Synopsis for Dissertation Submitted

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By

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SYNOPSIS

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TITLE: STRATEGIC MANAGEMENT FRAMEWORK FOR OSD GENERIC DRUG DEVELOPMENT IN US AND EU MARKETS: A COMPREHENSIVE ANALYSIS AND IMPLEMENTATION STRATEGY

Introduction: The pharmaceutical industry is heavily regulated, and the development of generic drugs involves rigorous processes to ensure safety, efficacy, and compliance with regulatory standards. This project focuses on the strategic management framework for the development of oral solid dosage (OSD) generic drugs in the US and EU markets, addressing the unique challenges and requirements of each region.

Objective: The primary objective of this project is to provide a comprehensive analysis and strategic framework for the development, budgeting, and regulatory filing processes of OSD generic drugs in the US and EU markets. The project aims to streamline the development process, identify potential risks, and propose effective mitigation strategies to enhance the chances of successful regulatory approval.

Methodology: The project is structured around a detailed examination of each phase of the drug development process:

1. **Pre-Formulation and Process Investigation (PPIF):** Initial studies to understand the drug's physical and chemical properties.
2. **New Product Development (NPD):** Designing and developing the generic product.
3. **Formulation and Analytical Development:** Developing the drug's formulation and analytical methods.
4. **Pilot Studies:** Small-scale studies to refine the formulation and process.
5. **Analytical Method Validation and Transfer (AMV/AMT):** Ensuring analytical methods are accurate and reproducible.
6. **Scale-Up:** Increasing production to commercial scale.

7. **Exhibit Batch Production:** Producing batches for regulatory submission.
8. **Pivotal Studies:** Conducting essential studies to support regulatory filings.
9. **Stability Data Collection:** Collecting data on the drug's stability over time.
10. **Regulatory Submissions:** Filing for approval with the US FDA (ANDA) and the EU EMA.

Key Components:

- **Timeline and Budgeting:** Detailed planning and estimation of time and costs associated with each phase of development.
- **Risk Management:** Identification of potential risks and development of mitigation strategies to address them.
- **Tools and Techniques:** Recommendation of project management tools and techniques to facilitate cross-functional collaboration and ensure efficient workflow.
- **Regulatory Compliance:** Guidelines for meeting regulatory requirements and preparing successful submissions to the US FDA and EU EMA.
- **Performance Metrics:** Establishing key performance indicators (KPIs) to monitor progress and ensure project objectives are met.

Findings: The project offers a structured approach to manage OSD generic drug development, emphasizing the importance of thorough planning, risk management, and adherence to regulatory standards. By following the proposed framework, pharmaceutical companies can enhance their development processes, reduce time-to-market, and increase the likelihood of regulatory approval.

Conclusion: This comprehensive analysis and implementation strategy for OSD generic drug development provide valuable insights and practical guidance for professionals in the pharmaceutical industry. By addressing the complexities of the development process and regulatory landscape, this project aims to support the successful introduction of generic drugs to the US and EU markets.