limited public financial disclosure, increasing partnership risk. One firm (Honour Lab) was excluded due to limited mutual benefit, given its positioning within the Hetero Group.

A staged, comparative approach was used to select partners, ensuring that final selection was based on relative strategic strength among already qualified firms rather than solely on meeting minimum inclusion criteria, consistent with best practice in strategic partner selection research. This structured two-stage process resulted in the identification of five firms demonstrating the strongest alignment with Company X's strategic priorities, regulatory expectations, and operational requirements.

The final five firms, Orchid Pharma, Concord Biotech, Alivus Life Sciences, Virchow Group, and Shamrock Pharmachemi, consistently outperformed peers in terms of regulatory depth, anti-infective portfolio strength, and overall strategic alignment. Final ranking and selection were informed by Suitability, Acceptability, Feasibility (SAF) scores and Partner Scorecard outputs, enabling systematic comparison of the combined X-partner configurations across the five shortlisted candidate firms.

3.5 Development of evaluation tools for top five candidates

The Partner Scorecard and SAF model from Johnson et al. (2020) were applied simultaneously to rank the top five firms derived from the evaluation framework, combining quantitative weighted scoring with qualitative assessment across strategic, operational, relational, and financial dimensions. A SWOT analysis complemented this, interpreting each potential X-partner alliance's capabilities, strengths, and weaknesses to deepen understanding beyond numerical scores and assess alignment with X Company.

The Partner Scorecard was adapted from the Balanced Scorecard (BSC) with integrated CSR principles (Thanaraksakul *et al.*, 2009) and aligned with literature on partner evaluation (Table 1). It evaluated financial strength, strategic alignment, operational capability, geographical access, regulatory compliance, cultural fit, R&D capability, reputation, management attitude, and CSR at the partnership level. Weights were assigned based on BSC-CSR principles and prior literature (Table 1), with Regulatory Strength & Reputation, Manufacturing Capability & Operational Reliability, Market Expansion Potential & Global Reach, and Strategic Fit each receiving 15% (60% in total), reflecting their critical importance in the potential partnership's success. The remaining 40% was allocated to R&D Capabilities, Financial Stability, Cultural Compatibility, Risk-sharing, and Sustainability & Ethical Practices, with the latter two weighted at 5% each, ensuring a balanced evaluation that prioritizes strategic and operational factors while incorporating relational and ethical considerations (Festel *et al.*, 2014; Thanaraksakul *et al.*, 2009). The developed Partner Scorecard, including evaluation criteria, weightings, is presented in Appendix 03.

The SAF analysis was constructed by adopting the feasibility criteria presented in Cadle (2010). The Suitability assessment incorporated strategic fit, market conditions, regulatory expectations, timeliness, competencies and process compatibility between X Company and each shortlisted partner. Acceptability considered organizational fit, cultural fit, and risk

exposure, and scalability at the alliance level. Feasibility drew from the technological capability, financial strength, return on investment, positive cash flow of the combined partnership configuration.

The SAF analysis criteria:

- Suitability: strategic fit, market conditions, regulatory expectations, timeliness, competencies, and process compatibility
- Acceptability: organizational fit, cultural fit, risk exposure, and scalability
- Feasibility: technological capability, financial strength, return on equity, positive cash flow

A five-point scoring system was applied across the SAF analysis, Partner Scorecard, and survey, ensuring methodological consistency. This approach enabled structured comparison of strategic, operational, relational, and financial factors across all evaluation tools. Although primary survey responses were ultimately not collected, the consistent use of five-point scales across instruments preserved comparability within the evaluation framework.

Ethical standards including informed consent, confidentiality, anonymity, and responsible handling of secondary data were upheld, enhancing credibility of the study. Rather than solely representing a limitation, the low response rate itself provides insight into the realities of B2B pharmaceutical research. It underscores the value of purposive sampling, secondary data triangulation, persona-based evaluation, and a structured, multi-method evaluation framework in generating reliable findings despite limited primary data.

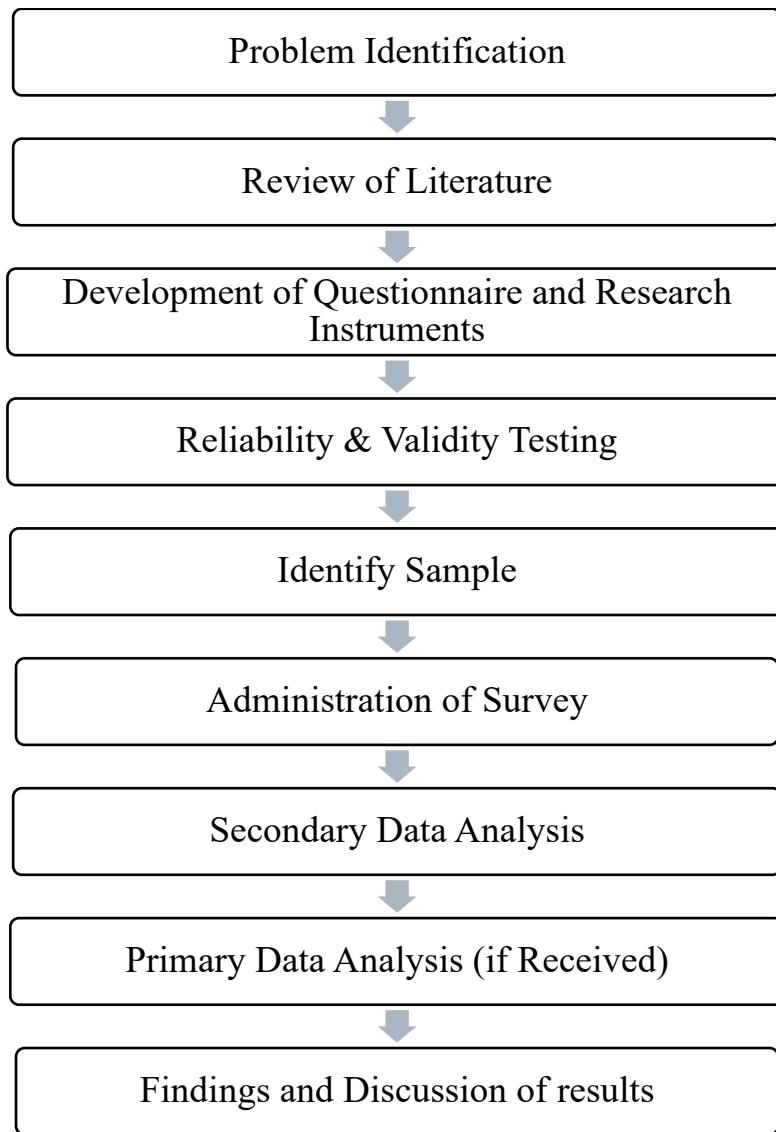


Figure 2 The Research Flow Diagram

04. Findings and Discussion

4.1 Environment Analysis

This section presents the research findings. X company's situation was assessed via SWOT analysis, followed by a PESTEL analysis. To meet the research objectives, both macro- and micro-environmental factors relevant to X's potential engagement in India were examined. The PESTEL analysis identified broader risks and opportunities, while Porter's Five Forces evaluated competitive pressures and profitability conditions in the Indian pharmaceutical industry.

4.1.1. SWOT of X Company after Reorientation

Business decisions reveal X's strong capabilities as well as critical constraints. The company is a global leader in anti-infective, critical care APIs. It serves a large B2B customer base with a strong global presence, supported by manufacturing sites, as well as an FDF facility and an R&D center. However, X faces substantial challenges: a narrow pipeline, high manufacturing costs relative to Asian competitors, heavy dependence on mature low-margin products, limited differentiation in a highly competitive market, and financial constraints (X Company, 2024). Opportunities lie in the rising global demand for anti-infectives driven by the AMR agenda, potential partnerships with Indian manufacturers, and expansion into adjacent critical care therapeutic areas. However, threats remain in the form of intensified Asian competition, regulatory complexities, product market volatility, and global supply chain vulnerabilities.

4.1.2. PESTEL Analysis

The Indian pharmaceutical environment presents substantial macro-level opportunities and risks for X. Politically, India maintains a stable environment and permits 100% FDI in greenfield (new) and 74% in brownfield (existing) projects in the pharmaceutical sector (Shenoy & Shailashri, 2022) which is particularly relevant for the pharmaceutical sector, as foreign firms can fully own new manufacturing or R&D facilities, while investments in existing plants often require a local partner. However, the expansion of price-controlled drugs introduces regulatory constraints (Surana & Bankar, 2021). Economically, the sector is

projected to reach \$130B by 2030 and \$450B by 2047, supported by low manufacturing and labour costs and high FDI inflows (Shenoy & Shailashri, 2022). Conversely, storage and transport limitations and high taxation create operational challenges (Kuchey et al., 2016). Additionally, the global biotechnology market valued around US\$1.38 trillion in 2023 and expected to exceed US\$4.25 trillion by 2033 signals growing investment flows into biopharmaceutical R&D, personalized medicine, and sustainable bio-manufacturing, further shaping India's economic landscape (Concord, 2025). At the international level, recent U.S. tariff measures targeting some Indian exports pose an external economic risk by potentially compressing export margins. Social factors, including a growing elderly population expected to reach 19.5% by 2050 (Surana & Bankar, 2021), increasing health awareness, lifestyle-related diseases, and an expanding middle class (Sanjana & Shailashri, 2022), contribute to rising pharmaceutical demand. The availability of a large pool of skilled pharmacists further strengthens industry capability (Kuchey et al., 2016).

Technologically, India benefits from strong process development and drug discovery capabilities (Kuchey et al., 2016), as well as increasing adoption of advanced technologies such as AI (Sanjana & Shailashri, 2022). Environmental considerations include the classification of pharmaceutical manufacturing as a red-category industry (Sanjana & Shailashri, 2022) and the push for carbon-neutral initiatives adopted by multinational firms (Surana & Bankar, 2021). Legally, India follows Trade-Related Aspects of Intellectual Property Rights (TRIPS)-aligned Intellectual Property regulations and operates under the amended Patents Act (2005), which grants a 20-year product patent term (Ramani & Maria, 2005). While regulatory approvals are relatively fast and cost-efficient (Sanjana & Shailashri, 2022), multi-framework compliance requirements pose significant burdens (Biswas et al., 2020). Further, The U.S. Bio-Secure Act, which limits reliance on certain foreign biotech companies, particularly China and the China-Plus-One policy, which encourages sourcing outside China, both push companies to diversify supply chains and tighten checks on biological imports and exports, raising compliance requirements for foreign partners. Overall, with global biotech expansion, shifting trade policies, and growing CDMO demand India offers cost advantages, skilled talent, and supportive regulatory pathways, but firms must carefully navigate compliance burdens, taxation, logistics constraints, and price control policies.

4.1.3 Porter's Five Forces Analysis

Competitive dynamics in India's pharmaceutical sector are complex. Rivalry among existing competitors is high, driven by a fragmented market (Sanjana & Shailashri, 2022) and strong competition from global low-cost producers, especially in China (Rathore et al., 2023). Key domestic competitors include Dr. Reddy's, Aurobindo, Biocon, Concord, and Sun Pharma. In addition, the China-Plus-One strategy is intensifying competition. The threat of substitutes is low to moderate, as there are limited direct substitutes for hospital-grade anti-infective APIs. Alternatives include other antimicrobials, biosimilars, and lower-cost Chinese APIs. The threat of new entrants is low, due to high capital investment needs, significant R&D requirements, complex licensing processes, and patent protections.

The bargaining power of buyers is moderate to high, as B2B and institutional customers are highly price sensitive. The bargaining power of suppliers is also moderate to high, driven by reliance on imported raw materials. Approximately 35% of fermentation-based APIs are sourced from China (Alivus Life Science, 2025), while around 43% of raw material inputs come from China (The Economic Times, 2024). A study by Rathore et al. (2023) found that competitive rivalry and the threat of substitutes are the most significant predictors of firm performance in the pharmaceutical industry, while the threat of new entrants, supplier power, and buyer power have comparatively limited influence.

4.1.4 Risk-Opportunity Assessment

The PESTEL and Five Forces assessment highlights four main risk types: regulatory, operational, competitive, and environmental, which align with X's existing weaknesses while revealing mitigation opportunities. Regulatory risks, including price controls, TRIPS-linked IP requirements, and complex compliance, increase costs but can be mitigated through India's fast approvals and supportive government, accessible via partnerships.

Operational risks, such as transport, storage, high taxation, and reliance on imported intermediates (43% from China), reinforce X's cost and supply vulnerability. Yet India's low manufacturing/labor costs, strong process development, and advanced technologies offer cost-saving, stabilize supply chains, and compensate for limited R&D. Additionally, the China-

Plus-One strategy, encouraging companies to diversify sourcing beyond China, and India's Bio-Secure Act, promoting local, compliant API production, increase the value of domestic partners, offering X opportunities for reliable, high-quality supply. By partnering with such Indian firms, X can ensure reliable production, faster approvals, and access to a compliant supplier network, improving cost-efficiency.

Competitive risks arise from fragmented Indian players, low-cost Chinese producers, and buyer power, emphasizing X's dependence on low-margin products and a constrained pipeline. However, India's growing domestic demand from ageing populations, lifestyle diseases, and an expanding middle-class, combined with recent US import tariffs, creates an opportunity: Indian API manufacturers may increasingly target EU and other regulated markets instead of the US, offering X access to alternative high-value markets.

Environmental risks, associated with India's red-category status and rising sustainability requirements, challenging fermentation production, but can be mitigated by partnerships with compliant firms and alignment with carbon-neutral initiatives. Cultural differences can also be addressed via cross-cultural alignment. Overall, India offers multiple opportunities including cost efficiency, technological advancement, skilled talent, fast approvals, rising demand, and a growing CDMO sector to offset risks and strengthen X's long-term positioning.

4.2. Partner Screening and Ranking Results

From the sample of 44 companies, five firms were shortlisted for potential partnership with Company X, based on the Partner Evaluation Framework. These firms, namely Orchid Pharma, Concord Biotech, Alivus Life Sciences, Virchow Group, and Shamrock Pharmachemi, demonstrated the strongest alignment with X's strategic priorities, regulatory expectations, and operational requirements. The selection process integrated Strategic Assessment Framework (SAF) scores and Partner Scorecard outputs, enabling systematic comparison across regulatory depth, capabilities, and overall strategic fit. For the purpose of detailed strategic evaluation, SAF, Partner Scorecard, and SWOT analyses were conducted for the top three candidates with sufficient publicly available information. The fourth- and fifth-ranked firms, while included in the final shortlist based on their SAF and Partner Scorecard performance, were not subjected to SWOT analysis due to private ownership structures, limited financial transparency, and restricted availability of publicly disclosed strategic and financial information. Conducting

SWOT analysis under such conditions would have increased analytical uncertainty and interpretive risk. Accordingly, the top three candidates were further analyzed using SWOT methodology. Details of all 44 companies, including those excluded at each stage and are provided in Appendix 02.

4.2.1. Case Study 01- Orchid Chemicals & Pharmaceuticals Limited

Orchid Pharma, established in 1992 and now part of the Dhanuka Group, is a leader in cephalosporins. Following its restructuring under the Dhanuka Group, the company strengthened its governance and strategic focus, operating as an Export Oriented Unit (EOU) that produces high-quality human and veterinary APIs. Orchid Pharma has a robust manufacturing base and a strong global export presence, positioning itself as a trusted partner in the anti-infective segment. Its therapeutic focus includes anti-inflammatory, central nervous system (CNS), cardiovascular (CVS) products, nutraceuticals, as well as other oral and sterile formulations (Orchid Pharma Limited, 2025). Building on Orchid Pharma's strong manufacturing base, regulatory approvals, and therapeutic focus, the following SAF and Partner Scorecard analyses evaluate the strategic potential of a partnership with X.

4.2.1.1.SAF Analysis and Partner Scorecard

SAF Analysis

Suitability (Score: 5/5)

The X-Orchid partnership demonstrates an exceptionally high strategic fit. Both companies complement each other in anti-infective and critical-care therapies. Orchid contributes injectable cephalosporins, antibacterial and antifungal APIs, and hospital-critical products, including cardiovascular, CNS, and anti-inflammatory segments. X provides global market access, regulatory expertise, B2B distribution, and commercialization capabilities. Orchid brings vertically integrated capabilities, including three R&D centers, two API facilities (including India's largest cephalosporin complex at Alathur), and three FDF sites. Its injectable facility, including a lyophilization/vial unit for Cefiderocol under sub-license with GARDP, and a downstream plant at Alathur to strengthen its API base, are currently under construction

(Orchid Pharma Limited, 2025). Orchid also holds USFDA and EUGMP approvals, 48 US DMFs, 15 CEPs, 8 JDMFs, and 24 patents (Orchid Pharma Limited, 2025).

Its fermentation capabilities via the 7-ACA project, producing 7-Aminocephalosporanic Acid, a key intermediate in cephalosporin production (Orchid Pharma Limited, 2025), enable co-development and the creation of new or improved cephalosporin APIs, expanding both companies' hospital-critical portfolio. X can leverage its regulatory expertise, global commercial network, and B2B distribution to bring these APIs to new markets and diversify revenue streams. The partnership leverages Orchid's 102 APIs (USD 105 million revenue) and the under commercialized Enmetazobactam API (EXBLIFEP, USD 250 million FDF value) (Orchid Pharma Limited, 2025) to unlock global growth opportunities. X can supply its APIs under long-term agreements to Orchid's upcoming injectable FDF facility, while Orchid gains reliable, regulatory-compliant API supply for regulated markets. Predictable demand supports X's production planning and capacity utilization. In parallel, X can leverage Orchid's cost-efficient API manufacturing capabilities, including the downstream plant, to optimize production costs. Orchid's Antimicrobial Solutions (AMS) division implements stewardship programs across hospitals, with projected turnover of Rs 300 crore by FY28 (Orchid Pharma Limited, 2025), which X can support through high-quality anti-infective API supply, aligning the partnership with global AMR stewardship expectations.

Significant opportunity exists for Enmetazobactam API licensing, critical for antibiotics targeting urinary tract and serious infections. Orchid is pursuing multiple regional licensing partners (U.S., Europe, Latin America, Southeast Asia), with at least one deal expected within 12 months (Orchid Pharma Limited, 2025). Although Orchid believes that building its own sales teams would require larger investments and take longer (Orchid Pharma Limited, 2025), centralizing licensing and regulatory coordination under X reduces operational complexity, lowers partner management costs, and accelerates global market access. Analyst commentary highlights underperformance of ADVANZ, the current European license holder (Orchid Pharma Limited, 2025), reinforcing Europe's commercial potential and X's positioning as a trusted, low-risk, B2B-aligned partner.

Acceptability (Score: 4.5/5)

The partnership exhibits high acceptability due to complementary organizational cultures and prior licensing and co-development experience (including EXBLIFEP). Long-term supply arrangements for injectable APIs, including those linked to AMS programs, reduce operational uncertainty and enhance stakeholder confidence. Risks exist from Orchid's reliance on a limited set of critical raw-material suppliers and regulatory complexity across multiple regions. These are mitigated via robust joint risk-management frameworks, governance committees, and phased commercialization strategies.

Orchid Bio-Pharma Ltd provides early-stage biotech co-development opportunities aligned with X's strategic goals, supporting scalability and long-term collaboration. Analyst commentary on ADVANZ underperformance reinforces X's strategic advantage in Europe, supporting a centralized licensing structure and enhancing partner and shareholder acceptance. No compliance issues have been reported for either company, strengthening stakeholder confidence.

Feasibility (Score: 4.5/5)

The partnership is operationally and financially feasible. Orchid operates three R&D centers, two API facilities with USFDA and EUGMP approvals, and has CRAM experience. A new injectable FDF plant and downstream API facility are under construction. Predictable demand from long-term supply agreements allows X to plan production and capacity utilization efficiently, while Orchid benefits from regulatory-compliant, cost-efficient API supply.

Financially, Orchid is stable with 2025 revenue of EUR 99.8 million, net profit of EUR 10.78 million, net profit margin of 11.55%, ROE of 8.04%, current ratio of 3.31, and debt-equity ratio of 0.13. Combined with X's global distribution network and regulatory expertise, this financial and operational base supports robust execution feasibility. Co-development opportunities via the 7-ACA fermentation project, AMS programs, and Enmetazobactam licensing create diversified revenue streams while enabling phased expansion into adjacent hospital-critical segments.

Overall, the partnership scores Suitability = 5, Acceptability = 4.5, Feasibility = 4.5, reflecting strong strategic alignment, high organizational fit, and operational and financial viability. It

leverages Orchid's regulatory, R&D, and API capabilities with X's global market reach, commercialization expertise, and B2B operations. The SAF assessment confirms robust synergy, revenue growth potential, and low-risk execution, strategically expanding hospital-critical and anti-infective portfolios for both companies.

Total score – 4.7/5

Table 3 Anti-infectives portfolio of Orchid
Source: Orchid Pharma Limited (2025)

CEPHALOSPORINS - ORALS



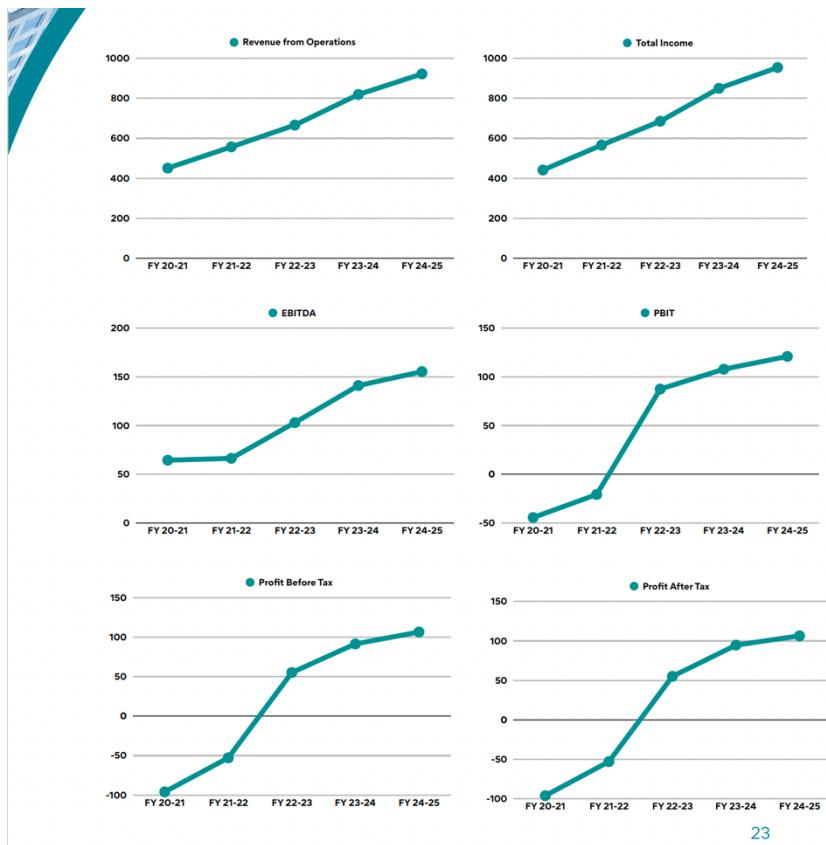
Product	Pharmacopeia	US DMF	EDMF	COS	Others
Cefazolin acid(Intermediate)	US	✓	✗	✗	Applicant part DMF
7-ADCA(Intermediate)	✗	✓	✗	✗	✗
Cefuroxime Acid(Intermediate)	✗	✓	✗	✗	✗
CAVA(Intermediate)	✗	✓	✗	✗	✗
Cefalexin	USP/EP/BP/JP	✓	✓	✓	Applicant part DMF as per COS
Cefadroxil	USP/EP/BP/JP	✓	✓	✓	Applicant part DMF as per COS
Cefradine	USP/EP / BP	✗	✓	✓	Applicant part DMF as per COS
Cefixime	USP/EP / BP	✓	✓	✓	Canada DMF/JDMF/Applicant part DMF as per COS
Cefuroxime Axetil (Amorphous) Chemical	USP/EP / BP	✓	✓	✓	Applicant part DMF as per COS
Cefuroxime Axetil (Crystalline)	USP / EP	✓	✓	✗	✗
Cefuroxime Axetil (Crystalline) (Enzymatic)(For Ranbaxy)	USP/EP	✓	✓	✗	✗
Cefprozil	USP/EP	✓	✓	✗	✗
Cefditoren Pivoxil (Amorphous)	In-house/USP/JP	✓	✗	✗	Applicant part DMF
Cefdinir(FORM -A)	USP / JP	✗	✗	✗	JDMF
Cefdinir(FORM -B)	USP	✓	✗	✗	✗
Cepodoxime Proxetil	USP / EP / JP	✓	✓	✗	JDMF
Cefepime Hydrochloride	USP	✓	✗	✗	✗
Ceftibuten	In-house/JP	✗	✗	✗	TIP/DMF
Cefcapene Pivoxil Hydrochloride	In-house/JP	-	-	✗	TIP
Ceftamet Pivoxil	In-house/JP	-	-	✗	✗

US DMF-US Drug Master File
COS- Certificate of Suitability
USP- United States Pharmacopeia
JP-Japanese Pharmacopeia
TIP- Technical Information Package
EP- European Pharmacopeia

CEPHALOSPORINS - INJECTABLES



Product	Pharmacopeia	US DMF	EDMF	COS	Others
Arginine (Sterile Bulk)	US/JP/EP	✓	✗	✗	Applicant part DMF
Sodium Carbonate (Sterile)	US/JP/EP	✓	✗	✗	✗
Cefotaxime Sodium (Sterile)	USP/EP/BP/JP	✓	✓	✓	Applicant part DMF as per COS
Ceftriaxone Sodium (Sterile)	USP/EP/JP	✓	✓	✓	Canada DMF/JDMF/Applicant part DMF as per COS
Ceftazidime Pentahydrate (sterile)	USP/EP/JP	✓	✗	✓	Applicant part DMF as per COS
Ceftazidime Pentahydrate with Sodium Carbonate for Injection	USP/EP/BP/JP	✓	✓	✓	Applicant part DMF as per COS
Cefazolin Sodium (Sterile)	USP / EP/BP/JP	✓	✓	✓	Canada DMF/JDMF/Applicant part DMF as per COS
Cefoxitin Sodium (Sterile)	USP / EP/BP	✓	✓	✓	Applicant part DMF as per COS
Cefepime Hydrochloride (Sterile)	USP / EP/JP	✓	✗	✓	Canada DMF/JDMF/Applicant part DMF as per COS
Cefepime + Arginine (Sterile)	USP / EP/JP	✓	✓	✗	Canada DMF/JDMF
Cefpirome Sulphate	In-house/JP	✗	✗	✗	Applicant part DMF
Cefuroxime Sodium (Sterile)	USP / EP	✗	TIP	✗	Australia DMF
Ceforanide + L-Lysine	In-house/USP	✗	✗	✗	Applicant part DMF
Cefalothin Sodium Buffered (Sterile)	USP/EP	✗	TIP	✗	Australia DMF
Ceftizoxime Sodium (Sterile)	USP	✗	✗	✗	Applicant part DMF
Cefoperazone Sodium (Sterile)	In-house/JP / EP	TIP	TIP	✗	✗
Cefotiam Hexetil	In-house/JP	-	-	✗	✗
Cefotiam Hydrochloride	In-house/JP	-	-	✗	✗
Cefozopran Hydrochloride	In-house/JP	-	-	✗	✗
Sterile Processing Details of Phase-18, Alathur, India (Type-V USDMF)	-	✓	✗	✗	✗



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Figure 3 Financial Results of Orchid Pharma

Source: Orchid Pharma Limited (2025)

Based on the above SAF analysis, the Partner Scorecard results for the combined X-Orchid partnership are presented below.

Partner Scorecard

Criteria	Weight (%)	Score (1-5)	Weighted Score
Regulatory strength & reputation	15	5	0.75
Manufacturing capability & operational reliability	15	5	0.75
R&D capabilities	10	4.5	0.45
Market Expansion Potential & Global Reach	15	5	0.75
Strategic fit and portfolio complementarity	15	5	0.75
Financial stability	10	5	0.5
Cultural compatibility	10	4.5	0.45
Willingness to share risks & rewards	5	4.5	0.225
Sustainability & ethical practices	5	4	0.2
Total Weighted score			4.83

Weighted score = Weight x Score

Total Weighted score = Sum of Weighted Score

A weighted score of 4.83/5 shows that Orchid is an excellent partner for X. The partnership demonstrates exceptional strengths in regulatory reputation, manufacturing capability, market expansion potential, and strategic fit. Financial stability, cultural compatibility, and willingness to share risks are also strong, supporting solid operational and strategic synergy. Overall, this partnership offers robust operational, strategic, and financial alignment, making it highly attractive for X.

The following SWOT analysis evaluates the potential X-Orchid partnership, building on the SAF scorecard assessment. It highlights the key internal strengths and weaknesses of both companies, as well as external opportunities and threats. This analysis provides a structured overview of how the partnership can leverage complementary capabilities, address risks, and capitalize on strategic growth opportunities globally.

SWOT of Potential Partnership

Strengths

The X-Orchid partnership combines complementary strengths in antibacterial and anti-fungal APIs, injectable cephalosporins, and hospital-critical therapies, including cardiovascular, CNS, anti-inflammatory. Orchid contributes vertically integrated capabilities, including three R&D centers, two API facilities (including India's largest cephalosporin complex at Alathur), and three FDF sites. Its injectable facility, including a lyophilization/vial unit for Cefiderocol under sub-license with GARDP, and a downstream plant at Alathur to strengthen its API base, are under construction (Orchid Pharma Limited, 2025). Orchid's strong regulatory portfolio (48 US DMFs (30 cephalosporin; 18 NPNC), 15 CEPs, 8 JDMFs (all cephalosporins), and 24 patents) (Orchid Pharma Limited, 2025), along with EUGMP and USFDA approvals, CRAM experience, wide FDF portfolio, and 2,000 workforces, further strengthens operational robustness.

Their licensing and co-development experience, including EXBLIFEP, demonstrate strong co-development and commercialization capability. Both have strong B2B operations. The partnership creates a broad Persona Type Ib portfolio, including anti-infective, CNS, anti-

inflammatory, and cardiovascular segments. X's direct commercial presence in the U.S. offsets Orchid's closure of its U.S. subsidiaries, while Orchid's R&D capacity and profitability strengthen X's innovation and mitigate margin constraints. Both firms benefit from robust risk-management frameworks. Geographic gaps of Orchid in Nordics, Baltics, Africa, Asia, Australia, Latin America, and Central America are mitigated by X's global reach, and cost efficiencies can be realized by leveraging Orchid's facilities. No compliance issues have been reported for either firm. The partnership enables X to maintain its core anti-infective focus while strategically expanding into adjacent critical care segments.

Weaknesses

The partnership inherits shared constraints. Orchid remains dependent on a limited set of critical raw-material suppliers (Orchid Pharma Limited, 2025), creating cost and supply-chain risks. Integration of supply chains, regulatory processes, and commercial coordination between X and Orchid requires careful management, though joint risk-management frameworks can mitigate operational and regulatory complexity.

Opportunities

The partnership creates strategic opportunities for both parties. Co-development via Orchid's 7-ACA fermentation project enables creation of new or improved cephalosporin APIs, expanding hospital-critical portfolios. X can leverage its regulatory expertise, global commercial network, and B2B distribution to bring these APIs to new and under-served markets. Within the upcoming injectable FDF facility, X supplies its own APIs under long-term supply arrangements, while Orchid gains reliable, regulatory-compliant API supply for regulated markets. Predictable demand from these agreements supports X's production planning and capacity utilization. X can leverage Orchid's cost-efficient API manufacturing, including the upcoming downstream plant, to achieve production cost synergies.

Centralized licensing and commercialization of Enmetazobactam under X across Europe, the U.S., Latin America, Southeast Asia, and other markets reduces Orchid's operational complexity, investment on sales teams, and partner management costs, while generating license-related revenues, distribution margins, and long-term income for X. Analyst commentary highlights underperformance of existing license holders in Europe (Orchid Pharma Limited, 2025), reinforcing the commercial potential and positioning X as a trusted, low-risk, B2B-aligned partner. Orchid's AMS division, implementing stewardship programs

across hospitals, can be supported by X's high-quality API supply, aligning with global AMR initiatives. These avenues collectively strengthen X's constrained profitability while allowing Orchid to offset X's pressures, creating strong operational and financial synergy.

Although Orchid has 102 APIs, its API revenue is only around USD 105 million (Orchid Pharma Limited, 2025), reflecting limited global presence. Partnering with X can significantly expand revenue potential for both firms by accessing untapped market opportunities. This partnership focuses on broadening the portfolio into adjacent critical care segments through alliances with generic pharma, with minor biotech co-development opportunities via Orchid Bio-Pharma Ltd.

Threats

Potential risks include competition from Indian and global API manufacturers, regulatory complexity across multiple regions, geopolitical or raw-material supply disruptions, price volatility, and delays in commissioning the downstream plant or injectable FDF facility. Delays or challenges in licensing Enmetazobactam could impact projected revenues. Integration of operations and co-development processes between X and Orchid requires careful oversight to prevent execution gaps.

Based on the SWOT of the X-Orchid partnership, the following strategies reflect joint actions that leverage complementary strengths to capture opportunities and manage shared risks.

TOWS Strategies: X–Orchid Partnership

<p>Strength-Opportunity Strategies</p> <ul style="list-style-type: none"> • Co-development of new cephalosporin APIs via 7-ACA fermentation project to expand hospital-critical portfolio with predictable demand. • Commercialize Enmetazobactam in global markets, including Europe, Latin America, and the U.S via X with less investment by Orchid • Combine Orchid's regulatory approvals, CRAM capability, with X's global reach to enter unserved or underpenetrated markets. • Boost revenue from Orchid's 102 APIs by leveraging X's B2B commercial network and distribution capabilities. • Leverage Orchid's cost-efficient API facilities by X for cost synergies and improved margins 	<p>Strength-Threat Strategies</p> <ul style="list-style-type: none"> • Mitigate regulatory, supply chain, and geopolitical risks by combining Orchid's and X's risk-management frameworks. • Counter competitive pressure from Indian and global API players through scale and differentiated anti-infective portfolios.
<p>Weakness-Opportunity Strategies</p> <ul style="list-style-type: none"> • Use long-term supply agreements for injectable APIs (including AMS-linked APIs) to reduce dependency on a limited set of critical raw-material suppliers. • Centralize Enmetazobactam licensing and commercialization under X to reduce Orchid's operational complexity, negotiation burden, and cost of partner management. 	<p>Weakness-Threat Strategies</p> <ul style="list-style-type: none"> • Diversify sourcing and reduce supply risk through joint planning and shared supplier networks. • Phase Enmetazobactam licensing and commercialization to mitigate revenue disruption from approval delays.

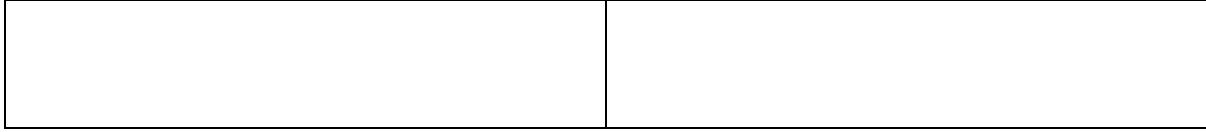


Figure 4 Global Presence of Orchid Pharma Limited
Source: Orchid Pharma Limited (2022)

4.2.2. Case Study 02- Concord Biotech Limited

Concord Biotech, incorporated in 2000, is a diversified biopharmaceutical manufacturer specializing in fermentation-based APIs and high-value niche therapies such as oncology, anti-infectives, immunosuppressants, positioning it as a strong partner. Building on Concord Biotech's strong manufacturing base, regulatory approvals, and therapeutic focus, the following SAF and Partner Scorecard analyses evaluate the strategic potential of a partnership with X.

4.2.2.1. SAF Analysis and Partner Scorecard

SAF Analysis

Suitability (Score: 5/5)

The partnership demonstrates a strong strategic fit with X's reorientation focus on B2B supply and anti-infectives. Concord's complementary capabilities, fermentation expertise, 30+ APIs (including antibacterial and antifungal), vertical integration, and partial capacity utilization allow X to expand its portfolio into existing and under-commercialized APIs without requiring significant capital investment in new production infrastructure. The partnership leverages favorable market conditions, as there is high demand for reliable API supply in Europe, the Middle East, Africa, and Asia. Regulatory compliance is already strong (USFDA, EU-GMP), reducing entry barriers, and the partnership timeline aligns with X's medium-term portfolio expansion plans, including the planned 10+ API pipeline. Concord's operational competencies and alignment with X's B2B commercialization capabilities make this partnership highly compatible with X's processes. Overall, the collaboration shows strong strategic alignment with X's therapy focus in anti-infectives and critical-care segments, justifying a maximum suitability score.

Acceptability (Score: 3.2/5)

From an organizational and cultural perspective, the partnership is moderately acceptable. Both companies have extensive experience in B2B operations, regulatory compliance, and managing operational complexity. The partnership leverages Concord's low-cost manufacturing and X's global distribution network, creating mutual value and scalability. Low-cost manufacturing helps offset X's cost pressures while improving Concord's capacity utilization. However, as

Concord is also a competitor in overlapping APIs, there is an increased competitive risk, slightly reducing acceptability. Risk exposure exists in the form of co-opetition on overlapping APIs, regulatory tightening, and potential delays in approvals for the new injectable plant. However, clearly defined market segmentation, licensing agreements, and governance structures can mitigate these risks. Concord's robust risk management framework, including an established risk management committee, further supports partnership stability. No compliance issues have been reported for either firm. Cultural differences and coordination challenges remain, but are manageable under structured governance.

Feasibility (Score: 5/5)

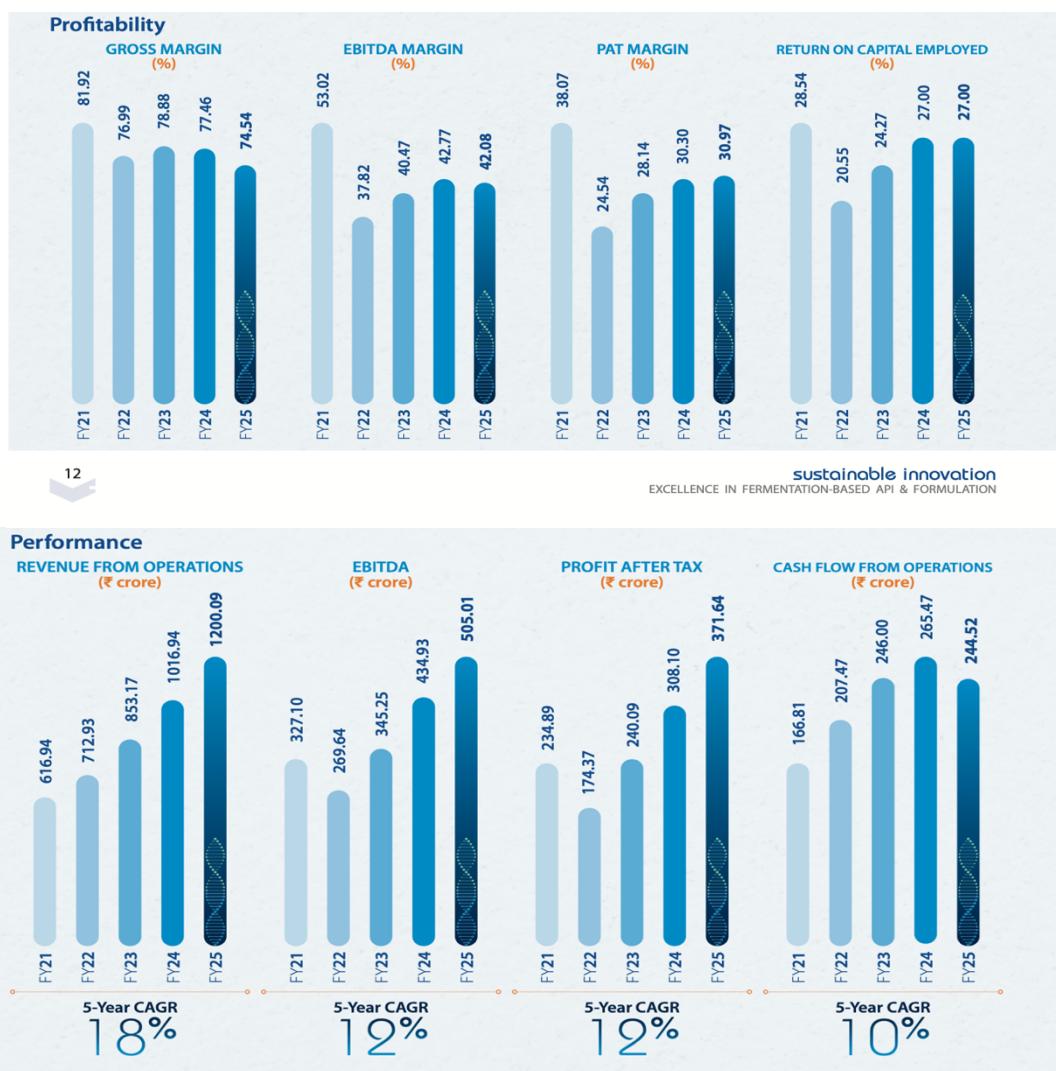
Technologically, the partnership is highly feasible. Concord has vertically integrated manufacturing capabilities across fermentation, injectables, and sterile products, supported by robust R&D and regulatory expertise. Financially, X benefits from low-cost production access without upfront capital investment, while Concord gains predictable revenue through long-term supply agreements, supporting cash flow and ROE. The planned 10+ API pipeline ensures a medium-term revenue stream, reducing operational and financial risk. Financial indicators further confirm feasibility. Concord's 2025 financials, converted from INR to EUR using the exchange rate at 31.03.2025 (1 INR = 0.01082), show revenue of EUR 129.84 million, profit of EUR 40.2 million, a net profit margin of 31%, ROE of 22%, a current ratio of 6.17, and a debt-to-equity ratio of 0.00 (Concord, 2025; Exchange-rates.org, 2025). These metrics indicate strong liquidity, financial stability, and low leverage, supporting the partnership's execution feasibility without additional financial strain.

Total Score – 4.4/5

The SAF analysis shows that Concord is a strong, moderately low-risk, high-value partner, combining robust technological and regulatory capability with solid financial strength and operational synergy. Its strong strategic and organisational fit with X, together with high execution feasibility, supports a valuable collaboration, although competitive overlap reduces overall acceptability. Overall, the partnership scores 4.4/5, positioning Concord to drive growth and reduce costs for both firms while requiring careful management of competitive risks.



Figure 5 Anti-infectives Portfolio of Concord
Source: Concord Biotech (2025)



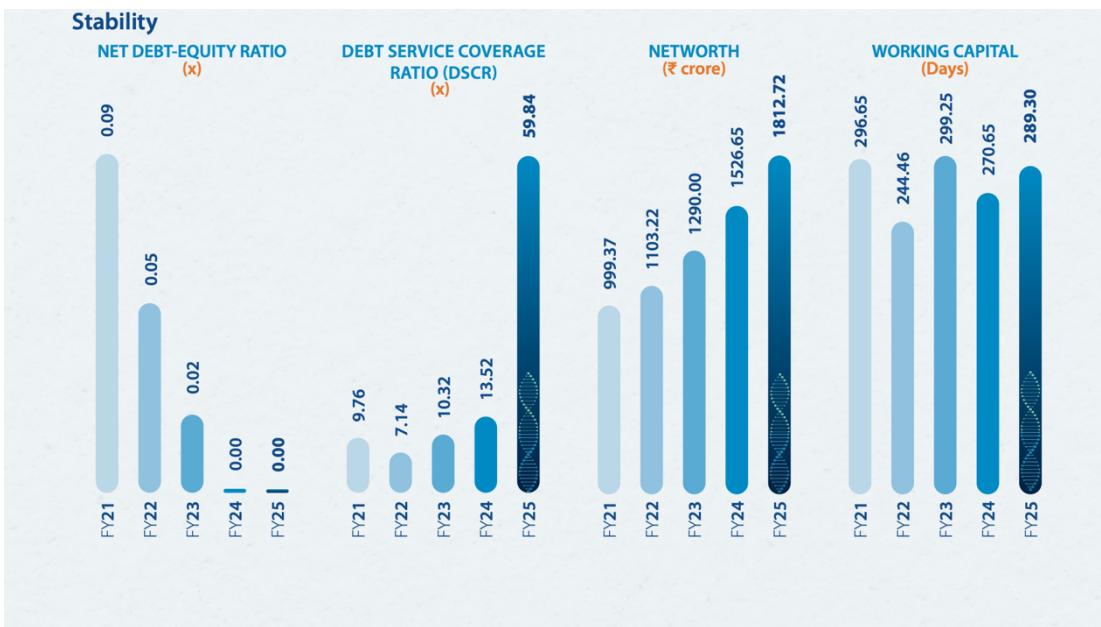


Figure 6 Financials of Concord
Source: Concord Biotech (2025)

Based on the above SAF analysis, the Partner Scorecard results for the combined X-Concord partnership are presented below.

Partner Scorecard

Criteria	Weight (%)	Score (1–5)	Weighted Score
Regulatory strength & reputation	15	5	0.75
Manufacturing capability & operational reliability	15	5	0.75
R&D capabilities	10	5	0.5
Market Expansion Potential & Global Reach	15	4.5	0.675
Strategic fit and portfolio complementarity	15	5	0.75
Financial stability	10	5	0.5
Cultural compatibility	10	3.8	0.38
Willingness to share risks & rewards	5	4	0.2
Sustainability & ethical practices	5	4	0.2
Total Weighted score			4.71

Total weighted score of 4.71/5.00 confirms that Concord Biotech represents a strong, moderate-risk strategic partner for X, with very high alignment across suitability and feasibility dimensions. Minor deductions arise due to competitive overlap and cultural alignment, but these are manageable through structured governance and defined risk-sharing mechanisms. Overall, Concord offers a high-value partnership capable of supporting portfolio expansion, operational efficiency, and strategic growth.

The following SWOT analysis evaluates the potential X-Concord partnership, building on the SAF scorecard assessment. It highlights the key internal strengths and weaknesses of both companies, as well as external opportunities and threats. This analysis provides a structured overview of how the partnership can leverage complementary capabilities, address risks, and capitalize on strategic growth opportunities globally.

SWOT of Potential Partnership

Strengths

The potential partnership demonstrates strong strategic alignment and complementary capabilities. Concord brings deep expertise in critical-care and 30+ fermentation-based APIs, including six APIs overlapping with X's portfolio. Its broader portfolio comprises 30 APIs, including antibacterial and antifungal APIs, supported by a 1,700-strong workforce (Concord Biotech, 2025). Its vertically integrated model, spanning fermentation APIs, injectables, sterile products, and CDMO services, together with backward integration into KSMs, ensures cost efficiency and supply reliability. Concord's four manufacturing units (two API and two formulation sites including injectables), strong B2B operations, ongoing R&D, robust risk management, and regulatory approvals (USFDA, EU-GMP) further enhance operational robustness. The partnership strongly aligns with Persona Type Ib, given Concord's diversified API portfolio spanning oncology, immunosuppressants, and anti-infectives, which complements X's focus and supports portfolio broadening beyond core anti-infective segments.

Partial capacity utilization at Concord allows production scaling, enabling Concord to generate additional revenue by producing more APIs and expand CDMO services, while X can commercialize these APIs globally, ensuring reliable supply to meet market demand and creating operational and financial synergy for both partners. Concord's low-cost manufacturing allows X to reduce production costs, while Concord benefits from guaranteed demand and improved capacity utilization, reinforcing mutual operational efficiency and profitability.

No compliance issues have been reported for either firm. The partnership allows Concord to leverage X's global regulatory expertise, commercial scale, and distribution network, addressing its limited global presence in Europe, the Middle East, and Asia, while turning partial competitive overlap into collaborative advantages.

Weaknesses

Some fermentation-based APIs overlap between the two companies, creating potential competition within the partnership, although such co-opetition is common in alliances (Bengtsson and Kock, 2000). By clearly defining roles, responsibilities, and market boundaries, and using strategies such as market segmentation or designating each company as a secondary supplier, this co-opetition can be managed to create mutual value. Cultural and regulatory differences also require careful management to prevent inefficiencies.

Opportunities

The partnership creates extensive strategic opportunities. Concord's limited global commercial reach, partial capacity utilization, and recent EU supply disruptions can be addressed via X's established presence. The partnership can accelerate Concord's expansion in Europe, where X can act as a second-source supplier, protecting Concord's longstanding EU customer relationships, especially after recent Nystatin supply disruptions (Concord Biotech, 2025). Concord's limited global presence (approximately USD 110 million API revenue in FY2025 despite 30 APIs) creates scope for revenue growth through under commercialized APIs and X's access in new and underserved markets, including the Nordics, Baltics, Middle East, Africa, and Asia. The new injectable plant is expected to receive approvals promptly, with X supplying APIs to ensure reliable production.

Because Concord Biotech currently operates with partially unused manufacturing capacity, has only one major commercial CDMO project, and engages in a limited number of smaller MNC collaborations, it can take on additional manufacturing work without significant new investment. Through a partnership with X, Concord can use this unused capacity to manufacture APIs supplied and commercialized by X, as well as APIs required by X's global customers. This immediately increases Concord's production volumes, improves utilization of its fermentation facilities, and enables it to expand its CDMO activities from a single project to multiple recurring programs, resulting in more stable and predictable manufacturing revenues.

At the same time, X benefits by gaining low-cost, reliable access to high-quality fermentation manufacturing without investing in its own production facilities. X earns revenue by selling APIs directly to its global customers under long-term supply agreements. Concord's

partnership-driven model, active engagement with innovators and generics, and its search for new markets such as EU, Latin America (driven partly by U.S. tariffs) further support growth (Concord Biotech, 2025). In addition, Concord has a planned pipeline of more than 10 APIs over the next 5–7 years, which can directly help reduce X's pipeline gap and expand its medium-term portfolio. Through the partnership, X can commercialize these APIs globally by leveraging its regulatory expertise, B2B distribution network, and established customer relationships, while Concord benefits from reduced commercial burden and faster market access.

Most importantly, this partnership aligns best with the direction of Biotech Partnership for Novel Anti-Infectives, as it focuses on closing X's pipeline gap, co-developing and commercializing Concord's anti-infective APIs, leveraging X's global regulatory and distribution capabilities, and strengthening both companies' positions in the critical-care anti-infectives market.

Threats

Regulatory tightening in Europe, price controls, and supply-chain disruptions could affect operational continuity. Geopolitical risks, tariff impacts, and market concentration threaten partnership stability. Co-opetition on overlapping APIs remains a risk if governance, market segmentation, and collaboration agreements are not carefully structured. Delays in obtaining approvals for the new injectable plant could impact projected revenue and growth plans.

Diversified Customer Base

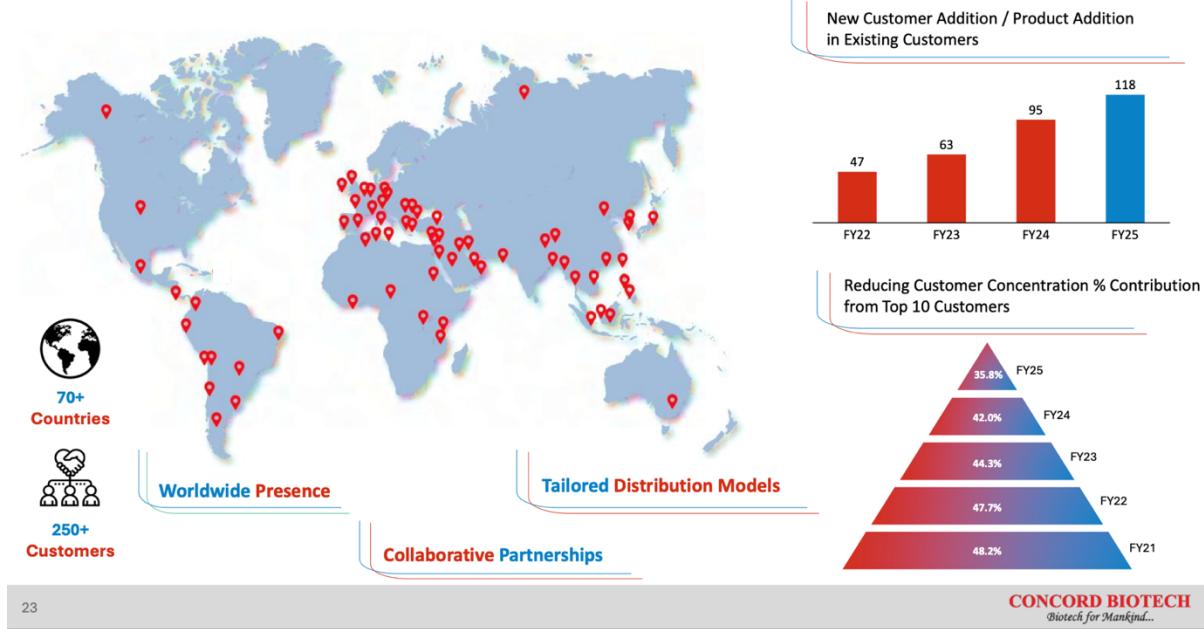


Figure 7 Global Presence of Concord
Source: Concord Biotech (2025)

Based on the SWOT of the X-Orchid partnership, the following strategies reflect joint actions that leverage complementary strengths to capture opportunities and manage shared risks.

TOWS Strategies: X-Concord Partnership

Strength-Opportunity Strategies	Strength-Threat Strategies
<ul style="list-style-type: none"> • Use X's B2B network and regulatory expertise to commercialize Concord's under-utilized APIs across EU, MEA, and Asia. • Scale API and CDMO manufacturing using Concord's underutilized capacity under long-term supply contracts. • Integrate Concord's 10+ API pipeline into X's medium-term portfolio expansion, with X commercializing these APIs globally 	<ul style="list-style-type: none"> • Leverage combined USFDA/EU-GMP compliance and X's regulatory capabilities to mitigate risks. • Implement long-term agreements with volume and pricing flexibility.

<p>while Concord benefits from accelerated market access and reduced commercial effort.</p>	
<p>Weakness-Opportunity Strategies</p> <ul style="list-style-type: none"> • Allocate geographies and customer segments to manage overlapping APIs. • Use X as second-source supplier to restore and protect Concord's EU customer base. 	<p>Weakness-Threat Strategies</p> <ul style="list-style-type: none"> • Define IP ownership and commercial boundaries upfront. • Begin the partnership with a few APIs to reduce risk, then scale to pipeline products.

4.2.3. Case study 3 - Alivus Life Sciences Limited

Alivus Life Sciences Limited, formerly part of Glenmark Pharmaceuticals' API business (established 2001), was spun off as Glenmark Life Sciences in 2019. Nirma Limited, a diversified conglomerate acquired a majority stake, and the company was rebranded as Alivus Life Sciences in 2024. It now has a broad API portfolio across Cardiovascular, CNS, Diabetes, Oncology, Urology, Anti-infectives. Building on Alivus' strong manufacturing base, regulatory approvals, and therapeutic focus, the following SAF and Partner Scorecard analyses evaluate the strategic potential of a partnership with X.

4.2.3.1. SAF Analysis and Partner Scorecard

SAF Analysis

Suitability (5/5)

The partnership demonstrates a strong strategic fit, leveraging Alivus' 165-API portfolio spanning multiple therapeutic areas, including anti-infective, oncology, CNS, cardiovascular, with 1 API identical to X's. Its 49-product pipeline, including 24 HPAPIs with an estimated aggregate value of USD 66 billion, complements X's medium-term portfolio and helps address pipeline gaps. Alivus' regulatory-compliant facilities (EU-GMP and USFDA), four manufacturing sites, and ongoing R&D across three centers provide high process compatibility. The B2B model and partnerships with top generic companies, combined with unserved regions in Asia, the Middle East, and additional EU markets, provide significant growth opportunities. Overall, the partnership aligns with X's strategic direction of forming alliances with generic pharma to broaden its portfolio, making it highly suitable.

Acceptability (3.1/5)

The partnership demonstrates high organizational and cultural compatibility, with Alivus showing a willingness to collaborate despite its larger scale. The robust risk management framework, including formal policies and committees, mitigates operational, regulatory, and governance risks associated with cross-continental integration. Scalability is supported through underutilized CDMO capacity (5%), partial facility utilization, and planned expansions (Alivus Life Sciences, 2025), allowing both firms to grow operations without significant new investment. While Alivus' large scale relative to other shortlisted partners may weaken X's

bargaining power, reducing acceptability, this can be mitigated through structured governance and long-term contractual arrangements. No compliance issues have been reported, supporting organizational acceptability, though scale-related challenges remain a consideration.

Feasibility (4.5/5)

The partnership is operationally and technologically feasible. Alivus possesses advanced capabilities across API manufacturing, CDMO services, supported by three R&D centers and four manufacturing facilities. Partial underutilization of CDMO capacity allows additional production without heavy capital expenditure, improving efficiency and revenue potential. Financial metrics for 2025 indicate strong financial health and support investment feasibility. Revenue reached EUR 258.19 million (23,869 million INR), with profit of EUR 52.52 million (4,857 million INR), a net profit margin of 20.35%, and ROE of 18.86%. The current ratio of 4.97 and debt-to-equity ratio of 2.01 reflect strong liquidity and moderate leverage. These figures demonstrate that Alivus has sufficient financial strength to invest in joint R&D, co-development, while mitigating risks and supporting both firms' revenue enhancement. A workforce of 2,203 provides sufficient operational capability.

Total score – 4.2/5

Alivus is a strong partner candidate. The partnership scores highly across strategic, operational, and financial dimensions, suggesting a low-risk, high-value collaboration capable of pipeline expansion, market growth, and cost optimisation, while requiring careful management of scale-related integration challenges.. Based on the above SAF analysis, the Partner Scorecard results for the combined X-Alivus partnership are presented below.

Partner Scorecard

Criteria	Weight (%)	Score (1–5)	Weighted Score
Regulatory strength & reputation	15	5	0.75
Manufacturing capability & operational reliability	15	5	0.75
R&D capabilities	10	5	0.5
Market Expansion Potential & Global Reach	15	3	0.45
Strategic fit and portfolio complementarity	15	4	0.6
Financial stability	10	5	0.5
Cultural compatibility	10	4.5	0.45

Willingness to share risks & rewards	5	4	0.2
Sustainability & ethical practices	5	5	0.25
Total Weighted score			4.45/5

Alivus shows strong regulatory compliance, operational reliability, financial stability, and R&D capabilities, making it as a suitable partner for X. Acceptability is moderate due to Alivus' larger scale relative to X, which may slightly reduce bargaining power and coordination ease. While market expansion potential and strategic fit with the EU partner are moderate due to Alivus' broad global presence, the partnership still offers substantial growth opportunities. Overall, the partner presents a high-value, low-risk opportunity, capable of supporting collaborative growth, efficient operations, and the commercialization of innovative products.

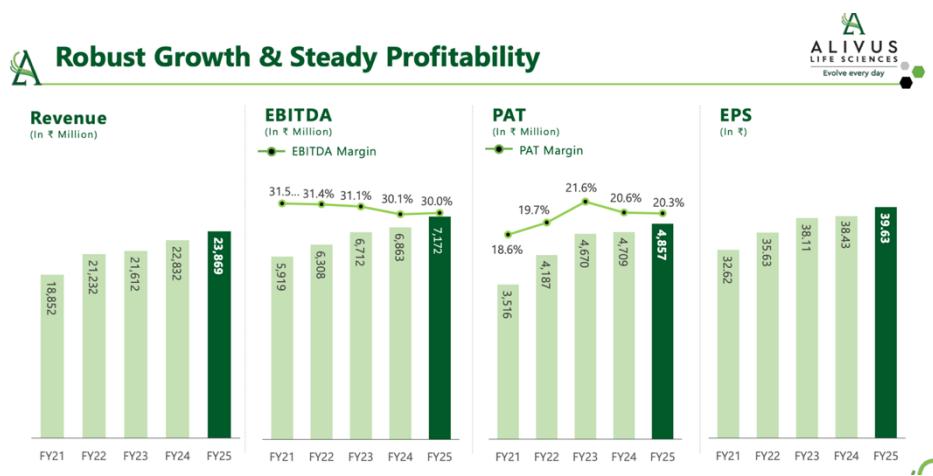


Figure 8 Financials of Alivus Life Sciences
Source: Alivus Life Sciences (2025)

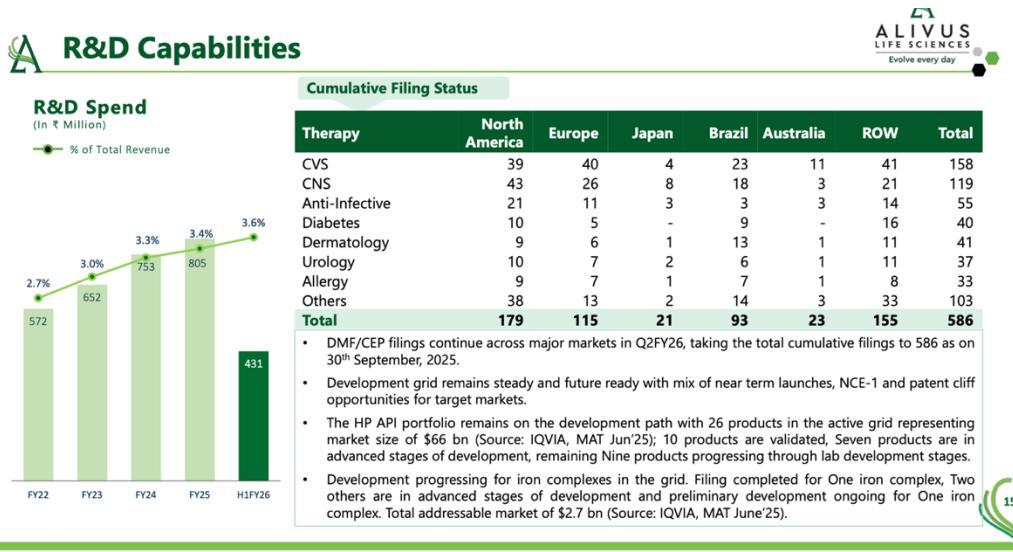


Figure 9 Alivus Life Sciences R&D Capabilities and Cumulative Filing Status
Source: Alivus Life Sciences (2025)

The following SWOT analysis evaluates the potential X-Alivus partnership, building on the SAF scorecard assessment. It highlights the key internal strengths and weaknesses of both companies, as well as external opportunities and threats. This analysis provides a structured overview of how the partnership can leverage complementary capabilities, address risks, and capitalize on strategic growth opportunities globally.

SWOT of Potential Partnership

Strengths

The partnership leverages complementary capabilities, with Alivus' 165-API portfolio spanning multiple therapeutic areas, including antifungal and antibiotic APIs (with 1 API identical to X's), oncology, CNS, and cardiovascular, along with CDMO and regulatory-compliant facilities, and a B2B model serving top generic companies in regulated markets (North America, Europe, Japan, Australia). Ongoing R&D, a 49-product pipeline including 24 HPAPIs (with an estimated aggregate value of USD 66 billion), three R&D centers (Alivus Life Sciences, 2025), four manufacturing facilities, and EU-GMP and USFDA approvals strengthen operational capacity. Financial stability, strong liquidity, ESG initiatives, a workforce of 2,203, and a robust risk management framework support long-term feasibility and risk-sharing. No compliance issues reported. Alivus aligns with Partner Persona Type II as a pure API player with a diversified therapeutic footprint rather than a narrow critical-care specialization.

Weaknesses

Cross-continental integration across R&D, manufacturing, and regulatory functions introduces complexity. Delays in in-licensing, co-development, could affect returns. Dependence on critical raw materials and cultural differences pose moderate operational and governance risks. Its larger scale relative to other shortlisted firms may weaken X's bargaining power compared to smaller partners.

Opportunities

The partnership enables Alivus to access X's global markets, leverage X's fermentation expertise, accelerate revenue growth, and commercialize its 49-product pipeline (including 24 HPAPIs) through X. Better utilization of underused CDMO capacity (5% contribution) allows

production scaling, generating additional revenue and expanding CDMO services. Partial capacity utilization at Alivus allows it to manufacture APIs supplied and commercialized by X, as well as APIs required by X's global customers, improving facility utilization and creating stable manufacturing revenues. X benefits by gaining low-cost, reliable access to high-quality manufacturing without investing in its own facilities, while Alivus earn revenue through long-term agreements. Alivus has a planned pipeline of 49 APIs, which can help address X's medium-term pipeline gaps. Through the partnership, X can commercialize these APIs globally by leveraging its regulatory expertise, B2B distribution network, and established customer relationships, while Alivus benefits from reduced commercial burden.

Most importantly, this partnership aligns with the strategic direction: Alliances with Generic Pharma to Broaden the Portfolio. Given that Alivus is not primarily specialized in critical-care or hospital-centric anti-infectives, it can leverage X's established critical-care portfolio, injectable expertise, and hospital market access to strengthen its positioning. Conversely, X benefits from Alivus' extensive API pipeline, enabling portfolio expansion beyond its core anti-infective focus. Alivus remains open to partnerships, showing willingness to collaborate despite its size. Further, the partnership creates opportunities for joint R&D, co-development, and commercialization of novel APIs, supporting diversification into high-margin therapies beyond anti-infectives and thereby enhancing revenues for both parties.

Threats

External risks include generic competition, pricing pressures, regulatory tightening, geopolitical challenges, and supply-chain disruptions, which may affect profitability and operational execution.

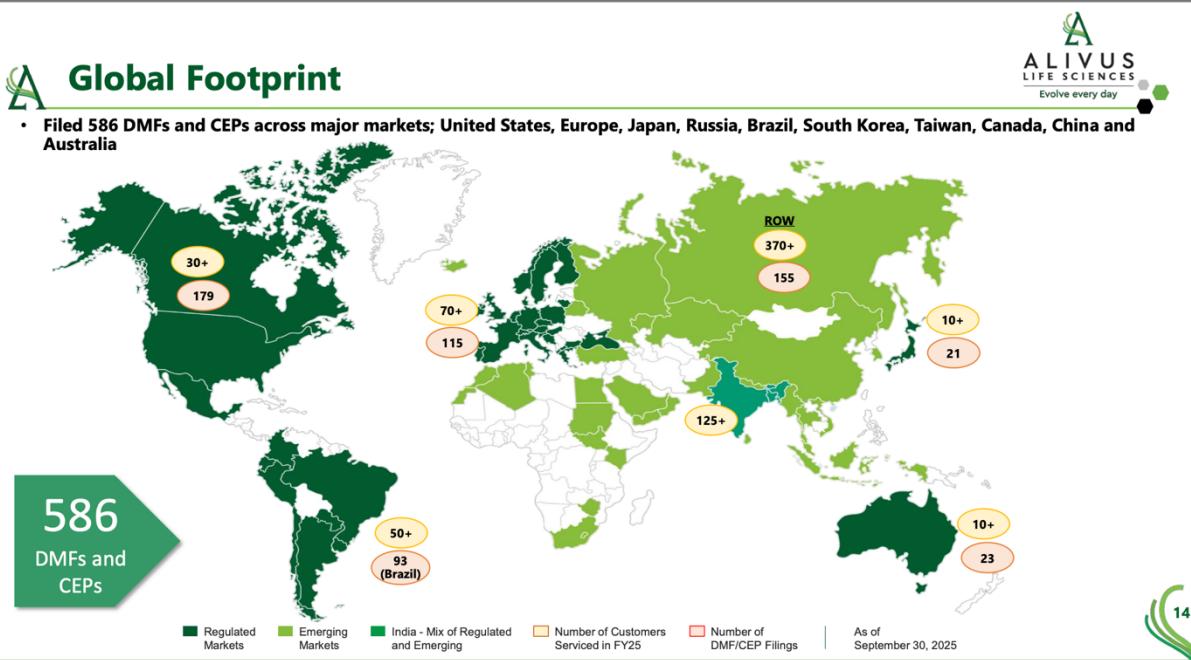


Figure 10 Global Presence of Alivus
Source: Alivus Life Sciences (2025)

TOWS Strategies: X-Alivus Partnership

Strength-Opportunity Strategies	Strength-Threat Strategies
<ul style="list-style-type: none"> Leverage Alivus' 49-API pipeline (24 HPAPIs) and X's global network to accelerate market entry, expand X's portfolio, and boost both s' revenue. Use Alivus' underutilized CDMO capacity to scale production, improving utilization and generating stable revenue Exploit low-cost manufacturing and approvals to reduce X's production costs and support margins. Combine Alivus' R&D with X's expertise to co-develop novel APIs, diversifying into high-margin therapies. 	<ul style="list-style-type: none"> Leverage EU-GMP and USFDA-approved facilities and compliance track record to maintain customer confidence and reduce regulatory risk. Diversify into HPAPIs to mitigate pricing pressure from generic competition.

Weakness-Opportunity Strategies	Weakness-Threat Strategies
<ul style="list-style-type: none"> Establish a joint governance framework covering R&D, regulatory, and manufacturing to manage cross-continental coordination and cultural differences. 	<ul style="list-style-type: none"> Implement a joint governance model where decision-making is balanced between X and Alivus to avoid dominance by either party.

The following table provides a comparative overview of three potential partners- Orchid, Concord, and Alivus- across key strategic, operational, and financial criteria. The analysis covers total API portfolios, anti-infective focus, regulatory compliance, pipeline strength, profitability, and financial stability, as well as partner evaluation scores based on the SAF framework and the Partner Scorecard.

Table 4: Summary of the Top Three Partners

Criteria	Orchid	Concord	Alivus
Total APIs	102	30	165
Anti infective APIs	30	14	12
No. of USDMFs	48	22	136
No. of CEPs	15	14	44
Pipeline		10+	24
Compliance	USFDA, EUGMP	USFDA, EUGMP	USFDA, EUGMP
NPP margin	11.55%	31%	20.35%
Debt equity ratio	0.13	0	2.01
SAF Score	4.7/5	4.4/5	4.2/5
Partner Scorecard Score	4.83/5	4.71/5	4.45/5

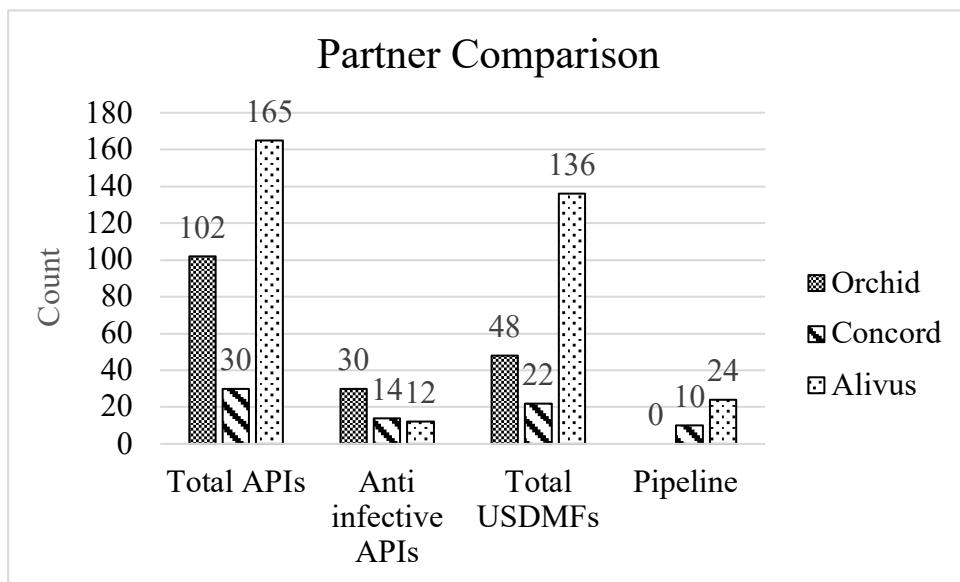


Figure 11 Top Three Partner Comparison

For the fourth- and fifth-ranked firms, Virchow Group and Shamrock Pharmachemi, SAF and Partner Scorecard evaluations were performed to assess strategic alignment, operational capabilities, and regulatory readiness. However, due to private ownership structures, limited financial disclosure, and restricted availability of detailed strategic information, a full SWOT analysis could not be conducted for these candidates. The insights from SAF and Partner Scorecard evaluations provide a high-level comparative perspective, while acknowledging the inherent analytical constraints associated with the limited publicly available data.

4.2.4. Case Study 04 - Virchow Group

Virchow Group is a privately held pharmaceutical company with global operations in active pharmaceutical ingredients (APIs), biotechnology, and finished dosage formulations. Through subsidiaries such as Virchow Labs, Virchow Biotech, and Covalent Labs, the Group offers vertically integrated manufacturing across anti-infectives, cardiovascular, oncology, and CNS therapies. The following SAF and Partner Scorecard analyses evaluate the strategic potential of a partnership with X.

4.2.4.1 SAF Analysis and Partner Scorecard

SAF Analysis

Suitability – Score: 4.5/5

The partnership demonstrates a strong strategic fit, particularly in anti-infectives and fermentation-based capabilities. The combined portfolio includes Cephalosporins, Sulfamethoxazole, and Tramadol, covering critical care, oncology, cardiovascular, and neurology segments. The partner operates multiple facilities, including six API units, biotech unit, and various formulation and marketing divisions such as Virchow Labs, Virchow Biotech, Andhra Organics, Covalent Labs, Virchow Drugs, Virchow Chemicals & Petrochemicals, Virchow Healthcare, and Emnar Pharma. Manufacturing capabilities include sterile injectables, oral dosage forms, vial filling, lyophilization, and blister packaging. Regulatory approvals are robust, with WHO-GMP, USFDA, EU-GMP, and KFDA certifications. Additionally, CRAMS and co-development expertise supports multiple international clients, with a market presence across over 100 countries including the USA, South-East Asia, CIS, Africa, LATAM, and South Asia (Virchow Group, 2025). Importantly, Virchow Biotech's fermentation platform enables co-development opportunities with X strengthening pipeline depth and innovation potential.

Acceptability – Score: 4/5

The organizational structure includes well-developed R&D functions, multiple subsidiaries overseeing production, and a global marketing network, supporting operational alignment. Cultural compatibility is high, with low operational risk and support from international offices. Risk exposure is moderate, primarily related to private ownership and governance transparency

rather than operational or regulatory concerns. Scalability potential is significant, supported by multiple API units. Overall, the partnership demonstrates moderate acceptability, reflecting moderate organizational fit, cultural alignment, and growth potential.

Feasibility – Score: 4/5

The partnership is technologically and operationally feasible. Virchow Labs is a leading global producer of Sulfamethoxazole and Trimethoprim, Virchow Biotech develops fermentation and recombinant biotech products, and Covalent Labs manufactures sterile and oral Cephalosporin APIs. Financial strength is moderate, with reported revenue of approximately EUR 161 million (INR 1,450 crore) based on available secondary data (Tracxn, 2025), with currency conversion using March 2024 exchange rates (Exchange-rate.org, 2024) demonstrating operational scale, although detailed ROE and cash flow information are not publicly disclosed. Execution feasibility is high from a technological standpoint, while financial feasibility is moderate due to limited disclosed data. Overall, the partnership demonstrates moderate feasibility with financial uncertainty.

Total Score – 4.16/5

Virchow Group demonstrates a strong strategic fit for collaborations in anti-infectives and fermentation, with a broad API portfolio, extensive manufacturing capabilities, and regulatory approvals across key markets. Its organisational structure, international presence, and CRAMS expertise operate effectively, with moderate risk and strong scalability. Technologically, the group is highly capable, though financial feasibility is moderate due to limited public data, indicating solid operational scale. Overall, Virchow is well-positioned for global partnerships, especially in emerging and regulated markets.

Active Pharmaceutical Ingredients

Acotiamide HCl Hydrate	Albendazole	Dabigatran Etexilate Mesylate	Dapaglitlozin Propanediol	
Empagliflozin	Fondaparinux Sodium	Gabapentin	Lacosamide	
Levetiracetam	Itraconazole	Olmesartan	Pantoprazole	Pitolisant HCl
Pregabalin	Sildenafil Citrate	Sitagliptin Phosphate	Sodium Bicarbonate USP	
Sulfadiazine	Sulfamethoxazole	Sulfanilamide	Sulfapyridine	Sulfasalazine
Tauroursodeoxycholic Acid	Telmisartan	Tramadol HCl	Trimethoprim	
Zinc Pyrithione	Zonisamide			



Oral Cephalosporins

Ceftibuten	Cefdinir	Cefditoren pivoxil	Cefixime
Cefpodoxime Proxetil	Cefprozil	Cefuroxime Axetil	Cefuroxime Axetil DC

Sterile Cephalosporins

Cefotaxime Sodium	Ceftriaxone Sodium	Cefuroxime Sodium
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Figure 12 API Portfolio of Virchow
Source: Virchow Group (2025)

Based on the above SAF analysis, the Partner Scorecard results for the combined X-Virchow partnership are presented below.

Partner Scorecard

Criteria	Weight (%)	Score (1–5)	Weighted Score
Regulatory strength & reputation	15	5	0.75
Manufacturing capability & operational reliability	15	5	0.75
R&D capabilities	10	5	0.5
Market Expansion Potential & Global Reach	15	4.5	0.675
Strategic fit and portfolio complementarity	15	4	0.6
Financial stability	10	3.5	0.35
Cultural compatibility	10	4	0.4
Willingness to share risks & rewards	5	4	0.2
Sustainability & ethical practices	5	2	0.1
Total Weighted score			4.33/5

Virchow Group is a strong potential partner for X, demonstrating strong regulatory compliance, manufacturing reliability, and R&D capabilities. Its API and FDF portfolio, combined with global CRAMS expertise, aligns well with X's strategic and operational objectives. While its presence in Western markets is limited, financial stability is moderate due to limited publicly available data. Sustainability and ethical practices are difficult to assess, as there is no publicly available information on CSR initiatives. Overall, Virchow represents a high-quality, strategically aligned partner, ranking fourth among evaluated candidates, with a potential for collaboration.



Figure 13 Global Presence of Virchow
Source: Virchow Health Care (2025)

4.2.5. Case Study 05 - Shamrock Pharmachemi Pvt Ltd

Shamrock Pharmachemi Pvt Ltd. is a privately held company established in 1990. Shamrock Pharmachemi Pvt Ltd acquired Unimark Remedies under a National Company Law Tribunal (NCLT) resolution plan, following Unimark's significant financial distress. The resolution plan was implemented with Shamrock, Intas and ARCIL, acting as the resolution applicants to restore Unimark's operations and manage its financial obligations (The Economic Times, 2023). The following SAF and Partner Scorecard analyses evaluate the strategic potential of a partnership with X.

4.2.5.1 SAF Analysis and Partner Scorecard

SAF Analysis

Suitability - Score: 4/5

The partnership demonstrates a strong strategic fit for API-focused collaboration, leveraging Shamrock's broad portfolio of 45+ APIs, including carbapenems, critical-care, and veterinary APIs, spanning therapeutic areas such as anesthetics, antidiabetics, CNS, Antihypertensives, and respiratory segments, supported by more than 30 USDMFs. The partner operates eight manufacturing facilities (four owned, four partnered), with extensive regulatory approvals including cGMP, WHO-GMP, USFDA, EUGMP, UK MHRA, TGA, ANVISA, COFEPRIS, KFDA, CEPs. Strong CRAMS capabilities enhance process compatibility (Shamrock Pharmachemi, 2025). While Shamrock has a presence in 40 markets, there are significant gaps across Europe, the USA, Australia, Africa, MENA, and parts of Asia. Historical strategic partnerships, such as the Hikma-Unimark API and ANDA co-development in 2011 (Pharma Letter, 2011), indicate experience in global engagement, though this occurred before Shamrock's acquisition and no public information is available on current status. Operational stability is moderated by past financial distress, NCLT restructuring, and organisational integration challenges (M&Acritique, 2023). Overall, the partnership offers good regulatory and technical alignment but is restricted by restructuring history.

Acceptability - Score: 3.5/5

Shamrock's long-standing operations (over 30 years) and strong CRAMS relationships contribute to organisational credibility, while the diversified human and veterinary product portfolio supports alignment with X's strategic needs. However, risk exposure is significant:

historical debt from Unimark and a recent auditor change (Business Standard, 2025) highlight potential governance issues. Scalability is moderate; regulatory approvals support expansion, but execution risks remain given the company's restructuring history and private ownership. Overall, organisational alignment is moderately acceptable, though weakened by governance, financial, and cultural risks.

Feasibility – Score: 3/5

The partnership is technologically feasible, with R&D capabilities and USFDA-inspected sites, supported by EU-GMP approvals. However, financial feasibility is weaker due to past Unimark debt and lack of publicly available financial information. While execution from a technical standpoint is strong, financial uncertainties and limited transparency moderate the overall feasibility of the partnership.

Total Score - 3.5/5

Shamrock is technically strong, with R&D capabilities, extensive manufacturing, and global regulatory approvals, but financially and organisationally risky. Its broad API portfolio and CRAMS capability make it highly suitable for API-focused collaboration. However, past debt of Unimark, auditor change, and limited financial transparency reduce acceptability and financial feasibility. Based on the above SAF analysis, the Partner Scorecard results for the combined X-Shamrock partnership are presented below.

Partner Scorecard

Criteria	Weight (%)	Score (1–5)	Weighted Score
Regulatory strength & reputation	15	4	0.6
Manufacturing capability and operational reliability	15	4	0.6
R&D capabilities	10	4	0.4
Market Expansion Potential & Global Reach	15	4.5	0.675
Strategic fit and portfolio complementarity	15	4.5	0.675
Financial stability	10	2	0.2
Cultural compatibility	10	3	0.3
Willingness to share risks & rewards	5	3	0.15
Sustainability and ethical practices	5	1	0.05
Total Weighted score			3.65/5

Shamrock is technically strong, with regulatory compliance, manufacturing capabilities, R&D, and market presence, making it a suitable operational partner. However, weak financial stability, moderate cultural alignment, and limited transparency regarding sustainability practices- no publicly available information on CSR initiatives is provided on the company website- increase investment and operational risk. Overall, Shamrock represents a competent partner with moderate risk, ranking fifth among evaluated candidates, capable of supporting collaboration while requiring careful oversight in financial and governance areas.



Figure 14 Global presence of Shamrock Pharmachemi

Source: Shamrock Pharmachemi (2025)

According to the SAF and Partner Scorecard results, Orchid ranks first, followed by Concord, Alivus, Virchow Group (fourth), and Shamrock Pharmachemi Pvt. Ltd. (fifth). The CSR synergy analysis was therefore conducted for the top-ranked partner, Orchid Limited.

4.3 CSR Collaborations: Orchid Trust and Company X

Orchid Trust demonstrates strong CSR through programs in education, rural health, self-employment, youth development, and women empowerment (140 Self Help Groups with over 1,800 members), and community asset creation across 24 villages. Its initiatives include schools, tuition centers, wells, community halls, primary health centers, and healthcare awareness, alongside environmental and safety measures such as hazardous-waste handling, bio-composting, and waste management, while complying with Indian CSR regulations and publishing Business Responsibility and Sustainability Reports. The company spent INR 11.40 lakh on CSR in 2024-25 (Orchid Pharma Limited, 2025).

Company X complements this with over ten years of global CSR engagement, supporting education, community development, women empowerment, renewable energy access, and broader ESG initiatives. X contributes approximately USD 10,000 annually to SOS Children's Villages, provides solar lighting for families without electricity, and emphasizes sustainable manufacturing, ethical sourcing, responsible water and effluent management, labor standards, and public health initiatives, including antimicrobial resistance, while promoting women empowerment, aligned with UNSDG goals of no poverty, gender equality, good health, and reduced inequalities (X Company, 2022).

Together, Orchid and X show strong CSR alignment: Orchid provides local reach, while X brings sustainability expertise and international standards. A joint CSR programme could:

- Expand access to education and youth development
- Improve health services and public health initiatives
- Provide essential medicines
- Support self-help groups (SHG) empowerment and self-employment
- Promote women empowerment
- Develop community assets
- Ensure environmental compliance and sustainable operations
- Increase use of renewable energy
- Maintain ethical sourcing and labor standards

This delivers measurable social impact and reinforces CSR commitments. It also supports achieving UNSDG goals together. To estimate the future CSR expenditure of the proposed X–Orchid collaboration, a three-year forecast was developed based on Orchid’s recent profitability trends and expected synergy benefits arising from the partnership.

The compound annual growth rate (CAGR) of Profit After Tax (PAT) was calculated using the last two years of available financial data. The growth rate was derived as follows:

PAT growth rate

$$\begin{aligned} &= (\text{PAT FY24–25} - \text{PAT FY23–24}) / \text{PAT FY23–24} \\ &= (106.5 - 94.7) / 94.7 \\ &= 12.4\%, \text{ rounded to } 12\% \text{ for forecasting purposes} \end{aligned}$$

In addition to organic growth, the collaboration is expected to generate synergy benefits through improved cost efficiency, expanded market reach, and operational optimization. According to EY (2022), typical pharmaceutical collaborations generate synergy gains in the range of 10–20%. A conservative midpoint assumption of 15% was therefore applied.

Accordingly, the expected combined growth rate was calculated as:

$$12\% \text{ base growth} + 15\% \text{ synergy impact} = 27\% \text{ expected annual growth}$$

Based on this growth rate, Orchid’s forecasted PAT for the next three years is estimated as:

PAT FY25–26 = INR 135.2 crore

PAT FY26–27 = INR 171.8 crore

PAT FY27–28 = INR 218.1 crore

Under Indian statutory CSR regulations, companies are required to spend at least 2% of the average net profits of the preceding three financial years on CSR activities (Orchid Pharma Limited, 2025). Applying this rule, the projected CSR expenditure is as follows:

CSR FY26 = 2% of average PAT (FY23, FY24, FY25)

$$= ((55+94.7 + 106.5) / 3) \times 2\%$$

= INR 1.71 crore

CSR FY27 = 2% of average PAT (FY24, FY25, FY26)

$$= ((94.7+106.5 + 135.2) / 3) \times 2\%$$

= INR 2.24 crore

CSR FY28 = 2% of average PAT (FY25, FY26, FY27)

$$= ((106.5+135.2 + 171.8) / 3) \times 2\%$$

= INR 2.76 crore

In addition, Company X contributes approximately USD 10,000 annually to CSR initiatives (X company, 2022). Using the average 2025 exchange rate of 1 USD = INR 87 (Exchangerates.org, 2025), this equates to INR 0.087 crore per year, which is added to Orchid's statutory CSR expenditure.

The total projected CSR expenditure under the X-Orchid collaboration is therefore estimated at:

Total CSR FY26 = INR 1.8 crore

Total CSR FY27 = INR 2.32 crore

Total CSR FY28 = INR 2.85 crore

Overall, the forecast indicates that the X-Orchid collaboration would enable a progressive increase in CSR spending over the next three years, strengthening social impact in education, healthcare, women empowerment, environmental sustainability, and community development, while aligning with statutory CSR requirements and international ESG expectations.

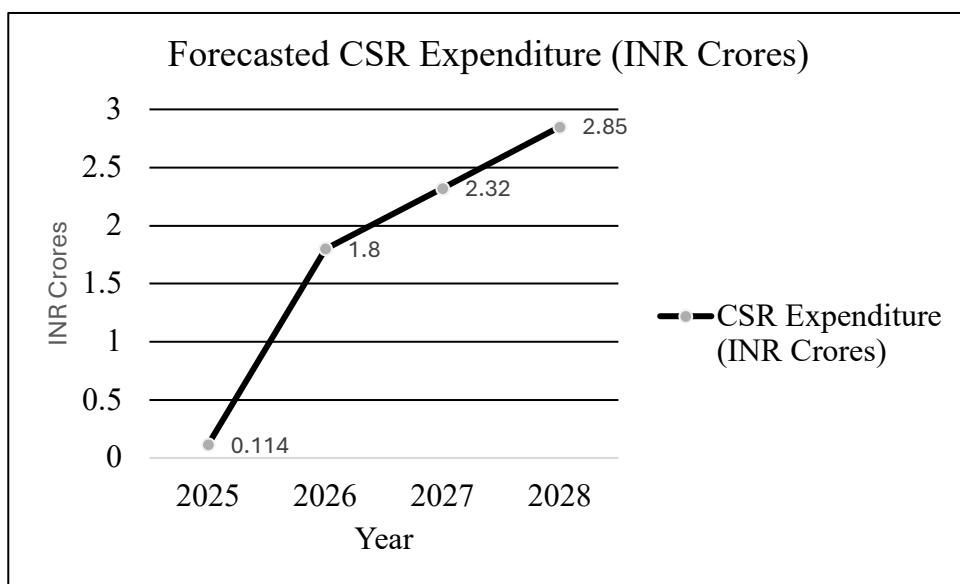


Figure 15 Forecast of CSR Expenditure for X-Orchid Collaboration

4.4 Discussion

This study aimed to identify suitable Indian partners for X Company to support growth, emphasizing strategic fit, technological complementarity, and market expansion. Using a structured evaluation framework, combined with SAF analysis and the Partner Scorecard, Orchid, Concord, and Alivus were identified as the most aligned partners, each addressing X's high-cost manufacturing, limited API base, and narrow pipeline while offering diversification and revenue improvement.

4.4.1. Interpretation of Findings

External and Internal Factors (RQ1)

For RQ1, India's external environment was analysed using PESTEL, Five Forces, and risk–opportunity assessment, revealing cost-efficient manufacturing, fast approvals, and strong R&D, while X faces high costs, limited APIs, and pipeline gaps, emphasizing the need for partners with broader portfolios, stronger R&D, and strategic alignment.

Evaluation Criteria and Tools (RQ2)

The partner evaluation framework (Table 2), based on literature, enabled systematic assessment across strategic, operational, relational, and financial dimensions. SAF confirmed feasibility, suitability, and acceptability, while the Partner Scorecard quantified technological and operational complementarity, regulatory readiness, R&D strength, and market expansion potential. An illustrative scorecard (Appendix 03) and the completed scorecards for the top five candidates are presented.

Most Suitable Partners (RQ3)

Following analysis using the SAF and Partner Scorecard, Orchid and Concord demonstrated strong regulatory capabilities, diverse portfolios, and fermentation and critical-care expertise, while Alivus offered scale, high R&D capability, and wider market access. All three firms possess broad API portfolios with revenue expansion potential, indicating scope for enhanced commercialization and strengthening their interest in partnering with X. While each firm can support X, their strategic contributions differ.

Virchows Group, ranked fourth, shows fermentation capabilities, an anti-infective API portfolio, and subsidiaries spanning biotech to FDFFs. However, its private ownership limits access to financial data, increasing uncertainty in risk assessment. Shamrock Pharmachemi, ranked fifth, engages in critical-care and carbapenem APIs, but moderate risk arises from debt inherited through the acquisition of Unimark Remedies. Although technically capable, their financial limitations and operational risks position them as secondary rather than primary partners.

From a strategic perspective, these partnerships position X to rebalance its portfolio toward high-growth, high-margin therapeutic segments, particularly oncology and cardiovascular diseases. This strategic shift is supported by global and European epidemiological trends, where cardiovascular diseases remain the leading cause of mortality in the European Union, and cancer prevalence continues to be high and rising, driving sustained demand for treatments in these therapeutic areas (OECD, 2025; World Health Organization, 2024).

4.4.2. Comparison with Existing Literature

Findings align with research showing alliances enhance technology access, market entry, and cost efficiency (Hagedoorn, 2002) and confirm India's advantages in manufacturing and regulation (Khanna, 2025; Festel *et al.*, 2014). Technological and operational complementarity, central in this study, reflects insights from Papadopoulou and Hecht (2021), Zhang *et al.* (2013), Cummings *et al.* (2012), Wu *et al.* (2009), and Mindruta *et al.* (2015). Relational factors, including collaborative willingness and reputation, align with Papadopoulou and Hecht (2021) and Cummings *et al.* (2012), while regulatory strength remains consistent with Festel *et al.* (2014) and Khanna (2025). Despite limited literature on culture and ethics (Zhang *et al.*, 2013; Cummings *et al.*, 2012), CSR alignment with Orchid Trust highlights their importance for credibility and stakeholder engagement.

The results also affirm that pipeline diversification is a key priority in partnerships (Hagedoorn, 2002; PricewaterhouseCoopers, 2025). The study extends the literature by showing that technological synergy can outweigh financial strength in partner selection, especially for biotech-like firms (Papadopoulou and Hecht, 2021; Khanna, 2025). Theoretically, it demonstrates the value of integrating SAF and Partner Scorecards into a multi-dimensional

evaluation method suitable for confidential B2B pharmaceutical contexts, consistent with Thanaraksakul *et al.* (2009) and Prayogi and Wandebori (2020).

4.4.3. Implications for X Company and Theoretical Contribution

X should prioritize partnerships with firms demonstrating regulatory readiness, technological and operational complementarity, and R&D capabilities. Orchid, Concord, and Alivus can enable co-development, cost reduction, portfolio expansion, and access to high-demand markets, strengthening competitiveness and enhancing revenue while reducing regulatory, operational, competitive, and environmental risks. Including lower-ranked firms like Virchows and Shamrock shows that technical skills alone are insufficient; financial and operational risks must be considered in partner selection. CSR alignment with Orchid Trust further reinforces stakeholder engagement in India.

05. Conclusion and Recommendations

5.1 Conclusion

The purpose of this study was to evaluate strategic partnership options for X Company, a Europe-based anti-infective API manufacturer, following its business reorientation towards strengthening core API capabilities for global B2B markets. This reorientation resulted in strategic constraints, including a high-cost structure, a limited API portfolio, and a weak future product pipeline, and financial constraints. To address these challenges, the study assessed X's strategic options through an integrated analysis of India's macro-environment (PESTEL), industry structure (Porter's Five Forces), and X's internal position (SWOT).

The analysis demonstrates that India represents a strategically attractive market for X. While regulatory, operational, competitive, and environmental risks exist, these can be mitigated through well-structured local partnerships. Partnerships provide advantages, including cost efficiency, access to advanced fermentation and manufacturing capabilities, R&D strength, faster regulatory approvals, and exposure to a large API market.

All research questions were addressed. RQ1 established the strategic rationale for pursuing partnerships in India as a growth pathway. RQ2 developed a structured, literature-based partner evaluation framework. RQ3 applied this framework to identify, shortlist, and rank the most suitable Indian partners for X. The structured two-stage partner evaluation, using a framework developed from the literature, narrowed 44 Indian firms based on Strategic, Operational, Relational, and Financial criteria to a shortlist of five candidates, which were subsequently ranked using an integrated Partner Scorecard and SAF (Suitability, Acceptability, Feasibility) analysis. The results demonstrate that partners aligned with Persona Ib and Persona II offer the highest strategic fit for X. The Partner Scorecard provided a weighted ranking of firms, while the SAF analysis validated the strategic appropriateness and feasibility of the highest-ranked candidates.

Among the shortlisted firms, Orchid Pharma emerged as the most suitable partner, aligning with broadening the portfolio through alliances with a generic player, while minor biotech co-development opportunities exist via Orchid Bio-Pharma Ltd. Orchid's capabilities in antibacterial and antifungal APIs, critical-care products, CRAM, robust regulatory approvals, and extensive R&D infrastructure, coupled with under-commercialized APIs such as Enmetazobactam, strengthen revenue potential and global reach. Orchid belongs to partner persona Ib.

Concord Biotech ranked second, aligns with co-development of novel anti-infectives, leveraging fermentation-based APIs and R&D pipeline, while X provides commercial scale. Its CDMO potential and moderate revenue contribution from its existing portfolio indicate opportunities for expansion and second-source supply arrangements. Concord belongs to persona Ib. Alivus Life Sciences, ranked third, aligns with broadening the portfolio through a generic partnership, leveraging its API pipeline to expand markets and diversify into high-margin therapies. Alivus' broad portfolio and pipeline of 49 products, including 24 HPAPIs, align with Persona II.

Although ranked lower, Virchow Group and Shamrock Pharmachemi should not be entirely discounted. Virchow Group's fermentation strength, subsidiaries, and anti-infective focus make it strategically relevant, though its private ownership limits financial transparency.

Shamrock Pharmachemi, despite engagement in critical-care and carbapenem APIs, carries moderate financial risk due to acquisition-related debt, requiring cautious consideration.

Overall, the findings demonstrate that Indian partnerships enable mutually beneficial outcomes, allowing X to access complementary technologies, scale operations, reduce pipeline gaps, access cost efficiencies, and enhance revenue, while partners also gain market access and commercialization opportunities, with Orchid representing the strongest strategic partner.

5.2 Recommendations

Based on the findings, X should prioritize partnership formation with Orchid Pharma. Formal engagement should be initiated within the next 6–12 months, aligned with Orchid’s ongoing licensing opportunities, upcoming injectable facility, fermentation capabilities, and broader therapeutic focus. Leveraging X’s global distribution network across its wider global presence could significantly expand Orchid’s limited regional presence and unlock under-served markets in Europe, Asia, Latin America, Africa, and Australia, thereby enhancing revenue potential for both firms. X should also develop commercialization strategy with Orchid and consolidating licensing activities under X’s distribution system would reduce Orchid’s dependence on multiple small licensing arrangements, lowering commercial complexity and cost.

To strengthen cost competitiveness, X should utilize Orchid’s large cephalosporin manufacturing complex, low-cost production base, and upcoming downstream facilities to offset X’s relatively high European cost structure. In parallel, a structured governance and risk-management framework should be implemented to address raw-material risks, regulatory variability, and cultural differences through clearly defined roles and shared risk-oversight mechanisms. The study further recommends launching a joint CSR program with Orchid, integrating X’s sustainability expertise with Orchid Trust’s strong community presence. Collaborative initiatives in education, rural healthcare, women’s empowerment, environmental sustainability, and access to essential medicines would enhance stakeholder acceptability and long-term partnership legitimacy.

Finally, Concord and Alivus should be pursued as complementary priority partners. Concord may serve as a second-source supplier for selected fermentation APIs, while Alivus offers

future opportunities in HPAPI development, CDMO collaboration, and pipeline expansion as capacity grows. Collectively, these partnerships would enable X to broaden its therapeutic exposure while maintaining a strategic focus on anti-infectives.

5.3 Limitations

This study is subject to several limitations. First, data availability varied across companies, with financial, regulatory, and operational information being incomplete or lagged for certain firms, particularly privately held entities. This may affect comparability across the full 44 company sample. Second, the research relied predominantly on secondary data sources, including annual reports, regulatory databases, DMF listings, media releases, and company presentations. Despite outreach efforts, no completed surveys or interviews were obtained, reflecting confidentiality constraints and limited accessibility common in the pharmaceutical industry. While this restricted primary insights, the limitation was mitigated through extensive triangulation of validated secondary data and a systematic analytical framework. Third, the study did not include detailed financial valuation techniques such as NPV, IRR, or payback analysis due to project time constraints. Fourth, the geographic scope was limited to India, excluding other emerging API hubs, which may influence long-term competitiveness. Finally, although Partner Scorecard weightings were grounded in literature, some degree of subjectivity may remain.

5.4 Future Research

Future research could extend this study by incorporating detailed financial valuation models to quantify partnership value creation. Comparative analyses across multiple low-cost API regions would further validate India's strategic position. Additionally, future studies should prioritize structured primary data collection, potentially facilitated through academic-industry networks, to gain deeper insights into partner motivations, and strategic intent. Such approaches would enhance internal validity and enrich the understanding of alliance dynamics in pharmaceutical partnerships.

Personal Reflection

Completing this thesis has been a highly enriching experience, allowing me to integrate theoretical knowledge from my MBA studies with practical insights into the pharmaceutical industry. Throughout the research, I gained a deeper understanding of cross-border partnerships, strategic evaluation frameworks, and the complexities of the pharmaceutical sector. Beyond the technical and analytical skills, this project strengthened my abilities in critical thinking, problem-solving, and decision-making. I learned to integrate diverse sources of information, assess complex strategic and operational factors, and make evidence-based recommendations.

While I do not have a scientific background, I recognize that certain technical perspectives may be better understood by professionals in the field. Nevertheless, I have sought to overcome this limitation by applying strategic frameworks, such as the Partner Evaluation Framework, SAF model, Partner Scorecard, and SWOT analysis, to address X Company's business challenges and propose actionable solutions. Although I could not conduct extensive interviews due to the confidential nature of the pharmaceutical industry, I was able to receive responses from three companies. I believe that with additional time and collaboration with an academic institution, broader access to industry insights could have been possible.

On a personal level, this thesis has reinforced my confidence in conducting independent research and managing a complex project from inception to completion. It has challenged me to be disciplined, organized, and reflective, while also fostering a sense of resilience and adaptability in addressing obstacles and refining my approach. Overall, this journey has not only enhanced my academic and professional competencies but has also strengthened my commitment to pursuing meaningful contributions in the field of international business and strategic partnerships.

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Appendices

Global and India Pharmaceutical Market Overview

Leading 10 biotech and pharmaceutical companies worldwide based on market capitalization as of 2025 (in billion U.S. dollars)

Top 10 biotech and pharmaceutical companies based on market cap 2025



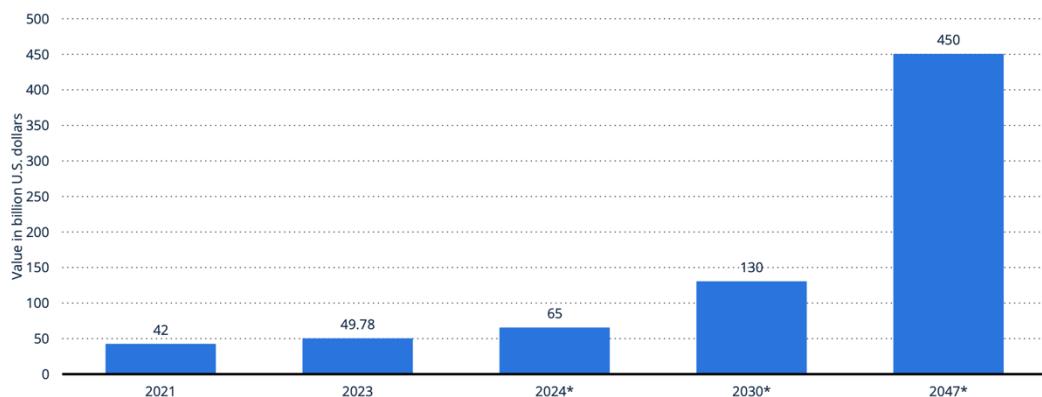
19 Description: As of early March 2025, Eli Lilly had a market cap of over 860 billion U.S. dollars and thus was the leader among big pharma companies based on market capitalization. The massive rise of Eli Lilly's market value, which started in 2023, is based in a large part on its strong pipeline. This statistic depicts the top 10 biotech and pharmaceutical companies worldwide based on market capitalization as of 2025. Biotech and pharmaceutical companies are best known for ... [Read more](#)

statista

(Statista, 2025)

Market size of pharmaceutical industry in India for 2021 and 2023, with forecast until 2047 (in billion U.S. dollars)

Market size of pharmaceutical industry India 2021-2047



9 Description: India's pharmaceutical market size was valued at about 50 billion U.S. dollars in 2023. The market is likely to increase to 130 billion U.S. dollars by 2030. India is the third-largest producer of pharmaceutical products worldwide. [Read more](#)

Notes: India 2021 and 2023: *Projected. [Read more](#)

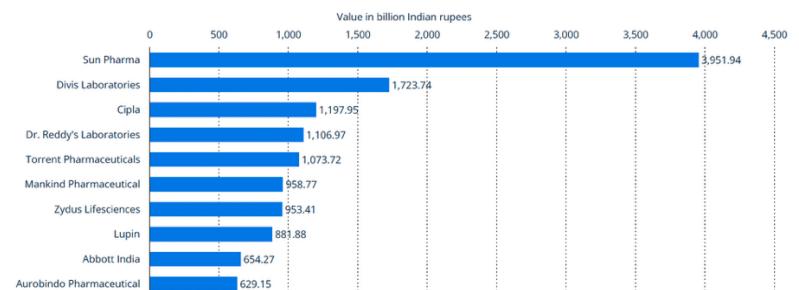
Source: India Brand Equity Foundation

statista

(Statista, 2024)

Leading pharmaceutical and drug companies in India as of June 2025, by market capitalization (in billion Indian rupees)

Leading pharmaceutical and drug companies India 2025, by market capitalization



statista

(Statista, 2025)

These figures are supplementary and not referenced in the main text.

Appendix 01. Draft of e-mail, survey sent to the potential partner companies, and optional interview questions

Email

Real Opportunity: To explore strategic partnership with a European API manufacturer

Dear Sir / Madam,

I'm conducting a consulting research project as an MBA candidate at Niels Brock Copenhagen Business College. This study aims to identify suitable partners for a particular Europe-based API manufacturer, and your organization has been recognized as a strong potential partner. This initiative goes beyond academic research - the company is genuinely interested in partnerships, and your insights may guide direct engagement.

I'd be grateful if you could spend 10 minutes completing this short, confidential questionnaire for evaluation purposes. If interested, you can also contact me for a follow-up interview here or at 59198@edu.nielsbrock.dk.

https://forms.office.com/Pages/ResponsePage.aspx?id=358J-Gl2p0aZeBu_D6X_zZesspk8Q_VDsadpRRrjzKVURVRRWDM4TjNOUkVMUTYyRERZM08xUkhHNi4u

Thank you for your time. Please feel free to forward this to your Business Development or Strategic Partnerships contact if more relevant.

Best regards,

Samurdi Sandaruwani

Survey

*1. What is your company name?

*2. What is your position?

Section 1 –Market Presence

*3. Does your company export to USA and/or EU ?

Region Export (Yes/No)

Europe Yes No

USA Yes No

*4. Does your company currently have a partner/distributor in EU and/or USA?

Region Partner/Distributor (Yes/No)

Europe Yes No

USA Yes No

5. Please indicate your satisfaction level on sales by region

Region

Satisfaction (1 = very unsatisfied, 5 = very satisfied)

Europe 1 2 3 4 5

USA 1 2 3 4 5

Section 2 – Regulatory Compliance

*6. Our company's product portfolio aligns well with the EU and USA market requirements.

(1 = Strongly disagree 5 = Strongly agree)

1 2 3 4 5

Section 3 – Financial capability & Risk Orientation

*7. Our company has sufficient financial strength and access to funding sources (e.g., banks or investors) to partner with a European API company.

(1 = Strongly disagree 5 = Strongly agree)

1 2 3 4 5

*8. Our company is open to pursuing new opportunities or innovative projects.

(1 = Strongly disagree 5 = Strongly agree)

1 2 3 4 5

Section 4 – Technical Capabilities

*9. Which of the following manufacturing technologies does your company currently use or specialize in? (Select all that apply.)

- Solid dosage / tableting
- Liquid parenterals / injectables
- Semi-solids / topical forms (creams, gels, patches)
- Sterile / specialized processes (aseptic filling, lyophilization)
- Biologics / recombinant proteins
- Other -----

*10. To what extent does your company handle or collaborate across different stages of production? (Select one per row.)

(Example: A company that only makes APIs and does not produce or package finished medicines works in one stage only.)

Scale:

Not involved → No activity or collaboration in that type.

Some involvement → Limited or partial collaboration/handling.

Fully involved → Highly integrated or fully managing that stage.

Stage / Type of Involvement Not involved Some involvement Fully involved

Horizontal: We work with

other companies

(e.g., co-development,

joint projects)

Vertical: We handle several

production steps by

Ourselves. (e.g., API

manufacturing, formulation,

packaging).

One stage only: We mainly focus on
one part of the process (e.g., only

API or only FDF manufacturing)

Section 5 – Strategic Fit, Market Opportunity & Barriers

(1 = Strongly disagree 5 = Strongly agree)

*11. Please indicate your level of agreement with the following statements.

Statement	1	2	3	4	5
Collaborating with a European partner could enhance our company's reputation and market positioning	<input type="checkbox"/>				
Market demand for our key products is growing significantly	<input type="checkbox"/>				
There are relatively few strong competitors for our company in the target EU markets.	<input type="checkbox"/>				
Regulatory complexity is a major concern in partnering with a European API manufacturer.	<input type="checkbox"/>				
Cultural differences could be a barrier to smooth collaboration.	<input type="checkbox"/>				
CSR and ethical business practices are important factors when selecting a western partner.	<input type="checkbox"/>				

Section 6 – Collaboration Interests & Expectations

*12. What could your company offer to a European API manufacturer in a partnership? (select all that apply)

- APIs (Active Pharmaceutical Ingredients)
- FDFs (Finished Dosage Forms)
- Intermediates
- Technical / analytical services
- Contract synthesis
- Other -----

*13. What would you expect from your European partner in return? (select one per row)

Instruction: For each item, please indicate how important it is for your company in the potential partnership.

Scale:

1 – Not important / Not required

5 – Very important / Critical

Expectation	1	2	3	4	5
Market access	<input type="checkbox"/>				
Technology sharing	<input type="checkbox"/>				
Regulatory support	<input type="checkbox"/>				
Investment or financial collaboration	<input type="checkbox"/>				
Distribution channel access	<input type="checkbox"/>				

*14. Which markets would your company like to access by partnering with a European API manufacturer? (Select one per row)

Scale Description:

1 – Not interested

5 – Very high interest / Core focus

Region	1	2	3	4	5
Europe (outside current markets)	<input type="checkbox"/>				
Asia-Pacific	<input type="checkbox"/>				
Middle East & Africa (MENA)	<input type="checkbox"/>				
North / Latin America	<input type="checkbox"/>				

*15. Which product areas would your company be interested in collaborating on with a European API manufacturer? (Select one per row)

Instruction: For each product area, please indicate your level of interest in collaborating with the European API manufacturer.

Scale Description:

1 – Not interested

5 – Very high interest

Product Area	1	2	3	4	5
Oncology	<input type="checkbox"/>				
Cardiovascular / Metabolic Disorders	<input type="checkbox"/>				
Anti-infective	<input type="checkbox"/>				
Central Nervous System (CNS)	<input type="checkbox"/>				

*16. What type of collaboration model does your company prefer with potential EU partner?
 (Select one per row)

Instruction: For each collaboration model, please indicate your level of preference or interest.

Scale Description:

1 – Not interested

5 – Very high interest / Preferred model

Collaboration Model	1	2	3	4	5
Long-term strategic partnership	<input type="checkbox"/>				
Project-based collaboration	<input type="checkbox"/>				
Technology co-development	<input type="checkbox"/>				
Licensing / distribution agreement	<input type="checkbox"/>				

17. Please share any expectations, thoughts, barriers, or suggestions your company may have regarding collaboration or partnership with a European API manufacturer

Microsoft form link: https://forms.office.com/Pages/ResponsePage.aspx?id=358J-Gl2p0aZeBu_D6X_zZesspk8Q_VDsadpRRrjzKVURVRRWDM4TjNOUKVMUTYyRERZ_M08xUkhHNi4u

Semi-structured interview questions (optional)

Interview Questions for Senior Management in Pharmaceutical Companies
 (Target Participant: Business Development Heads, R&D Directors)

Thank you for filling the survey. These are just following up questions to understand your company's perspective on potential EU company collaboration.

- 1.What key factors do you consider before entering a cross-border collaboration (e.g., technology, compliance, market access, trust)?
2. What benefits you seek by collaborating with a European API pharmaceutical company.
3. In your experience, what factors could influence the effectiveness of strategic partnership, and how can they be addressed?
4. Could you please describe the key Corporate Social Responsibility (CSR) activities your company is currently engaged in - particularly any initiatives related to healthcare access, environmental sustainability, or community development?

Interview Questions for Technical Managers in Pharma/Biotech Firms
 (Target Participant: Heads of Process Development, Quality and Compliance Managers)

Thank you for filling the survey. These are just following up questions to understand the technological, R&D, and compliance aspects of international collaborations, especially those related to API.

1. What are the main technical strengths and R&D capabilities your company has in API development?
2. How does your company currently integrate environmental sustainability into API development?
3. What benefits do you seek by collaborating with a European API pharmaceutical company?
4. In the context of a potential partnership with the European firm, what joint CSR or sustainability initiatives (e.g., waste reduction, energy efficiency, eco-friendly manufacturing, or ethical sourcing) could be realistically implemented at the operational or R&D level?

Appendix 02. Final Sample (44 Firms): Company Contacts and Response Status with the stage

Serial No.	Company Name	Designation of Contact Person	Company Email Contacted	Response Received within 21 days	Questionnaire Completed (Yes/No)	Rank & Reason For Not Selecting top 5 partners (in short)
Top Five Companies						
1.	Orchid Pharma Limited	Manager - International Marketing Manager - Marketing General Manager - Sales and Marketing	corporate@orchidpharma.com api@orchidpharma.com generics@orchidpharma.com	No	No	1

2.	Concord Biotech Limited	Senior General Manager - Sales, Marketing and Strategy Development Manager - API Business Development Assistant General Manager - Business Development Director - Business Development	salesfdf@concordbiotech.com corporate@concordbiotech.com	No	No	2
3.	Alivus Life Sciences Ltd	Lead - API Portfolio Assistant General Manager - International Marketing Manager - EU Vice President - Operations	api.web@alivus.com	No	No	3
4.	Virchow Group	Deputy Manager -	info@virchow.com	No	No	4

		International Business (Virchow Health Care) General Manager - Business Development (Virchow Group) Vice President - Business Development (Virchow Biotech Pvt Ltd)			
5.	Shamrock Pharmachemi Ltd	Director Global Operations, Alliances & Lead Strategist Business Development	globalops@shamrockpharmagroup.com pharma@shamrockindia.com marketing@unimarkremedies.com	Yes No	No 5
Companies Qualified for Second Stage					

6.	Maithri Drugs Limited	General Manager - Business Development Deputy Manager - Business Development	info@maithri.drugs.com	Yes No	No No	6 Private company with many anti-infectives and USDMFs, but lower capacity than top 5 due to private status and limited financial transparency; backed by MSN Group Anti infectives with USDMF Besifloxacin Hydrochloride – anti bacterial Doxycycline Hyclate – antibiotic Doxycycline Monohydrate – antibiotic Efinaconazole – anti fungal Nitrofurantoin Anhydrous – antibiotic Nitrofurantoin Anhydrous (Macrocrystals) - antibiotic Nitrofurantoin Hydrous – antibiotic Tigecycline – antiacne Voriconazole – anti fungal
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						Luliconazole – anti fungal Gemifloxacin Mesylate – antibiotic
7.	Chromo Laboratories India Pvt. Ltd	Head - Marketing and Business Development Manager - Business Development	bd2@chromolabs.com marketing@chromolabs.com info@chromolabs.com	No	No	7 Contract manufacturer with anti-infective specialization and many USDMF APIs, but limited financial transparency
8.	Honour Lab Limited	Associate Vice President - Head of Europe - Business Development Manager – Business Development	connect@honourlab.com bd@honourlab.com info@honourlab.com	No	No	8 Less anti-infective specialization and being spun off from Hetero indicate lower mutual benefit.
9.	Harman Finochem Ltd.	Manager - Business Development Senior Manager - Business Development	sales@harmanfinochem.com info@harmanfinochem.com	No	No	9 Less anti-infective specialization despite being a CMO with many APIs holding USDMFs.

10.	Cohance Life Sciences Pvt. Ltd	Manager – Corporate Strategy Manager – Business Development	Contact portal	No	No	10 Less anti-infective specialization and being larger with higher capabilities indicate lower mutual benefit for X.
11.	Sekhmet Pharmaventures Pvt. Ltd	Chief Commercial Officer Associate Manager - Marketing	info@sekhmetpharma.com	No	No	11 CDMO with less anti-infective specialization compared with top candidates; present in 77 countries, parent company in Singapore, with limited financial transparency,
12.	Lee Pharma Ltd	Assistant General Manager – Global Markets Assistant Manager – International Business Development	Contact Portal	No	No	Less anti-infective specialization and limited financial transparency
13.	Kopran Limited	Manager – Business	investors@kopran.com	No	No	Lesser USDMFs than the top candidates,

		Development	info@kopran.com			indicating lower global readiness
14.	FDC Limited	Senior Manager – Corporate Strategy Manager – Business Development	contact@fdciindia.com investors@fdciindia.com	No	No	Lesser USDMFs than the top candidates, indicating lower global readiness
15.	Innovare Labs Pvt. Ltd	Manager - Business Development Assistant General Manager – Supply Chain Management	info@innovarrelabs.com mktg@innovarrelabs.com	No	No	Less anti-infective specialization and limited financial transparency.
Companies Excluded in First Stage						
16.	Mach-Chem Pvt. Ltd	Assistant General Manager – EU & SEA (Business Development)	info@macchemgroup.com	Yes No	No No	All USDMFs are inactive indicating less global readiness
17.	Ind-Swift Laboratories Limited	Assistant Vice President – International Marketing	formulations.global@indswitflabs.com	No	No	Less anti-infective specialization

		Manager - Business Development	vivek.mishra@indswiflabs.com pardeep.verma@indswifflabs.com			
18.	Windlas Biotech Limited	Manager - Business Development Manager - Marketing	info@windlasbiotech.com	No	No	Manufactures only FDFs; injectable facility lacks USFDA and EU-GMP certification
19.	Nectar Lifesciences Limited	Manager - Business Development Manager - Marketing	Not available	No	No	CEP were suspended by EDQM GMP non-compliance
20.	Mangalam Drugs & Organics Limited	Manager - Business Development	contactus@mangalamdrugss.com	No	No	Limited anti-infective specialisation; predominantly antivirals; minimal US DMFs / weaker certifications, small scale
21.	Century Pharmaceuticals Limited	Manager - Marketing	marketing@centurypharma.com info@centurypharma.com	No	No	minimal US DMFs / weaker certifications, small scale
22.	Turtle Pharma Pvt. Ltd.	Director - Sales and Marketing	info@turtlepharma.com	No	No	minimal US DMFs / weaker certifications, small scale

23.	Brook Laboratories Limited	Manager - Business Development	investors@brookslabs.net planning@brookslabs.net nisha.bhambaru@brookslabs.net	No	No	Set to be acquired by OneSource, post-acquisition, the critical care API portfolio is gone; Brook Lab lacks FDA approval, while the acquiring subsidiary retains FDA-approved critical care injectables only as FDFs, with no APIs.
24.	Aizant Research & Technology Limited	Manager – Business Development	info@aizant.com bd@aizant.com	No	No	no APIs and no EU-GMP for injectables
25.	Apothecon Healthcare Limited	Manager – International Business Development	sales@apotheonpharma.com	No	No	Less anti-infective specialization
26.	Viyash Lifesciences Limited	Deputy General Manager – API Senior General Manager – API	info@viyash.com	No	No	Less anti-infective specialization with many anti virals. Set to be acquired by Sequent Scientific Ltd
27.	ACTIZA Pharmaceutical Pvt. Ltd	Manager Business Development	sales@actizapharma.com info@actizapharma.com	No	No	minimal US DMFs / weaker certifications, small scale

28.	Mankind Pharma Limited	General Manager - Business Development Manager – Business Development	api@mankindpharma.com	No	No	Less anti-infective specialization
29.	Panacea Biotec Limited	Manager Business Development	Contact Portal – Business Development	No	No	Only FDFs, EU presence with subsidiaries
30.	Flamingo Pharmaceuticals Ltd	Manager - Business Development	ashf@flamingopharma.com bd@flamingopharma.com	No	No	No EU-GMP for sterile facility; no APIs, only FDFs
31.	Torrent Pharmaceuticals Ltd	Manager - Strategic Planning Manager - Business Development	Not available	No	No	Has wholly owned subsidiaries in Germany, the UK, and Malta, with larger capacities and higher revenues than X indicating lower mutual benefit as a partnership target
32.	Venus Remedies Ltd	Manager - Business Development	bd@venusremedies.com info@venusremedies.com	No	No	No US FDA; high global presence including EU suggests limited mutual benefit

33.	Dishman Carbogen Amcis Ltd	Senior Manager - Operations	dishman@dishmangroup.com mumbai@dishmangroup.com	No	No	Netherlands subsidiary, high EU presence, limited anti-infective specialization, CDMO focus; indicates lower mutual benefit
34.	Alkem Laboratories Ltd.	General Manager - Corporate Strategy and Business Development Senior Manager- BD&L, Portfolio and Strategy	contact@alkem.com	No	No	Limited anti-infective API specialization; no EU-GMP certification for injectables
35.	Arene Life Sciences Pvt. Ltd	Manager - Marketing	info@arenelifelife.com	No	No	Limited anti-infective API specialization, primarily focused on antivirals
36.	Aurore Life Sciences Pvt. Ltd	Assistant Vice President - Strategic Business Development Manager - Business Development	info@aurorelife.com	No	No	Limited anti-infective API specialization, primarily focused on antivirals

37.	Everest Organics Ltd	Head - API Marketing and Sales Manager - Marketing	e.api@everestorganicsltd.com e.int@everestorganicsltd.com	No	No	Mostly antiviral focus, non-compliance for EU-GMP
38.	Emcure Pharmaceuticals Limited	Manager - Business Development Senior Manager - Business Development	corporate@emcure.com	No	No	Less anti-infective specialization, have subsidiaries in Europe, larger than X thus reducing mutual benefit
39.	Anuh Pharma Ltd	Manager - Business Development	info@anuhpharma.com	No	No	Limited anti-infective focus; primarily anti-malarial portfolio
40.	Swiss Parenterals Ltd.	General Manager - Business Development	web@swissiin	No	No	FDF-only, sterile injectables facility has no USFDA
41.	Smruthi Organics Ltd	Manager - Business Development	eaga@smruthiorganics.com business@smruthiorganics.com	No	No	Warning letters issued by EDQM for non-compliance
42.	Mepro Pharmaceuticals Pvt. Ltd	Manager – International Business	info@mepro.in	No	No	wider-EU presence; FDF-only, sterile injectables

						facility has no USFDA
43.	Medopharm Pvt. Ltd	General Manager - Strategic Business Development	info@tabletsmedo.com info@medopharm.com bd@medopharm.com	No	No	wider-EU presence; FDF-only, sterile injectables facility has no USFDA
44.	Umedica Laboratories Pvt. Ltd.	Manager - Business Development Manager – International Business Development	exports@umedicalabs.com	No	No	Focused only on FDFs with no sterile injectables for regulated markets; EU-GMP applies only to their non-sterile manufacturing, with no compliance for sterile products

Appendix 03. Partner Scorecard Developed for Evaluating Companies Based on Literature

Criteria	Weight (%)	Score (1–5)	Weighted Score
Regulatory strength & reputation	15		
Manufacturing capability and operational reliability	15		
R&D capabilities	10		
Market Expansion Potential & Global Reach	15		
Strategic fit with EU partner	15		
Financial stability	10		
Cultural compatibility	10		
Willingness to share risks & rewards	5		
Sustainability and ethical practices	5		
Total Weighted score			

Appendix 04: Ethic Forms



Faculty of Business and Law

Application to Gain Ethics Approval for Research Activities Undergraduate/Postgraduate Taught Students

(PGR students and staff to complete other form – see <http://dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/business-and-law-ethics-procedures.aspx>)

Students should complete this form in consultation with their supervisors.

Form to be completed electronically only and uploaded to the module on Blackboard in line with module leader's advice (manually completed forms not accepted). Please **submit through Turnitin** (**Note for Supervisors:** when providing a location for submission on Blackboard it is suggested to a) turn off originality setting; b) not request generation of similarity reports; c) ask for no submission to any other repository)

Please also see footnotes on Page 12

SECTION 1. Applicant	
Please complete all sections	
Last Name: Wellewattage	
First Name: Samurdi	
Student number: P2900404	
DMU Email address: 59198@edu.nielsbrock.dk	
Programme of Study (Course title) : Master of Business Administration	
Module (name): Research Methods and Consulting Project	
Module (code): BMBA5007	
Supervisor's Name: Supreet Kanwal	
Co-Applicants Name(s) if applicable:	

SECTION 2. The Research	
2a Title:	Exploring and Evaluating Strategic Partnership Opportunities for a Europe-based API Pharmaceutical Company
2b Start Date:	Sep 2025

2c End Date:	Dec 2025
2d Research Question(s) or aim(s)	To explore and evaluate potential partnership opportunities with Indian pharmaceutical and biotechnology companies for a Europe-based API pharmaceutical company to support growth and diversification strategies.
2e Please provide a description (in your own words) of your research and the methods you will use to gather data – (please note if you are employing more than one method of data collection you need only complete one ethics application form but ensure here you provide full details of both proposed methods)	<p>IMPORTANT: Please include the following details in your description of what you are planning to do</p> <ul style="list-style-type: none"> • Who your sample will include (<i>not names but job roles, positions in civic society etc</i>) • How will they be selected and recruited? • Provide details of your principal data collection methods (e.g. questionnaires, interviews, observation, social media sites, documents – be as specific as possible but ensure that you submit a copy of your questionnaire or your schedule of research questions with this application) • Where will you be collecting the Data? (<i>please provide details of the sites/locations where data collection will take place- and what times of day i.e during normal working hours i.e. 9am till 5 pm</i>) • If you are collecting data at a primary or secondary school/work premises/police stations/law courts etc. (but not the NHS) have you obtained, or will you obtain, written permission from the organisation <u>before</u> you start your research? If your answer is 'No' please state the reasons why. • If you are collecting data off DMU campus will a member of DMU Staff or responsible adult such as a relative or friend be made aware of the locations you intend to undertake research, dates and times and when you are expected to return? Please state the name and contact details of the DMU member of staff or responsible adult (Please see the Suzy Lamplugh Foundation Guidelines on lone working: https://www.suzylamplugh.org/) • Give details as to whether your project being funded by a third party? (this includes if funding has been applied for but not yet given) • If you are collecting data elsewhere other than the UK, will you also obtain ethical approval within that host country? If not, please explain. Have you identified and complied with all local requirements in that country concerning ethical approval & research governance and data protection*? Please also give contact details of a local person identified to field initial complaints locally so the participants can complain without having to write to or telephone the UK <p><i>*Please note that many countries require local ethical approval or registration of research projects, further some require specific research visas. You must also ensure you are aware of and abide by the national data protection legislation including legal requirements around research using data and transfer of data to and from the UK. If you do not abide by the local rules of the host country, you will invalidate your ethical approval from DMU, and may run the risk of legal action within the host country</i></p> <p>This study adopts a case study analysis using a company-by-company approach according to the criteria given by Europe-based API pharmaceutical company X within a mixed-methods approach (for supporting insights from survey and interviews), combining both quantitative and qualitative elements to evaluate strategic partnership opportunities between Europe-based API pharmaceutical company X and selected Indian pharmaceutical companies. The research primarily relies on secondary data obtained from credible sources to ensure depth and reliability. PharmaCompass, EudraGMP provided company profiles, API portfolios, and regulatory compliance data (e.g., USFDA, WHO-GMP). Company websites and annual reports offered insights into corporate strategies, R&D activities, product categories, and collaboration opportunities. Academic sources such as Emerald Insight, EBSCOhost, PubMed and ScienceDirect supplied peer-reviewed articles and case studies on partnerships,</p>

collaboration frameworks, and partner selection criteria. Additionally, Statista was used to obtain industry statistics and market trends relevant to pharmaceutical industry.

India has been selected as the focus country because it has many high-potential pharmaceutical companies, offers cost-effective production capacity, and aligns strategically with the objectives of the EU-based company seeking partnerships in this market.

Although online interviews could be used to collect primary data, they will be conducted only with companies that respond to the survey and provide consent, making the interviews optional and limited to willing participants. The potential respondents are senior managers spread across different parts of India, which makes scheduling multiple online interviews challenging. The project is time-sensitive, and coordinating interviews with many busy professionals would require significantly more time and effort. Additionally, online interviews may provide further insights, but they will be conducted optionally, only if the survey method yields a sufficient response. Using a structured online survey allows participants to respond at their convenience, ensures consistent and comparable data, and enables efficient collection of information from multiple companies within a limited timeframe.

Accordingly, primary data will be collected through an online survey distributed to senior professionals from potential partner companies in India. The sample will include Business Development Heads, R&D experts, and Managers who are involved in strategic decisions from potential partner companies in India. Participants will be identified and contacted via LinkedIn, official business email addresses, or the inquiry forms on company websites (when other contact methods are unavailable).

Companies have been preselected based on criteria defined by the EU company's manager and will be evaluated through a structured evaluation framework using constructs such as regulatory strength, technological capability, product portfolio fit, market reach, collaborative willingness, reputation and credibility, financial and operational stability, cultural compatibility, and strategic synergy. These constructs were also used to design the survey, with some, such as strategic fit, adapted from previously published research papers.

As the study focuses on predefined partner personas and specific selection criteria within a B2B context, the eligible respondent pool may be limited; therefore, this primary data will be used as supportive evidence to enrich the overall analysis. If strong responses are obtained to the survey and those responses are validated by the secondary data, semi-structured interviews may also be conducted. The data collection from interview method is optional; if carried out, they will provide additional depth and strengthen the project's findings. The primary data from the survey (created online using Microsoft Forms and distributed to managers via LinkedIn messages as well as company email addresses from the researcher's official Outlook account) will serve as supportive evidence, because the B2B context, specific partner selection criteria, and predefined personas naturally reduce the eligible respondent pool, which may lead to a lower response rate. Secondary data remain the main analytical base, while survey responses help enrich the analysis.

All participants will receive an information sheet and informed consent form before completing the survey, ensuring their participation is voluntary and confidential. The study is not funded by any third party and is conducted solely for academic purposes.

SECTION 3. Conflict of Interest

	Yes	No
3a Do you have any connection with the external organisation(s) being researched? Such as		X

<p>through personal, financial or family connections</p> <p>If 'Yes' please give details If you are employed by the external organisation please advise if you will receive any financial or in-kind benefits or payments for undertaking the research from the organisation</p>		
<p>SECTION 4. Research Ethics and the Protection of Participants' Interests</p> <p><i>NB. Participants should suffer no harm as a result of participation in the research</i></p>		
<p>4.1 Please provide details here as to whether participation by those in your sample will be</p>		
<p>a) Voluntary</p>		
<p>b) Based on informed consent</p>		
<p>(Please provide copies of the participation sheet and consent form -Templates available on BAL Ethics website http://dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/business-and-law-ethics-procedures.aspx)</p>		
<p>Participants will be informed that their participation in both the online survey and the optional semi-structured interviews is entirely voluntary. For the survey, participants will be informed that completing it is voluntary, and they may skip any questions they do not wish to answer (except for required questions) before submitting their responses. For the optional semi-structured interviews, participation will also be voluntary and based on informed consent. Interview recording will only take place with the participant's explicit permission. For both survey and optional semi-structured interviews, all participants will receive an information sheet, and consent form in accordance with the Faculty of Business and Law Ethics guidelines.</p>		
<p>4.2 Please also provide details as to how your participants' identities will be protected with regard to</p>		
<p>a) Confidentiality with respect to the data</p>		
<p>b) Anonymity in terms of any reported findings from the research</p>		
<p>research process will avoid emotional harm or upset to those taking part</p>		
<p>c) Data that has been gathered will be kept securely? (For example, will files and data sticks be encrypted? Or data stored on password protected computers? It is highly recommended that you use the DMU Figshare facility – see (for details of how to use this secure storage repository: https://library.dmu.ac.uk/rdmguide/dmufigshare)</p>		
<p>Please note: If using a recording device for interviews please advise when the original recording will be erased (e.g immediately upon uploading to a secure device such as your password protected computer)</p>		
<p>Participant identities will be fully protected throughout the research. Survey responses will be collected anonymously without names, emails, or phone numbers etc. For the optional semi-structured interviews, participants will be assigned coded identifiers (e.g., "Participant 1," "Participant 2") with only their job role mentioned where relevant, ensuring anonymity in all reported findings.</p>		

All data will be kept confidential and securely stored on the password-protected Niels Brock OneDrive, accessible only to the researcher. Interview recordings (if consented to) will be transferred immediately to this secure location and deleted from the recording device. All files will be deleted once the project is completed and the degree awarded.

The research has been designed to avoid any emotional discomfort or distress, and participants may withdraw or skip questions at any stage without consequence.

4.3 What steps you will undertake to avoid/minimise emotional harm or upset to those taking part (including measures signposting individuals should they become distressed later e.g To staff welfare services)

The research has been designed to avoid any potential emotional harm or discomfort to participants. The online survey will not include any sensitive or personal questions, and participants will be informed that they may skip any question (except required questions) or choose not to complete the survey if they feel uncomfortable.

For the optional semi-structured interviews, participants will be briefed beforehand on the nature of the questions, which will focus solely on professional perspectives rather than personal or sensitive matters. Participants may decline to answer any question or stop the interview at any point without providing a reason.

SECTION 5. Sensitive Research

If your research topic is concerned with the following 'sensitive research' areas: illegal activities, including the collection of source data, e.g. access to web sites normally prohibited on university servers, or extremism and radicalisation please complete the questions below. (For more information see <http://www.dmu.ac.uk/research/ethics-and-governance/sensitive-research.aspx>)

5a Does the intended research include research into illegal activities ⁱ that are previously unknown to the law enforcement agencies? (This may include, but is not limited to, research into hate crime ⁱⁱ , theft, fraud, or harmful and illegal cultural practices ⁱⁱⁱ ,	Yes	No
<p><i>Please note: the university does not permit any crime to be committed for research purposes, such as accessing images of paedophilia or child abuse, unless special</i></p>	5a	X

<i>permission has been granted by the Home Office.</i>		
5b Does the research involve deception? Are the participants fully informed of the nature of the research? If not, why not?	5b	X
5c Will the research require the use of sites usually prohibited on university computers (e.g. pornography or the sites of these prohibited organisations)? ^{iv}	5c	X
Does the intended research fit into any of the following categories? If you are unsure as to whether your research will involve any of these categories in 5d to 5h you are advised to answer 'Yes'	Yes	No
5d Terrorism, extremism, terrorist or extremist organisations or groups, extremist ideologies, radicalisation^v, de-radicalisation^{vi}	5d	X
5e Has the research been Commissioned by the military or GCHQ	5e	X
5f Has the research been Commissioned under an EU / US security call or similar	5f	X
5g Does the research involve the viewing, usage or transfer of sensitive personal data as defined by relevant Data Protection Regulations	5g	X
5h Does the research involve the acquisition of security clearances (including the Official Secrets Act)	5h	X
SECTION 6. Accessing Websites		

	Yes	No
6a Will your research involve visits to websites that might be associated with radicalisation or terrorist/extremist organisations or groups?		X
<i>If you answer 'Yes' to Q6a you are advised that such sites may be subject to surveillance by the police and accessing those sites might lead to police enquiries. It is strongly recommended that you use your university network address, once you have received ethical approval, which will ensure these activities are flagged as a legitimate part of your research. Whilst acquiring ethical approval for this project and adhering to University guidance on accessing websites and storing related materials securely will allow the University to verify the legitimacy of you accessing these websites, it cannot guarantee legal protection.</i>		

6b

Please acknowledge that you understand this risk by putting an 'X' in the 'I Agree' box.

I Agree	<input checked="" type="checkbox"/> X
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SECTION 7. Storage and Transmission of Research Materials

	Yes	No
7.1 Does your research involve the downloading and storage on a computer of any materials relating to extremism or radicalisation (for example, records, statements or other documents)?		X

If you answered 'Yes' to Q7.1, you should request a secure file share from ITMS to be created for your project, with access restricted to you, or if absolutely necessary, any internal co-investigator(s). The research materials should not be kept on a personal computer, and all online research in this area should be done on university servers^{vii}. Physical data should be scanned and uploaded to the password-protected server; where this is not possible, it should be kept in a locked filing cabinet or similar on university premises.

You will need to agree to store all materials relevant to Section 7.1, as well as any other materials related to your research project in

<p>accordance with this advice in order to gain ethical approval.</p> <p>Please confirm you will store all research documents in accordance with this advice by putting an 'X' in the 'I Agree' box.</p>	<input type="checkbox"/> I Agree	<input checked="" type="checkbox"/> X	
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7.2 Might your research involve the electronic transmission of such materials to project Co-Investigators? Yes/No

Note: The Terrorism Act (2006) and the Counter-Terrorism and Security Act (2015) outlaw the dissemination of terrorist publications if the individual concerned has the intention to encourage or induce others. Publications disseminated for the purposes of an approved and clearly defined research project should not amount to an offence, because the requisite intention is unlikely to be present. However, you are advised to exercise caution and avoid dissemination of raw research materials where possible.

You will need to agree to only transmit these materials to Co-Investigators after they have been password-protected and that you will only use '[Zend](#)^{viii}', which encrypts materials in transmission.

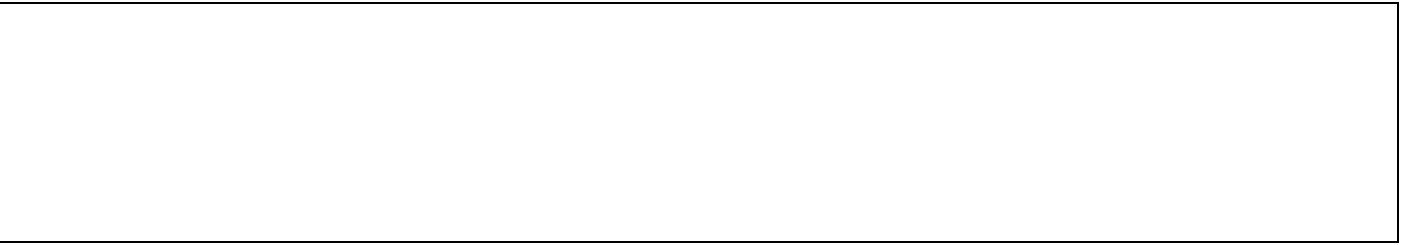
Please confirm you understand the risks in disseminating publications and that you will only transmit these materials to collaborators after they have been password-protected and via '[Zend](#)'. (see footnote at end of form)

I Agree	<input type="checkbox"/> X
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Section 8. Additional Questions

	Yes	No
8.1 Are you specifically recruiting (as participants) pregnant women		X
8.2 Will persons from any of the following groups be participating in the study		
8.3 Adults without capacity to consent		X
8.4 Those with learning disabilities		X
8.5 Prisoners		X
8.6 Adults at risk		X
If yes please give details of		
- the protection procedures you propose to adopt should there be any evidence of or suspicion of harm (physical, emotional or sexual) to adults at risk.		

<p>Include a referral protocol, identifying what to do and who should be contacted.</p> <ul style="list-style-type: none"> - of how you propose to ensure the well-being of adults at risk, particularly with respect to ensuring that they do not feel pressured to take part in the research and that they are free to withdraw from the study without any prejudice to themselves at anytime. You should indicate how you intend to ascertain that person's views and wishes. 		
8.7 Young offenders (16-21 years)		X
8.8 Those who would be considered to have a particular dependent relationship with the researcher (e.g. those in care homes, students, employees, colleagues)		X
8.9 Will you be recruiting (as participants) or have direct contact with any children under the age of 18? <p>If yes,</p> <ul style="list-style-type: none"> • please give details of the child protection procedures you propose to adopt should there be any evidence of or suspicion of harm (physical, emotional or sexual) to a child/young person. Include a referral protocol identifying what to do and who should be contacted. • Please give details of how you propose to ensure the well-being of the child/young person, particularly with respect to ensuring that they do not feel pressured to take part in the research and that they are free to withdraw from the study without any prejudice to themselves at any time 		X
<p>If you have answered yes to ANY question in Section 8 please give details</p> <ul style="list-style-type: none"> • of any staff or students who will have contact with adults at risk and/or will have contact with young people (under the age of 18) • of current Disclosure and Barring check for you (and also for those staff or students named above at a) 		



SECTION 9. Codes of Ethics

9 a) Which Code of Research Ethics will be adhered to during the course of your research?

Examples of Codes can be found at <http://www.dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/business-and-law-ethics-procedures.aspx>

Name: (not applicable)	Web address:		
		Yes	No
9b) I confirm that all information collected will be processed by use in accordance <u>GDPR 2018</u>		X	
9c) I confirm that I will follow DMU's ethical codes of conduct for <u>Good Research Practice</u>		X	
9 d) I confirm that I will follow DMU's <u>Policy on Managing Research Data</u>		X	

SECTION 10. Supporting Documents

SUPPORTING DOCUMENTS (all documents should have a version number and date)

Compulsory

PLEASE TICK AGAINST EACH ONE THAT YOU ARE SUBMITTING WITH THE APPLICATION FORM

Appendix A (for all applicants)

Research proposal (may help the supervisor understand your ethics application)

For those whose research involves human participants (Appendices B, C and D required)

Appendix B

Data Collection tools (e.g draft interview schedule, survey questionnaire)

Appendix C

Participant information sheet (see submission guidelines for example)

Appendix D

Consent form (see submission guidelines for example)

IMPORTANT!!!!

PLEASE MERGE ALL OF THE ABOVE FORMS WITH THIS ETHICS APPLICATION FORM SO THAT YOU ARE SUBMITTING A SINGLE DOCUMENT TO BLACKBOARD (ATTACH THESE FORMS TO THE BACK OF THIS ETHICS APPLICATION FORM)

SECTION 11. Declaration and Signatures

I confirm that I have read ***the Responsibilities of the Researcher*** guidelines at <http://www.dmu.ac.uk/research/ethics-and-governance/responsibilities-of-the-researcher.aspx> and I will comply with them.

I have considered my own personal safety and if/when my ethics application is authorised a separate Risk Assessment will / will not be completed (please delete as appropriate). See Section 13

11a Signature of Applicant	Samurdi Sandaruwani	Date: 31.10.2025
11b Signature of workplace supervisor (if applicable)	*Support/non-support (please give reasons for non-support)	Date:

Please upload to the relevant module on Blackboard.

MODULE LEADER ONLY:

(Note for Supervisors: when providing a location for submission on Blackboard it is suggested to (a) turn off originality setting; (b) not request generation of similarity reports; and (c) to ask for no submission to any other repository). You might also wish to create your own rubric and grading to reflect both risk level and application outcome

Supervisor and Module Leader to each review ethics application (unless the Supervisor and Module Leader is one and the same person- in which case the Supervisor and the Programme Leader should review the application. However, if the Supervisor, the Module Leader, and the Programme Leader are all one and the same person, then the Supervisor needs to find an academic colleague to also review the form).

Once each has reviewed the application, please sign Section 11e and scan the form and upload to Blackboard (or if preferred use a digital signature and upload to Blackboard). Note: if the other Reviewer does not have access to that particular module on Blackboard, the application form once authorised etc (and signed) should be forwarded to the supervisor by email for them to upload on Blackboard.

In medium and high risk case please send email to Dave Walsh (dave.walsh@dmu.ac.uk) to advise of medium and high risk cases with student name/module code for that application to be authorised

11c Risk Level Assessment

I determine the risk level of this application to be;

Please refer to FREC Ethics Guidelines (**Pages 9-11**) at:

<http://dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/business-and-law-ethics-procedures.aspx>

Note for Supervisor: For MEDIUM and HIGH risk applications, please notify FREC of the Module name, number and student name by emailing: BALResearchEthics@dmu.ac.uk
Low risk cases should be logged and filed.

Low Risk	X	Medium Risk		High Risk	
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11 d Please confirm that the applicant has addressed each of the following issues to your satisfaction (if applicable).	Yes	No	N/A
The study design is appropriate and within ethical parameters	X		
The research questions are clear and within ethical parameters	X		
Recruitment method is explicit, fair, free from duress and data protection is not breached	X		
Sample and sampling method is appropriate and ethical	X		
Participants are fully informed about the research in writing	X		
Participation is voluntary with informed consent?	X		
Vulnerable people have additional interventions to ensure informed consent (e.g. parents, guardians, carers, advocates etc)			X
Participants are given details of how to complain	X		
DMU consent form template has been used	X		
Data will be stored securely, and for the appropriate duration	X		
Permission has been, or will be, sought from external host organisation (where applicable) or good reasons given where it has not been sought	X		
Confidentiality, anonymity and privacy will be ensured and maintained	X		
Possible adverse outcomes to participants are identified and suggestions to minimise or deal with these are presented			X
Risks to the researcher are identified and suggestions to minimise or deal with these are presented (in the laboratory or off campus)			X
Do the procedures identified necessitate formal assessment by another ethical committee? If yes, which one?		X	

SECTION 11e. Outcome of review	Please tick one box only
I recommend this study is given ethical approval (no changes required)	<input checked="" type="checkbox"/> X
I do not support this application (please give reasons)	
I recommend the applicant addresses the changes listed below and the resubmission is re-reviewed by a Reviewer or the Chair	
Please list the specific changes the applicant must make to obtain ethical approval	
Please write any additional comment you may have (optional)	
Name: Supreet Kanwal (1st Reviewer) Signed: Supreet Kanwal (1 st Reviewer) Date: 31-10-2025	Name..... (2 nd Reviewer) Signed..... (2 nd Reviewer) Date.....

SECTION 12. Faculty Research Ethics Committee (For Medium and High-Risk Cases Only)

For applications identified as **Medium** or **High Risk** to be reviewed by FREC.

Faculty Research Ethics Committee

Approval /Rejection/Referral (please delete which does not apply)

*This is the final approval from the BAL faculty Research Ethics Committee that this Ethical Approval application has been approved as outlined in the application.

- * This Ethics application is rejected for the following reasons
- * This Ethics application is referred back to applicant
- * This Ethics application is referred to FREC/UREC for further consideration

Comments (if applicable)

Medium Risk cases

BAL FREC Reviewer Name.....

BAL FREC Signature..... (then send ethics application to
BALResearchEthics@dmu.ac.uk

High Risk Cases

BAL FREC Chair's Name:.....

BAL FREC Chair's Signature:.....

Date:

SECTION 13. HEALTH AND SAFETY – FOR THE APPLICANT AFTER AUTHORISATION!

Are you planning to undertake your research off- campus? No
Yes/No (please delete as appropriate)

If yes, if you are planning to undertake research off-campus then you must contact Lisa-Jayne Evans by sending her a copy of this AUTHORISED ethics application form explaining to her that you propose to undertake research off-campus and as such you recognise that a risk assessment is required (**Lisa-Jayne's email address is: lisa-jayne.evans@dmu.ac.uk**).

In most cases it is anticipated that Lisa-Jayne will send you a signed risk assessment form advising you how to remain safe and well while undertaking your research. In exceptional cases Lisa-Jayne will meet with you to assess risks.

Once you have received your authorised risk assessment from Lisa-Jayne please attach it to your authorised ethics application.

Appendix A – Research Proposal

The pharmaceutical industry is one of the most growing and dynamic sectors globally playing a pivotal role in safeguarding public health, driving innovation, and creating long-term economic value. The industry is fragmented across North America, Europe, Asia, and Africa, and is projected to grow from US\$ 16.81 billion in 2025 to US\$ 55.16 billion by 2032, reflecting a compound annual growth rate of 18.5% (Coherent Market Insights, 2025). The United States leads globally, while Switzerland, the UK, and France are major European players (Rathore et al., 2023). With Europe's life sciences sector expanding rapidly, this project provides the researcher with an opportunity to apply analytical and academic skills to a real-world business challenge, while developing expertise relevant to a strategic management career.

This report focuses on a situational analysis of a European Active Pharmaceutical Ingredients (API) company, referred to as X company, along with the applied methodology. X has over 120 years of experience in fermentation-based anti-infective APIs. In 2024, X reoriented its business, signalling a strategic focus on fermentation-based APIs and selected finished dosage forms (FDF) for global B2B markets. However, the absence of an active product pipeline creates a long-term growth challenge, thereby forming the research problem.

X's current analysis highlights both strong capabilities and critical challenges. Its strengths lie in being a leader in fermentation-based anti-infective APIs, serving large B2B customer base, and operating manufacturing sites in Europe and Asia. The company's focus on critical care APIs and its wholly owned subsidiary in India further enhance its global reach. However, weaknesses include a limited pipeline, high costs, dependence on mature low-margin products, financial losses leading to negative equity, and limited internal R&D. Key opportunities arise from the growing demand driven by the Antimicrobial Resistance (AMR agenda), potential collaborations with Indian firms, expansion into adjacent critical care areas, and partnerships or spin-offs with divesting firms. Yet, threats such as low-cost Asian competition, regulatory complexities, market volatility, and global supply chain disruptions continue to pressure X's long-term sustainability.

Management has identified external alliances as a potential solution, consistent with literature that emphasizes international partnerships as a response to global competition, providing access to foreign markets, manufacturing capacity, R&D expertise, and patents (Hagedoorn, 2002). Emerging markets such as India are particularly attractive due to their strong manufacturing base, cost efficiency, and rapidly growing biotech sector (Feller, 2003). To address its growth challenge, X aims to pursue partnerships in these markets. Accordingly, to solve the problem below research aims, objectives and question were identified.

Research Aim

To explore and evaluate potential partnership opportunities with Indian pharmaceutical and biotechnology companies for a Europe-based API pharmaceutical company X to support growth and diversification strategies.

Research Objectives

- To analyse the external and internal factors influencing partnership opportunities with potential Indian companies.
- To identify and apply appropriate criteria for evaluating potential partners.
- To assess shortlisted Indian Pharmaceutical and biotechnology companies for operational and strategic suitability.
- To recommend partners that best align with Europe-based API pharmaceutical company X's long-term growth and diversification goals.

Research Questions

1. What external and internal factors influence partnership opportunities with Indian pharmaceutical and biotechnology companies?
2. What criteria are most appropriate for evaluating potential partners?
3. Which Indian pharmaceutical and biotechnology companies are most suitable for partnership?
4. How can selected partners best support X Company's growth and diversification objectives?

Research Design

This study adopts a case study analysis using a company-by-company approach according to the criteria given by Europe-based API pharmaceutical company X within a mixed-methods approach (for supporting insights from survey and interviews), combining both quantitative and qualitative elements to evaluate strategic partnership opportunities between Europe-based API pharmaceutical company X and selected Indian pharmaceutical companies. This approach helps to understand potential partners better by combining measurable data with insights from industry information and company materials. The study is applied in nature, as it seeks practical outcomes that support strategic decision-making in international partnerships. Additionally, primary data are considered supportive due to the B2B context and the limited pool of eligible respondents.

Research Approach

The study first conducted PESTEL and Porter's Five Forces analyses from the perspective of Europe-based API pharmaceutical company X for India to identify micro and macro-level risks and opportunities. These findings were then matched with Europe-based API pharmaceutical company X's SWOT analysis to determine strategic alignment and inform the shortlisting of potential partners.

Potential companies were identified using high-level screening criteria to ensure relevance and feasibility:

Company type: API manufacturers, CDMOs, biotechnology firms, or generic drug companies with in-house API capabilities

Geographic focus: India, due to the cost advantages for the Europe-based API pharmaceutical company X and the larger scope of potential pharmaceutical partners available for collaboration

Alignment with Europe-based API pharmaceutical company X'S predefined partner personas

Operational scale, regulatory compliance, and strategic relevance, complementarity

The research primarily relies on secondary data obtained from credible sources to ensure depth and reliability. PharmaCompass, EudraGMP provided company profiles, API portfolios, and regulatory compliance data (e.g., USFDA, WHO-GMP). Company websites and annual reports offered insights into corporate strategies, R&D activities, product categories, and collaboration opportunities. Academic sources such as Emerald Insight, EBSCOhost, PubMed and ScienceDirect supplied peer-reviewed articles and case studies on partnerships, collaboration frameworks, and partner selection criteria. Additionally, Statista was used to obtain industry statistics and market trends relevant to pharmaceutical industry. These sources provide both quantitative indicators (e.g., production capacity, regulatory approvals, market presence) and qualitative insights (e.g., strategic direction, collaboration history, reputation, culture (Esmaelnezhad et al., 2023), which help in evaluating potential partners.

To complement and validate the findings, primary data will be collected through an online survey distributed to senior professionals from potential partner companies in India. The sample includes Business Development Heads, R&D experts, and Managers who are involved in strategic decisions. Participants will be identified and contacted via LinkedIn, official business emails, or inquiry forms on company websites (when other contact methods are unavailable).

However, if strong responses are obtained to the survey and those responses are validated by the secondary data, semi-structured interview method may also be conducted. The data collection from interview method is optional; if carried out, they will provide additional depth and further strengthen the project's findings. The primary data from the survey (created online using Microsoft Forms and distributed to managers via LinkedIn messages as well as company email addresses from the researcher's official Outlook account) will serve as supportive evidence, because the B2B context, specific partner selection criteria, and predefined personas naturally reduce the eligible respondent pool, which may lead

to a lower response rate. Secondary data remain the main analytical base, while survey responses help enrich the analysis.

Justification of the Approach

This research adopts a case study design to explore strategic partnership opportunities in India for Europe-based API pharmaceutical company X. The case study allows an in-depth understanding of company-specific strategies, potential partners, and operational challenges. Primary data is collected through a self-designed survey (with some constructs adapted from previously published papers) and, optionally, through semi-structured interviews if the researcher receives positive responses from the survey. The survey captures key variables related to partnership criteria and market perceptions informed by published research in the pharmaceutical sector. Secondary data, including industry reports and company information, supports and contextualizes the findings.

Although online interviews could be used to collect primary data, they will be conducted only with companies that respond to the survey and provide consent, making the interviews optional and limited to willing participants. The potential respondents are senior managers spread across different parts of India, which makes scheduling multiple online interviews challenging. The project is time-sensitive, and coordinating interviews with many busy professionals would require significantly more time and effort. Additionally, online interviews may provide further insights, but they will be conducted optionally, only if the survey method yields a sufficient response. Using a structured online survey allows participants to respond at their convenience, ensures consistent and comparable data, and enables efficient collection of information from multiple companies within a limited timeframe.

This approach provides a comprehensive, applied analysis by combining qualitative insights and descriptive quantitative data to guide Europe-based API pharmaceutical company X's strategic decision-making. The main analytical frameworks used include SWOT, Value Chain Analysis, the Suitability, Acceptability, and Feasibility (SAF) framework, and the Partner Scorecard, which together help identify the three best companies for potential partnerships in India. Subsequently, Europe-based API pharmaceutical company X Company can apply this evaluation framework to select potential partners in other markets.

Population and Sampling

The study population consists of Indian pharmaceutical and biotechnology companies involved in API-related activities, including API manufacturers, CDMOs, biotechnology firms, and generic drug manufacturers with in-house API capabilities. This broader inclusion allows the study to capture the full ecosystem of potential partners. India has been chosen because it has many high-potential pharmaceutical companies, offers cost-effective production capacity, and aligns strategically with the EU-based company's regional priorities.

A purposive sampling technique was applied to identify firms that meet the predefined partner personas by Europe-based API pharmaceutical company X and selection criteria. The sample unit includes senior managers or decision-makers

such as heads of Business Development, Operations, or technical divisions capable of providing accurate and relevant data on operational, technological, and partnership aspects. Approximately 50 companies are expected to be shortlisted based on information from Pharma Compass, EudraGMP, company annual reports, and company websites.

The sample size is small and focused due to the consultancy-oriented B2B context, which limits the number of eligible and relevant respondents. In addition, the specific partner selection criteria and predefined personas naturally reduce the pool of potential companies. A smaller, targeted sample ensures that the data collected are in-depth, and comparable, while remaining manageable for analysis.

Evaluation Framework

Once companies were identified, they were evaluated in detail using a structured Partner Evaluation Framework, which defines what is measured for each partner. This framework assesses each potential partner across constructs identified from prior literature, including Regulatory strength, Technological capability, Product portfolio fit, Market reach, Collaborative willingness, Reputation and credibility, Financial and operational stability, Cultural compatibility, Strategic synergy.

The framework is applied across four key dimensions:

Strategic Fit – capabilities, market alignment, persona fit

Operational Fit – value chain, technology, regulatory compliance

Relational Fit – trust, reputation, cultural compatibility

Financial & Risk Profile – stability, sustainability, and risk

These constructs were also used to design the survey, with some, such as strategic fit, adapted from previously published research papers. Evaluation is performed using a Partner Scorecard (weighted scoring of constructs), followed by SWOT and SAF analyses for the top candidates, considering strategic alignment, operational feasibility, and stakeholder acceptability.

Integration of Data and Analysis

The study integrates primary and secondary data to provide a comprehensive evaluation of potential partners. Secondary data serve as the main analytical base, offering quantitative indicators such as production capacity, regulatory approvals, and market presence, as well as qualitative insights including company strategy, reputation, collaboration history, and organizational culture. Primary survey data act as supportive evidence, enriching the secondary analysis. Quantitative responses from the survey, including choice questions and Likert-scale ratings, allow partners to be ranked and compared numerically, while qualitative open-ended responses provide insights and explanations that help interpret the ratings. This combination helps the study to rank and compare companies using the Partner Scorecard, understand their strategy and context through qualitative insights, and ensure the findings are accurate by combining numbers with real-world perspectives.

Informed consent, confidentiality, anonymity, and data security will be maintained throughout both primary and secondary data collection. Relevant ethics approval forms will be submitted before data collection.

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Appendix B – Data collection Tools

Data Collection Methods

The study employs both primary and secondary data sources to ensure comprehensive coverage and credibility. Secondary data serve as the main analytical base, collected from sources such as PharmaCompass, EudraGMP company websites, to know about their regulatory approvals, and market reports (e.g., Statista) to support company selection and provide contextual understanding. Primary data, collected through a structured online survey, serve as supportive evidence to enrich the secondary analysis.

The survey includes Likert-scale items (1–5) and rating/selection-type questions. Additionally, there are open-ended responses to capture participants' perspectives, explanations, or contextual information not reflected in the closed-ended items. The 5-point Likert scale captures varying degrees of agreement and facilitates ranking of partners. Rating-type measures allow differentiation of partnership compatibility across firms. Open-ended responses provide qualitative

context to help interpret the ratings. Data will be collected digitally using Microsoft Forms, which supports structured question formats, secure online submission, and automated data collation. This approach ensures convenience, accessibility, and efficiency, particularly given the geographical dispersion of respondents across India. The survey captures key variables related to partnership criteria and market perceptions informed by published research papers in the pharmaceutical sector. Secondary data including industry report and company information supports and contextualise the findings.

Optional Semi-Structured Interviews:

If strong responses are obtained from the survey and validated against secondary data, semi-structured interviews may also be conducted. These interviews are optional but would provide additional depth and further strengthen the project's findings.

Data Analysis Techniques

Quantitative data from the survey, including Likert-scale and rating questions, are analysed using descriptive statistics and weighted scoring to rank and compare potential partners. Qualitative data from the open-ended responses, are analysed thematically to identify explanations, and insights that help interpret the quantitative ratings. Together, the primary and secondary data enable a more comprehensive understanding of each company's partnership potential, with the secondary data forming the main analytical foundation and the survey enriching the findings.

Survey Development and Validation

The survey was developed based on constructs from the Partner Evaluation Framework, identified through a review of relevant literature. As no publicly available surveys exist specifically for assessing pharmaceutical partnership opportunities (except some of the constructs which are important in looking for partnership opportunities), the items were adapted to the EU-India partnership context to ensure relevance to the study objectives. To enhance clarity, validity, and reliability, the survey is pilot tested with four respondents, including an industry expert and, research supervisor. Validity of the survey is ensured through expert review and readability test. The online survey, prepared on Microsoft Forms, will be sent to managers via LinkedIn messages as well as to the official emails of pharmaceutical companies in India (using the researcher's official Outlook account) and the draft of semi-structured interview questions (optional) is also presented below.

Survey

- *1. What is your company name?
- *2. What is your position?

Section 1 –Market Presence

- *3. Does your company export to USA and/or EU ?

Region	Export (Yes/No)
Europe	<input type="checkbox"/> Yes <input type="checkbox"/> No
USA	<input type="checkbox"/> Yes <input type="checkbox"/> No

*4. Does your company currently have a partner/distributor in EU and/or USA?

Region	Partner/Distributor (Yes/No)
Europe	<input type="checkbox"/> Yes <input type="checkbox"/> No
USA	<input type="checkbox"/> Yes <input type="checkbox"/> No

5. Please indicate your satisfaction level on sales by region

Region	Satisfaction (1 = very unsatisfied, 5 = very satisfied)
Europe	1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>
USA	1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/>

Section 2 – Regulatory Compliance

*6. Our company's product portfolio aligns well with the EU and USA market requirements.

(1 = Strongly disagree 5 = Strongly agree)

1 2 3 4 5

Section 3 – Financial capability & Risk Orientation

*7. Our company has sufficient financial strength and access to funding sources (e.g., banks or investors) to partner with a European API company.

(1 = Strongly disagree 5 = Strongly agree)

1 2 3 4 5

*8. Our company is open to pursuing new opportunities or innovative projects.

(1 = Strongly disagree 5 = Strongly agree)

1 2 3 4 5

Section 4 – Technical Capabilities

*9. Which of the following manufacturing technologies does your company currently use or specialize in? (Select all that apply.)

- Solid dosage / tabling
- Liquid parenterals / injectables
- Semi-solids / topical forms (creams, gels, patches)
- Sterile / specialized processes (aseptic filling, lyophilization)
- Biologics / recombinant proteins
- Other -----

*10. To what extent does your company handle or collaborate across different stages of production? (Select one per row.)

(Example: A company that only makes APIs and does not produce or package finished medicines works in one stage only.)

Scale:

Not involved → No activity or collaboration in that type.

Some involvement → Limited or partial collaboration/handling.

Fully involved → Highly integrated or fully managing that stage.

Stage / Type of Involvement	Not involved	Some involvement	Fully involved
Horizontal: We work with other companies (e.g., co-development, joint projects)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vertical: We handle several production steps by Ourselves. (e.g., API manufacturing, formulation, packaging).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
One stage only: We mainly focus on one part of the process (e.g., only API or only FDF manufacturing)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section 5 – Strategic Fit, Market Opportunity & Barriers
(1 = Strongly disagree 5 = Strongly agree)

*11. Please indicate your level of agreement with the following statements.

Statement	1	2	3	4	5
Collaborating with a European partner could enhance our company's reputation and market positioning	<input type="checkbox"/>				
Market demand for our key products is growing Significantly	<input type="checkbox"/>				
There are relatively few strong competitors for our company in the target EU markets.	<input type="checkbox"/>				
Regulatory complexity is a major concern in partnering with a European API manufacturer.	<input type="checkbox"/>				
Cultural differences could be a barrier to smooth collaboration.	<input type="checkbox"/>				
CSR and ethical business practices are important factors when selecting a western partner.	<input type="checkbox"/>				

Section 6 – Collaboration Interests & Expectations

*12. What could your company offer to a European API manufacturer in a partnership? (select all that apply)

- APIs (Active Pharmaceutical Ingredients)
- FDFs (Finished Dosage Forms)
- Intermediates
- Technical / analytical services
- Contract synthesis
- Other -----

*13. What would you expect from your European partner in return? (select one per row)

Instruction: For each item, please indicate how important it is for your company in the potential partnership.

Scale:

1 – Not important / Not required

5 – Very important / Critical

Expectation	1	2	3	4	5
Market access	<input type="checkbox"/>				
Technology sharing	<input type="checkbox"/>				
Regulatory support	<input type="checkbox"/>				
Investment or financial collaboration	<input type="checkbox"/>				
Distribution channel access	<input type="checkbox"/>				

*14. Which markets would your company like to access by partnering with a European API manufacturer? (Select one per row)

Scale Description:

1 – Not interested

5 – Very high interest / Core focus

Region	1	2	3	4	5
Europe (outside current markets)	<input type="checkbox"/>				
Asia-Pacific	<input type="checkbox"/>				
Middle East & Africa (MENA)	<input type="checkbox"/>				
North / Latin America	<input type="checkbox"/>				

*15. Which product areas would your company be interested in collaborating on with a European API manufacturer? (Select one per row)

Instruction: For each product area, please indicate your level of interest in collaborating with the European API manufacturer.

Scale Description:

1 – Not interested

5 – Very high interest

Product Area	1	2	3	4	5
Oncology	<input type="checkbox"/>				
Cardiovascular / Metabolic Disorders	<input type="checkbox"/>				
Anti-infective	<input type="checkbox"/>				
Central Nervous System (CNS)	<input type="checkbox"/>				
Respiratory	<input type="checkbox"/>				

*16. What type of collaboration model does your company prefer with potential EU partner? (Select one per row)

Instruction: For each collaboration model, please indicate your level of preference or interest.

Scale Description:

1 – Not interested

5 – Very high interest / Preferred model

Collaboration Model	1	2	3	4	5
Long-term strategic partnership	<input type="checkbox"/>				
Project-based collaboration	<input type="checkbox"/>				
Technology co-development	<input type="checkbox"/>				
Licensing / distribution agreement	<input type="checkbox"/>				

17. Please share any expectations, thoughts, barriers, or suggestions your company may have regarding collaboration or partnership with a European API manufacturer

Microsoft form link:

https://forms.office.com/Pages/ResponsePage.aspx?id=358J-GI2p0aZeBu_D6X_zZesspk8Q_VDsadpRRrjzKVURVRRWDM4TjNOUKVMUTYyRERZM08xUkhHNi4u

Semi-structured interview questions (optional)

Interview Questions for Senior Management in Pharmaceutical Companies
(Target Participant: Business Development Heads, R&D Directors)

Thank you for filling the survey. These are just following up questions to understand your company's perspective on potential EU company collaboration.

- 1.What key factors do you consider before entering a cross-border collaboration (e.g., technology, compliance, market access, trust)?
2. What benefits you seek by collaborating with a European API pharmaceutical company.
3. In your experience, what factors could influence the effectiveness of strategic partnership, and how can they be addressed?

4. Could you please describe the key Corporate Social Responsibility (CSR) activities your company is currently engaged in - particularly any initiatives related to healthcare access, environmental sustainability, or community development?

Interview Questions for Technical Managers in Pharma/Biotech Firms
(Target Participant: Heads of Process Development, Quality and Compliance Managers)

Thank you for filling the survey. These are just following up questions to understand the technological, R&D, and compliance aspects of international collaborations, especially those related to API.

1. What are the main technical strengths and R&D capabilities your company has in API development?
2. How does your company currently integrate environmental sustainability into API development?
3. What benefits do you seek by collaborating with a European API pharmaceutical company?
4. In the context of a potential partnership with the European firm, what joint CSR or sustainability initiatives (e.g., waste reduction, energy efficiency, eco-friendly manufacturing, or ethical sourcing) could be realistically implemented at the operational or R&D level?

Appendix C – Participant Information Sheet

A participant information sheet will be provided for both the online survey and prior to the optional semi-structured interviews, if these are carried out.

Project title: Exploring and Evaluating Strategic Partnership Opportunities for a Europe-based API Pharmaceutical Company

Student name: Samurdi Sandaruwani Wellewattage

Thank you for taking an interest in this research. Before you continue it is important for you to understand why the research is being done and what it will involve. So, please take time to read the following information before confirming your consent to take part.

What is this study about?

This study aims to explore and evaluate potential partnership opportunities with Indian pharmaceutical and biotechnology companies for a Europe-based API pharmaceutical company, aiming to support growth and diversification strategies.

How long will it take to participate?

The study will take approximately 10 minutes to complete.

Why should I take part?

By taking part in this research, you will directly help with the study of exploring strategic partnership opportunities with a Europe-based pharmaceutical company. The findings of this research will be useful because they will directly help explore strategic partnership opportunities between a European API manufacturer and Indian pharmaceutical firms. The findings will offer practical insights to enhance collaboration, innovation, and sustainable growth in the industry.

Who is doing the research?

My name is Samurdi Sandaruwani, and I am studying the MBA programme at NBCBC

Why are you asking me to participate?

You have been invited because you are a Senior Manager or Technical Manager at an Indian pharmaceutical company identified as a potential partner in this research.

Do I have to take part?

Taking part in this research is completely voluntary. If you decide to take part, you are still free to withdraw without giving a reason.

Is the study confidential?

Yes. We take great care to ensure that we maintain the privacy of people who take part in research. The data will be used only for research purposes, and your name will not be used in any research reports or publications.

What if I want to withdraw?

If you want to stop participating, you are free to do so at any time without giving a reason.

Who has reviewed the study?

This study has been reviewed and approved by Niels Brock Copenhagen Business College.

What if I have a complaint?

If you have a complaint regarding anything to do with this study, you can initially approach my academic supervisor Supreet Kanwal and her email suka@nielsbrock.dk. If this achieves no satisfactory outcome, you should then contact the Dean of Academic Affairs Dong Hoang at dth@nielsbrock.dk

What if I have further questions?

If you have any questions about the study, please do not hesitate to contact Samurdi Sandaruwani and 59198@edu.nielsbrock.dk

Appendix D – Consent Form

A participant information sheet will be provided for both the online survey and prior to the optional semi-structured interviews, if these are carried out.

Participant Consent Form for the optional semi-structured interviews:

Research Participant Consent Form

Title of Research Project: Exploring and Evaluating Strategic Partnership Opportunities for a Europe-based API Pharmaceutical Company

Name of Researcher: Samurdi Sandaruwani

Please tick and initial all boxes if you agree

1. I confirm that I have read and understood the information sheet [date and version number] for the study above. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I agree to my data being anonymised and stored. I agree to it being shared in a relevant archive in this form.
3. I understand that my participation is voluntary. I also understand I am free to withdraw at any time- without giving any reason and without there being any negative consequences. I can decline to answer any particular question, or questions.
4. I agree that non identifiable quotes may be published in articles, used in conference presentations, or used for standard academic purposes such as assessment.
5. I agree to the interview being digitally audio recorded
6. I agree to the interview being digitally video recorded
7. I understand that the data collected during the study may be inspected by a supervisor from De Montfort University. I give permission for the supervisor to have access to my data.
8. I also acknowledge that if I am being interviewed this date may be transcribed by a third party, authorised by the university to undertake such duty.
9. I agree to take part in the above research project.

.....
 Print name of participant Date
 Samurdi Sandaruwani 31.10.2025.....
 ...Samurdi.....
 Print name of person taking consent Date
 Signature

Participant Consent Form for the survey:

Title of Research Project: Exploring and Evaluating Strategic Partnership Opportunities for a Europe-based API Pharmaceutical Company

To be able to participate in this survey, you must agree with the following statements by ticking the boxes:

- I understand the subject and purpose of the research and agree to participate in the questionnaire.
- I consent that my personal information will remain anonymous by the researcher.
- I confirm that my age is above 18.
- I hereby give my permission for the researcher to use the data.

**Preliminary Ethics Review for Taught Students
(undergraduate/Postgraduate/PGRs)**

NOTE: To be completed before collecting any data.

Applicant Name:	Samurdi Sandaruwani Wellewattage	Supervisor Name:	Supreet Kanwal			
Email Address:	59198@edu.nielsbrock.dk	Start Date:	Sep 2025	End Date:	Dec 2025	
Course and Module Title:	BMBA5007 Research Methods and Consulting Project					
Project Title:	Exploring and evaluating strategic partnership opportunities for a Europe-based API pharmaceutical company					
Ethical Considerations					YES	NO
Will your research involve interviewing or surveying individuals, groups or organisations?					X	
Will your research involve the administration of a questionnaire?					X	
Will your research involve the observation of human behaviour?						X

Will your research involve the gathering of information about human beings (and organisations) through interfering in normal physiological and/or psychological processes?		X
Will your research involve researching <u>and</u> identifying specific illegal activities <i>that are previously unknown to the authorities</i> (such as the police)?		X
Will your research involve visiting pornographic websites or ones that might be associated with radicalisation or terrorist/extremist organisations or groups		X
Will your research involve re-use of primary data originally related to any of the research activities mentioned above?		X

If you answered **NO** to **ALL** questions, ethical approval is not required. Please now sign this form and pass to your supervisor **with your research proposal- then once signed proceed to NEXT STEPS below** (if you have ticked 'yes' to one or more question also see NEXT STEPS below)

<p>I declare that I have answered 'NO' to all above questions. As such, the research that I will undertake does not require ethical approval.</p> <p>I understand that should my project brief change in such a way that I would answer 'YES' to any of the above questions, then I must seek ethical approval before undertaking any data collection.</p>			
Signature of Applicant:	Samurdi Sandaruwani	Date:	31.10.2025
I declare that the research student named above will be working under my supervision and that the work that he or she will undertake does not require ethical approval.			
Signature of Supervisor (If known, otherwise Module/Programme Leader):	Supreet Kanwal	Date:	31-10-2025

Footnotes

ⁱ **Illegal activities** incorporates **any illegal activity**; for example, trespassing, theft, or online piracy.

ⁱⁱ **Hate Crimes** are those committed against someone because of their disability, gender-identity, race, religion or belief, or sexual orientation.

ⁱⁱⁱ **Harmful and illegal cultural practices**: these include violence against women and girls, Female Genital Mutilation (FGM), forced marriage, child sexual exploitation and honour-based violence.

^{iv} **Accessing prohibited websites**: You will need to seek permission from ITMS; advice on how to gain permission is available from the [ITMS helpdesk](#).

^v **Radicalisation** refers to the process by which a person comes to support terrorism and forms of extremism leading to terrorism

^{vi} **De-radicalisation** usually refers to activity aimed at a person who supports terrorism and in some cases has engaged in terrorist related activity, which is intended to effect cognitive and/or behavioural change leading to a new outlook on terrorism and/or disengagement from it.

^{vii} **Secure File Share:** You will need to ask ITMS to create a Secure File Share for your project, with access restricted to yourself, or if absolutely necessary, any internal co-investigator(s). Advice is available from the [ITMS helpdesk](#).

^{viii} **Zend:** advice on using Zend is available from the [ITMS helpdesk](#).

**IMPORTANT: A COPY OF THIS COMPLETED AND
AUTHORISED ETHICS APPLICATION IS RECOMMENDED
TO BE SUBMITTED WITH THE
DISSERTATION/INDEPENDENT STUDY/PROJECT AS AN
APPENDIX ITEM**

Additional forms (such as participation information sheet, consent form, interview questions/questionnaire to be copied and pasted here to enable all forms to be merged into one document

