

STRATEGIC FRAMEWORK AND IMPLEMENTATION ROADMAP FOR ACCELERATED OSD GENERIC DRUG DEVELOPMENT IN EMERGING MARKETS

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by

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Under the Supervision and Guidance of

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CERTIFICATE

This is to certify that Akanksha Pal in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur has successfully completed her internship at IIHMR University, Jaipur during March 10th - June 9th, 2025.

IIHMR University, Jaipur

Date: 17th June, 2025

A handwritten signature in blue ink, appearing to read 'Rahul Sharma'.

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CERTIFICATE

This is to certify that the dissertation titled “**Strategic Framework and Implementation Roadmap for Accelerated OSD Generic Drug Development in Emerging Markets**” is a record of the research work undertaken by **Akanksha Pal** in partial fulfilment of the requirements for the award of the degree of MBA (Pharma Management) from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific and analytical.

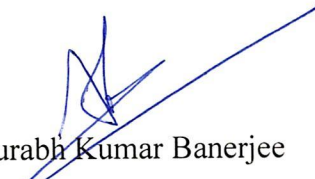
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DECLARATION BY STUDENT

I hereby declare that this dissertation titled **“Strategic Framework and Implementation Roadmap for Accelerated OSD Generic Drug Development in Emerging Markets”**. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.



(Signature)

Akanksha Pal

Date: June 17th, 2025

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Title: "Strategic Framework and Implementation Roadmap for Accelerated OSD Generic Drug Development in Emerging Markets"

Abstract:

This project encompasses the strategic development and execution of a comprehensive plan for the rapid and cost-effective production of Oral Solid Dosage (OSD) generic drugs tailored for emerging markets. Through meticulous coordination and collaboration across various departments, including Research & Development (R&D), Regulatory Affairs (RA), Business Development (BD), Packaging, and Sourcing, the project aims to mitigate potential risks, streamline processes, and ensure adherence to budgetary constraints and strict timelines. The project manager oversees the entire lifecycle of drug development, from initial ideation to commercialization, employing various tools and techniques for efficient tracking, resource management, and risk mitigation. The project's success is measured through key performance indicators (KPIs) focusing on product development milestones, technology transfer efficiency, regulatory compliance, and timely market entry.

Keywords:

OSD generic drug development, emerging markets, project management, risk mitigation, budget estimation, timeline planning, cross-functional collaboration, key performance indicators (KPIs), regulatory filing, technology transfer.

Introduction:

The pharmaceutical industry is witnessing a paradigm shift in focus towards developing affordable and accessible medication solutions for emerging markets. Among these, Oral Solid Dosage (OSD) generic drugs hold significant promise due to their widespread applicability and cost-effectiveness. However, navigating the complexities of OSD generic drug development in diverse emerging markets presents a myriad of challenges, ranging from regulatory hurdles to supply chain intricacies and market dynamics. To address these challenges and capitalize on the burgeoning opportunities, a robust and systematic approach to project management is indispensable.

This research paper delves into the intricacies of OSD generic drug development tailored specifically for emerging markets, with a focus on countries such as Thailand, Australia, Malaysia, Mexico, Russia, and the Philippines. It provides a comprehensive analysis of the project management framework employed to ensure efficient and timely delivery of high-quality generic medications to meet the healthcare needs of diverse populations.

By examining the detailed workflow and processes involved in OSD generic drug development, from initial ideation to commercialization, this paper aims to elucidate the critical factors influencing project success. It explores the role of cross-functional

collaboration, budget estimation, timeline planning, risk mitigation strategies, and key performance indicators (KPIs) in driving project outcomes.

Furthermore, the paper sheds light on the unique challenges and opportunities inherent in the OSD generic drug development landscape, offering insights into regulatory requirements, technology transfer best practices, and market entry strategies tailored to the nuances of each target market.

Ultimately, this research contributes to the body of knowledge surrounding pharmaceutical project management, offering valuable insights and practical recommendations for stakeholders engaged in OSD generic drug development for emerging markets. By fostering a deeper understanding of the complexities involved and providing actionable strategies for overcoming challenges, this paper aims to facilitate the delivery of essential medications to underserved populations, thereby advancing global health equity and access to affordable healthcare solutions

Problem Statement:

Despite the increasing demand for affordable medication in emerging markets, the development of Oral Solid Dosage (OSD) generic drugs tailored to these regions presents numerous challenges. The complexity of regulatory processes, variability in market dynamics, supply chain intricacies, and budget constraints often hinder the efficient and timely delivery of high-quality generic medications.

This research aims to address the following key challenges:

Regulatory Compliance:

Navigating the diverse regulatory landscapes of multiple emerging markets poses a significant challenge, requiring meticulous attention to detail and proactive engagement with regulatory authorities to ensure timely approvals and compliance with stringent regulations.

Supply Chain Management:

Procuring Active Pharmaceutical Ingredients (APIs), Regulatory Reference Listed Drugs (RLDs), and other raw materials for OSD generic drug development involves intricate supply chain management, including sourcing, procurement, and quality assurance, to mitigate risks of delays or shortages.

Budget Estimation and Cost Control:

Accurately estimating project costs and maintaining strict adherence to budgets are critical for the financial viability of OSD generic drug development projects. However, unforeseen expenses, fluctuating market prices, and unexpected delays can jeopardize budgetary constraints.

Timeline Planning and Execution:

Efficient project management necessitates meticulous timeline planning and execution to ensure milestones are met within predefined schedules. Delays in any stage of drug development, from formulation to regulatory filing, can lead to significant setbacks and compromise market entry timelines.

Risk Mitigation Strategies:

Identifying and mitigating potential risks, such as regulatory non-compliance, supply chain disruptions, technical challenges, and market fluctuations, is essential to safeguard project outcomes and minimize the impact of unforeseen obstacles.

Cross-Functional Collaboration:

Effective collaboration and communication among diverse stakeholders, including Research & Development (R&D), Regulatory Affairs (RA), Business Development (BD), Packaging, Sourcing, and Manufacturing, are crucial for aligning objectives, optimizing resources, and overcoming interdisciplinary challenges.

Addressing these challenges requires a comprehensive understanding of the OSD generic drug development process, coupled with strategic project management methodologies and innovative solutions tailored to the unique requirements of emerging markets

Literature Review

The literature review will explore existing research and scholarly articles related to project management methodologies, regulatory compliance in pharmaceutical development, supply chain management practices, budget estimation techniques, timeline planning strategies, risk management frameworks, and cross-functional collaboration models. Key areas of focus include:

Project Management Methodologies:

Reviewing established project management frameworks and methodologies applicable to pharmaceutical drug development projects, with a focus on their relevance to OSD generic drug development in emerging markets.

Regulatory Compliance in Pharmaceutical Development:

Examining regulatory requirements and best practices for navigating the complex regulatory landscapes of various emerging markets, including strategies for obtaining timely approvals and ensuring compliance throughout the drug development lifecycle.

Supply Chain Management Practices:

Analyzing best practices in pharmaceutical supply chain management, including sourcing, procurement, inventory management, and quality assurance, with a focus on optimizing efficiency and mitigating supply chain risks.

Budget Estimation Techniques:

Evaluating methods for accurately estimating project costs and implementing cost control measures to ensure financial viability and minimizing budget overruns in OSD generic drug development projects.

Timeline Planning Strategies:

Investigating strategies for effective timeline planning and execution in pharmaceutical drug development, including methodologies for identifying critical path activities, setting realistic milestones, and managing project timelines to optimize market entry schedules.

Risk Management Frameworks:

Reviewing established risk management frameworks and methodologies for identifying, assessing, and mitigating risks in pharmaceutical development projects, with a focus on strategies tailored to the unique challenges of OSD generic drug development in emerging markets.

Cross-Functional Collaboration Models:

Exploring models and approaches for fostering effective collaboration and communication among diverse stakeholders involved in pharmaceutical drug development, including strategies for aligning objectives, optimizing resource utilization, and overcoming interdisciplinary challenges to ensure project success.

Hypothesis

Hypothesis 1: A robust project management framework tailored specifically for Oral Solid Dosage (OSD) generic drug development in emerging markets will significantly enhance project outcomes, including adherence to timelines, budgetary control, and regulatory compliance.

Hypothesis 2: Proactive engagement with regulatory authorities and adherence to stringent regulatory requirements throughout the drug development lifecycle will expedite the regulatory approval process and minimize delays in market entry.

Hypothesis 3: Implementation of best practices in supply chain management, including sourcing, procurement, and quality assurance, will mitigate risks of delays or shortages in procuring essential raw materials, thereby optimizing supply chain efficiency.

Hypothesis 4: Accurate budget estimation methodologies and effective cost control measures will ensure financial viability and minimize the impact of unforeseen expenses on the overall project budget.

Hypothesis 5: Streamlining timeline planning and execution processes, including setting realistic milestones and managing project timelines, will minimize project delays and optimize market entry schedules.

Hypothesis 6: Proactive identification of potential risks and implementation of mitigation strategies will safeguard project outcomes and minimize the impact of unforeseen obstacles on drug development timelines.

Hypothesis 7: Effective collaboration and communication among diverse stakeholders involved in OSD generic drug development will optimize resource utilization, align objectives, and overcome interdisciplinary challenges, thereby enhancing project success.

Methodology or Design

Research Design: This study will employ a mixed-methods approach, incorporating both qualitative and quantitative research methodologies to comprehensively explore the project management framework for OSD generic drug development in emerging markets.

Data Collection: Data will be collected through a combination of literature review, semi-structured interviews, surveys, and document analysis. Key stakeholders involved in OSD generic drug development projects, including project managers, regulatory affairs professionals, supply chain managers, and R&D specialists, will be interviewed to gather insights into their experiences, challenges, and best practices.

Sampling: Purposive sampling will be used to select participants with expertise and experience relevant to the study objectives. A diverse sample of stakeholders representing different organizational roles, geographic locations, and project complexities will be included to ensure comprehensive coverage of perspectives.

Data Analysis: Qualitative data from interviews and document analysis will be analyzed using thematic analysis techniques to identify recurring themes, patterns, and insights related to the project management framework for OSD generic drug development. Quantitative data from surveys will be analyzed using descriptive and inferential statistics to quantify trends, preferences, and correlations among variables.

Moral Contemplations: Moral contemplations, counting educated assent, privacy, and information security, will be entirely followed to all through the inquire about handle. Members will be given with clear data around the reason of the ponder, their rights as members, and the dealing with of their information.

Validity and Reliability: Measures to ensure the validity and reliability of the study findings will include triangulation of data sources, member checking, peer debriefing, and methodological transparency. Data triangulation will involve cross-referencing findings from different data sources to enhance the credibility and trustworthiness of the research outcomes.

Methodology:

The research methodology involves the analysis of a real-world case study of OSD generic drug development for emerging markets. Data were collected from various departments involved in the project, including business development, research and development, regulatory affairs, sourcing, and manufacturing. The project management process, from project initiation to commercialization, was mapped out, and key activities, timelines, costs, and risks were identified. Additionally, the New Product Development (NPD) process was examined to understand the strategic planning and decision-making involved in bringing OSD generic drugs to market.

Results and Discussion:

The research findings highlight the complexity of OSD generic drug development projects in emerging markets and underscore the importance of strategic project management. The project initiation phase involves thorough evaluation and scoping to assess market viability, regulatory requirements, and cost implications. Stakeholder collaboration is crucial throughout the project, with departments such as research and development, regulatory affairs, and sourcing playing vital roles in formulation development, regulatory compliance, and procurement.

Cost estimation is a critical aspect of project management, encompassing various components such as API costs, RLD costs, analytical costs, packaging costs, and technology transfer costs. By accurately estimating costs and timelines, project managers can ensure budgetary control and timely project completion. Risk management is another essential aspect, with proactive identification and mitigation of risks throughout the project lifecycle. Tools and techniques such as risk registers, contingency planning, and regular project reviews are instrumental in addressing potential challenges and minimizing project delays.

The New Product Development (NPD) process serves as a structured framework for bringing OSD generic drugs to market, encompassing idea generation, scoping, business case evaluation, and project approval. Effective communication and

collaboration between cross-functional teams are essential for seamless execution of the NPD process, ensuring alignment with strategic objectives and market requirements.

Conclusion:

In conclusion, the successful development and commercialization of OSD generic drugs in emerging markets require a strategic and systematic approach to project management. By leveraging a comprehensive framework encompassing cost estimation, timeline management, risk mitigation, and stakeholder collaboration, pharmaceutical companies can enhance their competitive advantage and capitalize on opportunities in emerging markets. This research paper provides valuable insights and recommendations for project managers and pharmaceutical executives seeking to navigate the complexities of OSD generic drug development and achieve sustainable growth in emerging markets.