

IIHMR University, Jaipur

DISSERTATION DEFENSE

Synergies and Challenges in Managing Regulatory and Supply Chain in Pharmaceutical Company

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Abstract

- ▶ • This dissertation explores the critical intersection between regulatory compliance and supply chain management (SCM) in the pharmaceutical industry, with a focus on emerging markets.
- ▶ • Using a mixed-methods approach, it uncovers how alignment between these functions improves efficiency, compliance, and agility.
- ▶ • The study reveals best practices adopted by leading firms, identifies major barriers to integration, and offers strategic recommendations.
- ▶ • Findings emphasize the transformative role of technology and cross-functional collaboration in managing pharmaceutical operations.

Introduction

- ▶ • In emerging markets, pharmaceutical companies must navigate a dual challenge: meeting complex regulatory requirements while managing an increasingly globalized supply chain.
- ▶ • Regulatory bodies ensure safety and efficacy, while SCM ensures timely delivery and cost efficiency.
- ▶ • Misalignment between these departments leads to delays, non-compliance, and financial loss.
- ▶ • This research addresses the importance of aligning these functions and explores synergies that can lead to operational excellence.

Objectives

- ▶ **1. Understand the current structure and practices in regulatory and supply chain operations.**
- ▶ **2. Identify the common barriers that hinder integration between the two departments.**
- ▶ **3. Explore successful case studies where integration has improved performance.**
- ▶ **4. Recommend actionable frameworks, tools, and policies for effective integration in emerging pharmaceutical firms.**

Literature Review – Regulatory Landscape

- ▶ • Regulatory frameworks such as ICH, FDA, CDSCO set the global standards.
- ▶ • Emerging countries often add layers of regional regulations, increasing compliance complexity.
- ▶ • Companies face duplication of efforts, documentation overload, and extended approval timelines.
- ▶ • Early collaboration with regulators and internal clarity reduces errors and speeds up market access.

Literature Review – SCM Challenges

- ▶ • Pharma SCM involves procurement, manufacturing, warehousing, and distribution of sensitive goods.
- ▶ • Delays or disruptions can lead to patient risk, stockouts, or wastage.
- ▶ • SCM is heavily dependent on global suppliers, and even minor geopolitical disruptions can cripple operations.
- ▶ • Integration with compliance teams allows better planning for audits, documentation, and transport validations.

Research Design

- ▶ • **Mixed-methods research:**
 - ▶ → **Qualitative:** Semi-structured interviews with regulatory and SCM managers.
 - ▶ → **Quantitative:** Data from secondary sources like annual reports, WHO, Pharma case studies.
- ▶ • **Sampling:**
 - ▶ → **Qualitative:** Purposeful sampling of pharma experts with 5+ years experience.
 - ▶ → **Quantitative:** Stratified sampling across firm size and geography.
- ▶ • **Data Analysis:**
 - ▶ → **Thematic analysis** for interviews.
 - ▶ → **KPI analysis** (e.g., lead time, inventory turnover, compliance scores).

Key Findings

- ▶ • Early involvement of regulatory teams in supply planning reduces documentation errors and saves time.
- ▶ • Centralized digital platforms facilitate real-time information sharing and approvals.
- ▶ • Joint planning meetings increase accountability, reduce redundancies, and improve timelines.
- ▶ • Companies using integrated models reported improved KPIs: e.g., 30% faster launches, 25% fewer deviations.

Challenges

- ▶ • **Disconnected systems lead to duplicated effort and conflicting priorities.**
- ▶ • **Regulatory requirements vary drastically between regions, creating friction in global operations.**
- ▶ • **SCM disruptions due to COVID, political sanctions, and single-supplier dependency.**
- ▶ • **Underinvestment in compliance tech, training, and change management.**

Best Practices

- ▶ **1. Create cross-functional compliance-SCM task forces.**
- ▶ **2. Invest in supply chain visibility tools and audit tracking systems.**
- ▶ **3. Conduct regular training and mock audits for cross-departmental understanding.**
- ▶ **4. Maintain supplier risk registers and engage in multi-vendor sourcing.**
- ▶ **5. Establish proactive regulatory engagement strategy to reduce last-minute issues.**

Recommendations

► For Practitioners:

- • Establish integrated dashboards linking SCM and compliance KPIs.
- • Automate document versioning and traceability with regulatory tech.
- • Appoint a compliance-SCM liaison officer for alignment.

► For Policymakers:

- • Harmonize international regulations.
- • Incentivize technology adoption through tax credits or subsidies.
- • Promote industry-academic collaboration for regulatory training.

Conclusion

- ▶ • Strategic alignment of regulatory and SCM functions improves operational performance, compliance rates, and time to market.
- ▶ • Technology, training, and proactive cross-functional planning are key enablers.
- ▶ • Regulatory compliance must not be viewed as a bottleneck but as a partner in efficiency.
- ▶ • Future-ready pharma companies will be those that embrace agility, innovation, and integration.

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Thank You

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