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Strategic approaches to capacity planning and management in highly regulated Pharmaceutical manufacturing systems: A comprehensive literature review

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Abstract
Capacity planning and management in pharmaceutical manufacturing is a critical determinant of operational efficiency, regulatory compliance, and market responsiveness. Highly regulated environments impose stringent constraints on production flexibility, making strategic capacity planning essential for balancing cost, quality, and service levels. This review synthesizes insights from contemporary research on conceptual frameworks and methodologies for capacity planning in pharmaceutical systems. It examines approaches ranging from classical lot-sizing and ramp-up models to integrated supply chain planning, Lean Six Sigma practices, and regulatory-driven strategies. The analysis highlights the interplay between capacity utilization, resource allocation, and compliance requirements, while identifying gaps in existing literature such as limited integration of tactical and strategic planning and insufficient consideration of uncertainty in multi-product environments. By consolidating findings across diverse studies, this paper provides a structured understanding of capacity planning paradigms and offers directions for future research aimed at enhancing resilience and adaptability in pharmaceutical operations.

Keywords: Capacity planning, pharmaceutical manufacturing, regulatory compliance, production scheduling, lean six sigma, supply chain optimization, Good Manufacturing Practicess (GMP), Trade-Related Aspects of Intellectual Property Rights (TRIPS), Mixed-Integer Linear Programming (MILP), Quality by Design (QBD)

Introduction

Capacity planning and management in pharmaceutical manufacturing is a cornerstone of operational excellence, particularly in environments governed by stringent regulatory frameworks such as Good Manufacturing Practices (GMP), TRIPS compliance, and global quality standards. Unlike other industrial sectors, pharmaceutical production operates under unique constraints—multi-product batch operations, campaign scheduling, and rigorous validation requirements—that amplify the complexity of aligning capacity with fluctuating market demand. The consequences of inadequate capacity planning are severe: production delays, inventory imbalances, compliance risks, and ultimately, compromised patient access to essential medicines.

The pharmaceutical industry faces a dual challenge: maintaining flexibility to respond to dynamic market conditions while adhering to rigid regulatory protocols that limit rapid capacity adjustments. Traditional approaches to capacity planning, such as deterministic lot-sizing and static scheduling, often fail to capture the stochastic nature of demand and the operational intricacies of sterile and non-sterile manufacturing environments. Moreover, the increasing prevalence of biologics, personalized therapies, and modular manufacturing systems has introduced new dimensions to capacity management, necessitating frameworks that integrate strategic, tactical, and operational perspectives.

Recent literature underscores the evolution of capacity planning methodologies from classical models toward integrated, multi-objective approaches. Studies by Lindahl *et al.* (2023) [2] and Hansen & Grunow (2015) [5, 6] highlight the importance of modeling ramp-up phases and campaign scheduling using Mixed-Integer Linear Programming (MILP) and heuristic optimization techniques. Similarly, research on Lean Six Sigma applications (Bora, 2021; Byrne *et al.*, 2021) [68, 69] demonstrates how process improvement strategies complement capacity planning by reducing variability and enhancing throughput. Tactical Sales and Operations Planning (S&OP) frameworks (Pereira *et al.*, 2020) [12] further emphasize the need for cross-functional integration, bridging procurement, production, and distribution decisions to achieve holistic capacity alignment.

Despite these advancements, significant gaps persist. First, most existing models prioritize cost minimization and throughput optimization without adequately addressing regulatory compliance as a dynamic constraint. Second, the literature reveals limited exploration of uncertainty management in multi-site, multi-product contexts—a critical consideration given the volatility of pharmaceutical supply chains. Third, while emerging paradigms such as modular and continuous manufacturing promise enhanced agility, their implications for capacity planning remain under-researched.

This review aims to consolidate conceptual insights from diverse studies to develop a structured understanding of strategic approaches to capacity planning in pharmaceutical manufacturing. By synthesizing frameworks, methodologies, and best practices, the paper seeks to identify research gaps and propose directions for future inquiry. The scope is deliberately confined to conceptual models and managerial strategies, excluding AI-driven or fully automated solutions, in alignment with the objective of providing a human-centric perspective suitable for highly regulated environments.

The remainder of the paper is organized as follows: Section 2 outlines the methodology adopted for literature selection and thematic categorization. Section 3 presents a comprehensive review of capacity planning approaches, grouped into strategic frameworks, supply chain integration, operational excellence practices, and regulatory considerations. Section 4 discusses the comparative insights and managerial implications, while Section 5 concludes with recommendations for future research.

Methodology
This literature review adopts a structured approach to identify, classify, and synthesize research on capacity planning and management within pharmaceutical manufacturing systems. The methodology was designed to ensure academic rigor and relevance to highly regulated environments.

Literature Selection Criteria
The review draws on peer-reviewed journal articles, conference proceedings, and authoritative books published between 1997 and 2025, with a primary focus on pharmaceutical manufacturing and related capacity planning frameworks. Sources were selected based on the following criteria:

- **Domain relevance:** Studies addressing capacity planning, production scheduling, supply chain optimization, and operational excellence in pharmaceutical or closely related industries.
- **Conceptual orientation:** Preference for frameworks and methodologies rather than empirical case studies or AI-driven automation models, in line with the paper's objective.
- **Regulatory context:** Inclusion of research that considers compliance requirements such as GMP, TRIPS, and quality assurance standards.

Data Sources and Extraction

The dataset comprises 70+ references compiled from SCOPUS-indexed journals, Springer, Elsevier, IEEE, and other reputable sources. Each entry was analyzed for:

- Year of publication and authorship.
- Focus and scope of the study.
- Techniques and models employed (e.g., MILP, lot-sizing, Lean Six Sigma).
- Key parameters such as capacity utilization, ramp-up curves, and inventory levels.
- Managerial and theoretical implications.

Analytical Framework
A thematic categorization approach was applied to organize the literature into five major domains:

1. Strategic capacity planning frameworks.
2. Integration with supply chain and S&OP.
3. Lean Six Sigma and operational excellence.
4. Regulatory and compliance considerations.
5. Emerging trends in modular and continuous manufacturing.

This classification enables a systematic comparison of methodologies and highlights gaps in existing research. The review deliberately excludes AI-based predictive analytics and fully automated frameworks to maintain alignment with the conceptual focus.

Limitations
The review is limited to conceptual and methodological studies and does not include empirical performance benchmarking or proprietary industrial data. While the dataset spans multiple geographies and manufacturing contexts, the emphasis on regulated pharmaceutical environments may restrict generalizability to other sectors.

Thematic Literature Review
1. Strategic Capacity Planning Frameworks
Capacity planning in pharmaceutical manufacturing has traditionally relied on deterministic models such as lot-sizing and static scheduling. However, these approaches often fail to accommodate the complexity of regulated environments, where production flexibility is constrained by validation requirements and campaign-based operations. Early conceptualizations, as discussed by Elmaghraby (2011) [27], emphasized the ambiguity of capacity definitions—nominal, operational, planned, and realized—highlighting the need for probabilistic approaches rather than single-point estimates.

Recent advancements have introduced integrated frameworks that combine capacity planning with production scheduling to improve feasibility and cost efficiency. Almeder *et al*. (2015) [3] addressed limitations in classical multi-level capacitated lot-sizing problems (MLCLSP) by incorporating lead time considerations and scheduling decisions. Their mixed-integer programming (MIP) formulations—batching and lot-streaming models—demonstrated cost savings of up to 40% compared to traditional models, underscoring the importance of synchronizing production batches with resource availability. Similarly, Hansen and Grunow (2015) [5, 6] proposed a volume-dependent ramp-up model for secondary pharmaceutical production, replacing time-based learning curves with cumulative production volume as a predictor of capacity utilization. This approach mitigates the risk of overestimating capacity during product launch phases, a common challenge in regulated environments where validation delays and quality checks extend ramp-up durations.

Lindahl *et al*. (2023) [2] advanced the field by developing a seven-step methodology for integrated capacity and production planning in pharmaceutical supply chains. Their framework leverages Mixed-Integer Linear Programming (MILP) and State-Task Network (STN) formulations to optimize campaign scheduling under regulatory constraints. By incorporating setup times, inventory levels, and demand profiles, the model enables early-stage planning without detailed cost data—a critical advantage in environments where cost structures are opaque during initial phases.

Collectively, these studies converge on a key insight: strategic capacity planning in pharmaceutical manufacturing requires models that balance operational feasibility with regulatory compliance. While classical approaches provide foundational principles, modern frameworks emphasize integration, flexibility, and scenario-based planning to address uncertainty and complexity.

2. Integration with Supply Chain and S&OP
Capacity planning in pharmaceutical manufacturing cannot be viewed in isolation; it is intrinsically linked to supply chain dynamics and tactical Sales and Operations Planning

(S&OP). The complexity of pharmaceutical supply chains—characterized by multi-site production, stringent regulatory compliance, and volatile demand—necessitates integrated frameworks that synchronize procurement, production, and distribution decisions.

Pereira *et al*. (2020) [12] emphasize the evolution of S&OP from aggregate production planning toward a holistic decision-making model that spans procurement, manufacturing, and sales. Their review identifies a critical gap in modeling-focused literature, advocating for optimization-based approaches that enable mid-term tactical planning. Similarly, Sampat *et al*. (2020) address multisite supply planning under uncertainty, proposing stochastic programming models to allocate capacity efficiently across geographically dispersed facilities. These models account for variability in production yields, site downtimes, and demand fluctuations—factors that significantly influence capacity utilization in regulated environments.

Marques *et al*. (2017, 2020) [9, 10] extend this perspective by integrating process design and planning decisions during product launch phases. Their simulation-optimization framework combines Mixed-Integer Linear Programming (MILP) with Monte Carlo simulation to evaluate scenarios under technical and market uncertainties. This approach is particularly relevant for pharmaceutical firms introducing new products while maintaining existing commercial production in shared facilities.

The literature also highlights the role of inventory strategies in complementing capacity planning. Smirnov *et al*. (2021) [15] explore the trade-offs between long-term capacity investments and short-term inventory buffers in high-tech and pharmaceutical contexts. Their findings suggest that excess capacity, while costly, may be justified in environments with high demand volatility and long lead times.

Collectively, these studies underscore the necessity of integrated planning frameworks that align capacity decisions with broader supply chain objectives. By embedding capacity planning within S&OP processes, pharmaceutical firms can enhance responsiveness, mitigate risks, and achieve a balanced approach to cost, compliance, and service levels.

3. Lean Six Sigma and Operational Excellence

Operational excellence initiatives such as Lean and Six Sigma have become integral to capacity planning in pharmaceutical manufacturing, primarily due to their ability to reduce variability, eliminate waste, and enhance process reliability. Unlike traditional capacity planning models that focus on resource allocation and scheduling, Lean Six Sigma (LSS) frameworks address systemic inefficiencies that constrain effective capacity utilization.

Lean principles emphasize waste elimination across production processes, targeting non-value-added activities such as excessive changeover times, redundant documentation, and inefficient material flows. Studies by Bora (2021) [68] and Byrne *et al*. (2021) [69] demonstrate the application of Lean Six Sigma methodologies—particularly the DMAIC cycle—in reducing batch rejection rates, minimizing downtime, and improving throughput. For instance, Byrne *et al*. reported significant reductions in packaging line downtime through root cause analysis and process streamlining, resulting in measurable cost savings.

Six Sigma complements Lean by focusing on variation reduction and process capability improvement. Al-Shourah *et al*. (2018) [57] highlight the synergy between Lean and Six Sigma in pharmaceutical contexts, where compliance-driven processes demand high precision and consistency. Tools such as Statistical Process Control (SPC), Pareto analysis, and control charts are frequently employed to monitor critical quality attributes (CQAs) and ensure adherence to regulatory standards.

Recent literature also explores the integration of Lean Six Sigma with sustainability objectives. Kartika *et al*. (2023) [74] propose a “Green Lean” approach, aligning waste reduction with environmental performance metrics such as energy consumption and carbon footprint. This dual focus reflects the growing importance of eco-efficiency in pharmaceutical operations, driven by global sustainability mandates.

Collectively, Lean Six Sigma frameworks contribute to capacity planning by improving process stability, reducing cycle times, and enabling predictable resource utilization. While these methodologies do not directly replace mathematical optimization models, they serve as complementary strategies that enhance the effectiveness of capacity planning decisions in highly regulated environments.

4. Regulatory and Compliance Considerations

Capacity planning in pharmaceutical manufacturing is inseparable from regulatory compliance. Unlike other industries, pharmaceutical operations must adhere to stringent standards such as Good Manufacturing Practices (GMP), International Conference on Harmonisation (ICH) guidelines, and country-specific regulations. These requirements influence not only production processes but also strategic decisions on capacity expansion, resource allocation, and scheduling.

Studies such as Singh and Kaur (2024) [16] provide empirical evidence of how regulatory frameworks like TRIPS and economic reforms have shaped capacity utilization in the Indian pharmaceutical industry. Their analysis using Data Envelopment Analysis (DEA) and Tobit regression reveals that compliance-driven constraints often lead to excess capacity, as firms maintain buffer resources to mitigate risks associated with audits and product recalls.

Regulatory compliance also impacts operational flexibility. Hansen and Grunow (2015) [5, 6] highlight that ramp-up phases in secondary pharmaceutical production are prolonged due to validation protocols, resulting in overestimated capacity during product launches. Similarly, Marques *et al*. (2020) [10] argue that decision-support systems in pharmaceutical supply chains must incorporate compliance as a dynamic constraint, influencing campaign scheduling and inventory strategies.

Emerging trends such as Quality by Design (QbD) and Continuous Manufacturing (CM) further reinforce the regulatory dimension of capacity planning. Sarkis *et al*. (2021) [9] note that QbD frameworks demand robust process understanding and control, which in turn affects equipment utilization and throughput. Compliance with environmental and safety standards adds another layer of complexity, particularly in sterile injectable manufacturing where contamination risks necessitate stringent controls on facility design and personnel movement.

In summary, regulatory considerations are not peripheral but central to capacity planning in pharmaceutical manufacturing. They dictate operational parameters, shape strategic investments, and impose constraints that must be integrated into planning models. Future research should explore adaptive frameworks that balance compliance with agility, enabling firms to respond to market dynamics without compromising regulatory integrity.

5. Emerging Trends in Modular and Continuous Manufacturing

Pharmaceutical manufacturing is undergoing a paradigm shift from traditional batch processes to modular and continuous production systems. These innovations aim to enhance flexibility, reduce time-to-market, and improve resource utilization—factors that directly influence capacity planning strategies.

Modular manufacturing introduces standardized, interchangeable units that can be rapidly deployed or reconfigured to meet changing demand. Bhosekar and Ierapetritou (2021) [4] highlight the benefits of modular systems in enabling distributed manufacturing networks, which reduce dependency on centralized facilities and mitigate risks associated with supply chain disruptions. Their framework integrates production feasibility analysis with supply chain optimization, demonstrating how modularity supports economies of scale and scope.

Continuous manufacturing (CM), endorsed by regulatory bodies such as the FDA and EMA, offers further advantages by eliminating batch-to-batch variability and reducing cycle times. Yamada *et al*. (2023) [58, 79] propose a comprehensive design methodology for injectable manufacturing processes that incorporates continuous operation modes alongside single-use technologies. Their multi-objective optimization approach evaluates trade-offs between equipment cost, scheduling efficiency, and defect rates, underscoring the strategic implications of CM for capacity planning.

Emerging technologies such as single-use systems, digital twins, and advanced process analytical technologies (PAT) complement these trends. Digital twins enable real-time simulation of production scenarios, facilitating proactive capacity adjustments without physical trials. Similarly, PAT frameworks enhance process control, ensuring compliance while optimizing throughput in continuous environments.

Despite these advancements, the transition to modular and continuous manufacturing poses challenges. High capital investment, regulatory validation complexities, and workforce skill gaps remain significant barriers. Future research should focus on developing adaptive capacity planning models that integrate these technologies while addressing compliance and cost constraints.

Table 1: Summary of Thematic Literature Review

Theme	Year Range	Complete Author List	Core Techniques	Key Insights
Strategic Capacity Planning	2015–2025	Mahipal Singh; Rajeev Rathi; Mahender Singh Kaswan; Simon B. Lindahl; Deenesh K. Babi; Krist V. Gernaey; Gürkan Sin; Christian Almeder; Diego Klabjan; Renate Traxler; Bernardo Almada-Lobo; Klaus R.N. Hansen; Martin Grunow; Karolis Jankauskas; Suzanne S. Farid; Lazaros G. Papageorgiou; Qi Ahn; Ou J.; Feng J.; Elmaghraby S.E.; Tursunov B.O.; Guide V.D.R.; Srivastava R.; Spencer M.S.; Sugarindra M.; Nurdiansyah R.; Yao X.; Almatooq N.; Askin R.G.; Gruber G.; Krivyakin K.; Hakimov Z.; Song J.-S.; van Houtum G.-J.; Van Mieghem J.A.; Throughput Inc.; ElMaraghy H.A.; Deif A.M.; Laskowski S.E.	MILP, Lot-sizing, Ramp-up modeling, RCCP, GA, Monte Carlo	Integration of scheduling with capacity planning; ramp-up curves improve accuracy
Supply Chain & S&OP Integration	2018–2025	Atharv Bhosekar; Marianthi Ierapetritou; Marques C.M.; Moniz S.; de Sousa J.P.; Barbosa-Póvoa A.P.; Reklaitis G.V.; Sampat A.M.; Kumar R.; Kurup R.P.; Chiu K.; Saucedo V.M.; Zavala V.M.; Pereira D.F.; Oliveira J.F.; Carravilla M.A.; Smirnov D.; van Jaarsveld W.; Atan Z.; de Kok T.; Odumbo O.; Oluwagbade E.; Ogbuagu O.O.; Alemede V.; Adefolaju I.; Byreddy M.R.; Adekola A.D.; Dada S.A.; Debnath R.; *et al*.	Simulation-Optimization, Monte Carlo, Stochastic Programming, MINLP, Predictive Analytics	Tactical planning aligns procurement and production; multisite planning under uncertainty
Lean Six Sigma & Operational Excellence	2018–2025	Hardiansyah Sucipta; Ratih Dyah Kusumastuti; Anna Borucka; Edward Kozłowski; Katarzyna Antosz; Rafał Parczewski; Bora N.; Byrne B.; McDermott O.; Noonan J.; Davarasingi K.P.; Prasanthi N.L.; Kumar K.T.S.; Nataraj K.S.; Alifiya F.; Wiedyaningsih C.; Ardiningtyas B.; Khan M.A.; Pachorkar P.; Khan Z.; Pavlović K.; Božanić V.; Kartika A.; Parid M.; Wiedyaningsih C.; Parthasarathy R.; Rao S.; Sharma V.; Gupta R.; Mehta A.; Joshi D.	DMAIC, VSM, SPC, SMED, Lean tools	Waste reduction and variability control enhance throughput and compliance
Regulatory & Compliance	2020–2023	Singh J.; Kaur K.; Sarkis M.; Bernardi A.; Shah N.; Papathanasiou M.M.; Levinson W.A.; Patil S.S.; Khandekar S.S.; Destro F.; Inguva P.K.; Srisuma P.; Braatz R.D.; Russell A.; Capece M.; Lim H.-S.; Aglave R.; Doyle A.	DEA, Tobit Regression, QbD frameworks, PAT, SPC	Compliance drives excess capacity; QbD and PAT integrate quality with efficiency
Emerging Trends	2021–2025	Miriam Sarkis; Andrea Bernardi; Nilay Shah; Maria M. Papathanasiou; Bhosekar A.; Ierapetritou M.; Yamada M.; Badra S.; Hayashi Y.; Zenitani K.; Kubota K.; Nakanishi H.; Sugiyama H.; Stamato H.; Korang-Yeboah M.; Rangineni J.; Bogner R.; Altahir Cheng; Escotet-Espinoza M.S.; Rogers A.; Ierapetritou M.G.; Yadav K.S.; Bhardwaj P.; Chauhan A.; Mishra S.; Michno T.; Michno A.	Modular modeling, Continuous manufacturing, PAT, Digital Twins	Modular and continuous systems improve agility; digital twins enable real-time optimization

Discussion

The literature reviewed demonstrates a clear evolution in capacity planning methodologies for pharmaceutical manufacturing, transitioning from static, deterministic models toward integrated, multi-objective frameworks. This shift reflects the growing complexity of pharmaceutical operations, shaped by regulatory constraints, market volatility, and technological advancements.

Comparative Insights

Classical approaches such as lot-sizing and hierarchical planning (Almeder *et al*., 2015; Ou & Feng, 2019) [3, 11] provide foundational principles but lack flexibility in handling dynamic demand and compliance-driven constraints. In contrast, integrated models using MILP and heuristic optimization (Lindahl *et al*., 2023; Marques *et al*., 2017) [2, 9] offer superior adaptability by embedding scheduling, inventory, and capacity decisions within a unified framework. These models demonstrate significant cost and time savings, yet their computational complexity and reliance on precise data remain barriers to widespread adoption.

Lean Six Sigma methodologies complement mathematical models by addressing operational inefficiencies that undermine effective capacity utilization. Evidence from Bora (2021) [68] and Byrne *et al*. (2021) [69] suggests that process improvement initiatives can reduce cycle times and variability, thereby enhancing the predictability of capacity planning outcomes. However, these approaches are inherently reactive and require integration with strategic planning tools to deliver sustainable benefits.

Regulatory Influence

Regulatory compliance emerges as a dominant theme across all studies. Validation requirements, GMP protocols, and TRIPS-related obligations impose rigid constraints on production flexibility, often necessitating excess capacity as a risk mitigation strategy (Singh & Kaur, 2024) [16]. While frameworks such as QbD and PAT aim to harmonize quality and efficiency, their implementation adds layers of complexity to capacity planning models. Future research must explore adaptive strategies that incorporate compliance as a dynamic variable rather than a static constraint.

Emerging Paradigms

Modular and continuous manufacturing represent transformative trends with profound implications for capacity planning. Modular systems enable rapid scalability and distributed production, while continuous processes reduce cycle times and variability (Bhosekar & Ierapetritou, 2021; Yamada *et al*., 2023) [4, 58, 79]. Despite these advantages, high capital costs and regulatory validation challenges hinder adoption. The literature suggests a need for hybrid models that combine traditional batch planning with modular flexibility, supported by scenario-based simulations.

Research Gaps

Despite significant progress, several gaps remain unaddressed:

1. **Absence of Line-Wise Capacity Mapping Methods:** Current literature focuses on aggregate capacity planning at plant or network level. There is no detailed methodology for mapping capacity line-by-line across pharmaceutical production stages, which is critical for identifying bottlenecks and optimizing resource allocation.
2. **Lack of Dedicated Capacity Optimization Frameworks:** While optimization techniques (e.g., MILP, GA, RCCP) are mentioned, they primarily address scheduling or inventory management. There is no comprehensive framework for systematic capacity optimization tailored to regulated pharmaceutical environments.
3. **Integration of Compliance and Agility:** existing models inadequately address the trade-off between regulatory rigidity and operational flexibility.
4. **Uncertainty Management:** Limited exploration of stochastic approaches for multi-site, multi-product environments under demand volatility.
5. **Human-Centric Decision Frameworks:** Overemphasis on computational models without addressing managerial decision-making and practical implementation.

Managerial Implications

For practitioners, the findings underscore the importance of adopting a layered approach to capacity planning—combining strategic optimization models with operational excellence initiatives. Investments in modular infrastructure and continuous manufacturing technologies should be complemented by robust compliance management systems and workforce training programs to ensure seamless implementation.

Conclusion

Capacity planning in pharmaceutical manufacturing remains a complex and critical challenge, shaped by stringent regulatory requirements, technological advancements, and market volatility. This review consolidates insights from diverse studies to provide a structured understanding of strategic approaches to capacity management in highly regulated environments. The analysis reveals a clear progression from traditional deterministic models toward integrated frameworks that combine optimization techniques, operational excellence practices, and compliance considerations.

Despite these advancements, significant gaps persist. Most notably, the literature lacks line-wise capacity mapping methodologies that can provide granular visibility into production constraints across individual lines and stages. Additionally, there is no comprehensive framework for capacity optimization tailored to regulated pharmaceutical environments; existing studies focus primarily on scheduling or inventory management rather than systematic capacity optimization. Other gaps include insufficient integration of compliance with agility, limited uncertainty management in multi-product contexts, and an overemphasis on computational models without addressing managerial decision-making.

For practitioners, these findings underscore the need for a layered approach that combines strategic optimization models with operational excellence initiatives and compliance-driven planning. Future research should prioritize the development of line-level capacity mapping tools, dedicated optimization frameworks, and adaptive models that balance regulatory constraints with operational flexibility. Such advancements will be essential for building resilient, efficient, and compliant pharmaceutical manufacturing systems capable of meeting global healthcare demands.

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