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

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

Pharmaceutical Management

by

Akanksha Pal

Under the Supervision and Guidance of

Dr. Rahul Sharma

2025

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Appendix D: Declaration by Student

DECLARATION BY STUDENT

I hereby declare that this dissertation titled ……is the bonafide record of my original research work. 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 Information derived from the published or unpublished work of others has been duly acknowledged in the text.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)
Name of Student
Date

Appendix E: Completion Certification

CERTIFICATE

This is to certify that (Name of Student) 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/his internship at (name of the organization) during Mar 10 - May 31, 2025.

Place:
Date:

Preceptor/Head of the Organization
Name of the organization

Appendix F: Certificate from Faculty Guide and School Dean

CERTIFICATE

This is to certify that dissertation titled ..... is a record of the research work undertaken by (Name of Student) in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

Faculty Guide
IIHMR University, Jaipur

Date

School Dean
IIHMR University, Jaipur

Date

SYNOPSIS

Introduction:

The increasing demand for affordable and high-quality medications in emerging markets has prompted pharmaceutical companies to focus on the development of Oral Solid Dosage (OSD) generic drugs. These formulations, known for their cost-effectiveness and ease of administration, face significant challenges in terms of regulatory approvals, supply chain complexities, project cost control, and timely market entry. This study aims to develop a strategic framework and actionable implementation roadmap to address these challenges and accelerate OSD generic drug development tailored to the unique needs of emerging markets such as Thailand, Mexico, Russia, and others.

Problem Statement:

Despite the surging need for generic medications in emerging markets, the path to developing and commercializing OSD generics is fraught with challenges, ranging from regulatory hurdles and procurement issues to inadequate budget control and delays in project execution. A strategic project management framework is essential to streamline this process and ensure product success.

Objectives:

1. To identify key challenges in the development of OSD generics in emerging markets.
2. To develop a strategic project management framework for accelerated drug development.
3. To assess the role of cross-functional collaboration, budgeting, risk mitigation, and regulatory planning in successful project execution.
4. To propose an implementation roadmap that ensures timely and cost-effective product launch.

Hypotheses:

1. A structured project management framework enhances drug development timelines and regulatory compliance.
2. Proactive regulatory engagement minimizes approval delays.
3. Optimized supply chain practices reduce material procurement risks.
4. Accurate budget estimation supports financial viability.
5. Cross-functional collaboration improves resource utilization and project success.

Methodology:

The study adopts a mixed-methods research design, combining qualitative insights through interviews and document analysis, and quantitative data via surveys. Data was sourced from stakeholders across key departments—Business Development, R&D, Regulatory Affairs, Sourcing, and Manufacturing. The project management lifecycle was mapped and analyzed with special focus on risk identification, cost planning, and timeline control. The New Product Development (NPD) process was reviewed to understand market launch dynamics.

Key Findings:

- Strategic Planning is critical during project initiation to evaluate cost, timelines, and regulatory challenges.
- Cost Estimation must include detailed components such as API, RLD, packaging, and analytical costs to avoid overruns.
- Risk Management tools like risk registers and contingency plans are crucial.
- Cross-Functional Collaboration ensures alignment between departments and supports timely execution.
- Regulatory Strategy must be market-specific and proactive to avoid delays.

Conclusion:

A robust, end-to-end project management framework customized for OSD generics in emerging markets significantly improves project efficiency, cost-effectiveness, and market readiness. This dissertation provides actionable strategies and insights that can guide pharmaceutical companies in navigating challenges, reducing development time, and increasing accessibility to essential drugs in underserved markets.

Keywords:

OSD generic drug development, emerging markets, project management, regulatory compliance, supply chain, budget planning, cross-functional teams, risk mitigation, NPD process