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ARTIFICIAL INTELLIGENCE (AI) IN DRUG DEVELOPMENT AND REGULATORY DECISION-MAKING

Key Insights from FDA Draft Guidance:

"Considerations for the Use of Artificial Intelligence in Drug and Biological Product Regulation"

Kishore Hotha, PhD, MBA

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FDA GUIDANCE ON AI IN DRUG AND BIOLOGICAL PRODUCT REGULATORY DECISION-MAKING

Purpose:

Define a framework for using AI to support safety, efficacy, and quality assessments.

Encourage stakeholder engagement to establish credible and transparent AI applications.

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SCOPE OF THE GUIDANCE

What's Included vs. Excluded

INCLUDED

AI applications in nonclinical, clinical, post marketing, and manufacturing.

Focus on safety, effectiveness, and quality decision-making.

EXCLUDED

AI used for operational efficiencies or internal workflows.

Drug discovery applications.

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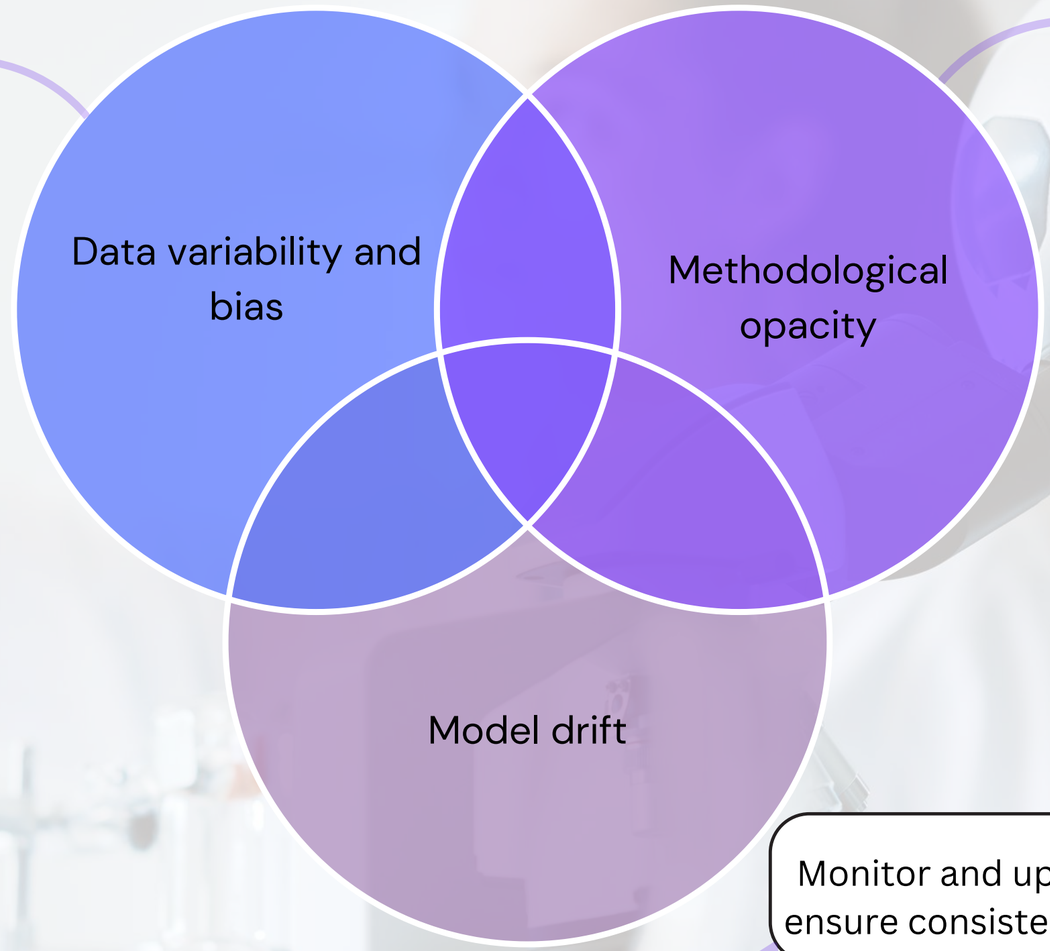
CHALLENGES IN USING AI

Key Challenges and Recommendations

Ensure datasets are representative, complete, and accurate.



Require detailed documentation of model development.

Monitor and update models to ensure consistent performance.

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RISK–BASED CREDIBILITY ASSESSMENT FRAMEWORK

Step 1:
Define the question of interest.
Example: Determine low-risk patients for outpatient monitoring.

Step 2:
Define the Context of Use (COU).
Example: AI stratifies patients into risk categories for adverse reactions.

Step 3:
Assess AI model risk.
Model Influence: Is AI the sole decision driver?
Decision Consequence: What's the impact of an incorrect decision?

Step 4:
Develop a credibility assessment plan.
Include data, model architecture, and evaluation criteria.

Step 5:
Execute the plan.

Step 6:
Document results and deviations.

Step 7:
Determine adequacy of AI model for COU.

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AI LIFECYCLE MAINTENANCE

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Monitor Performance Metrics:
Track data drift and accuracy metrics over time.

Plan for Model Updates:
Retrain or revise models based on new data.

Regulatory Compliance:
Notify FDA about impactful changes.

Risk-Based Oversight:
Tailor monitoring frequency and rigor to model risk level.

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EXAMPLES OF AI APPLICATIONS IN DRUG LIFECYCLE

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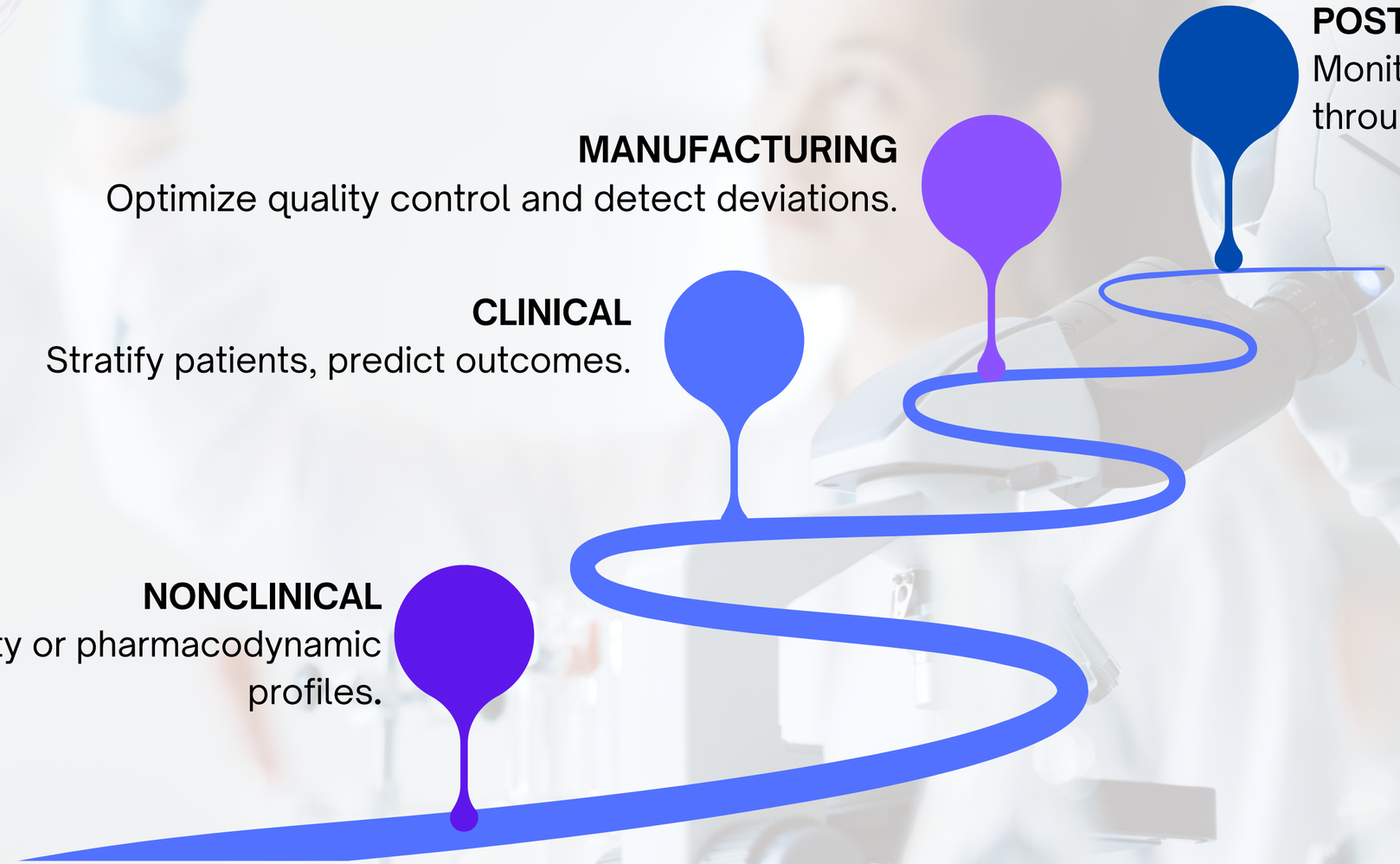
POST MARKETING
Monitor adverse events through real-world data.

MANUFACTURING
Optimize quality control and detect deviations.

CLINICAL
Stratify patients, predict outcomes.

NONCLINICAL
Predict toxicity or pharmacodynamic profiles.



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FDA EARLY ENGAGEMENT OPTIONS

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ENGAGEMENT OPTION	USE CASE	CONTACT
Clinical Trial Innovation	AI in trial designs.	CDERclinicaltrialinnovation@fda.hhs.gov
Emerging Drug Safety Technology Program	AI in pharmacovigilance for postmarketing.	AIMLforDrugDevelopment@fda.hhs.gov
Manufacturing Early Engagement Programs	AI in pharmaceutical manufacturing.	CDER-ETT@fda.hhs.gov

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RISK MATRIX FOR AI MODELS

Decision Consequence vs. Model Influence

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DECISION CONSEQUENCE	MODEL INFLUENCE	RISK LEVEL
Low	Low	Low Risk
Low	High	Medium Risk
High	Low	Medium Risk
High	High	High Risk

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KEY TAKEAWAYS

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AI offers immense potential across drug lifecycle phases.

The 7-step credibility framework ensures robust implementation.

Address challenges like bias, transparency, and drift systematically.

Engage early with FDA to align expectations and strategies.

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RELATED READINGS AND GUIDANCE

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FDA Draft Guidance

Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products (2025).

Artificial Intelligence and Medical Products

How CBER, CDER, CDRH, and OCP are Working Together (2024).

Artificial Intelligence in Drug Manufacturing

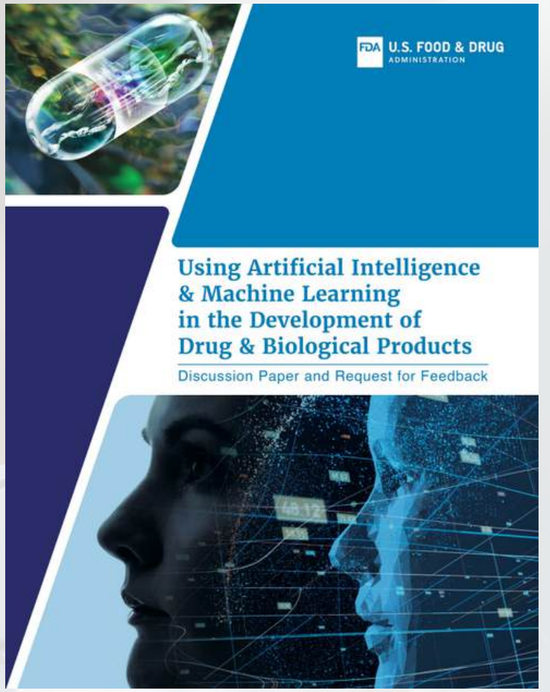
FDA Center for Drug Evaluation and Research Discussion Paper (2023).

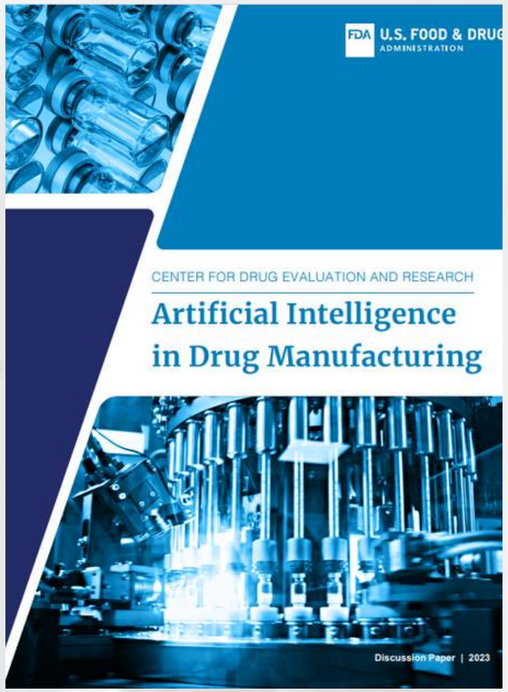
Using Artificial Intelligence & Machine Learning in the Development of Drug and Biological Products

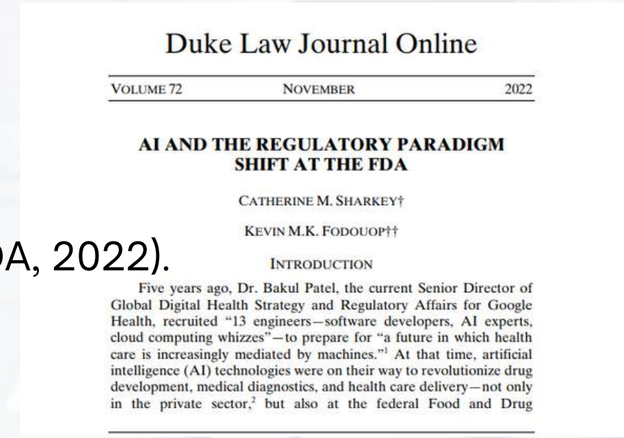
FDA Discussion Paper (2023).

AI in the Drug Development Lifecycle

Workshop Summary (Duke University and FDA, 2022).







Duke Law Journal Online

VOLUME 72 NOVEMBER 2022

AI AND THE REGULATORY PARADIGM SHIFT AT THE FDA

CATHERINE M. SHARKEY†

KEVIN M.K. FODOUOP††

INTRODUCTION

Five years ago, Dr. Bakul Patel, the current Senior Director of Global Digital Health Strategy and Regulatory Affairs for Google Health, recruited "13 engineers—software developers, AI experts, cloud computing whizzes"—to prepare for "a future in which health care is increasingly mediated by machines."[1] At that time, artificial intelligence (AI) technologies were on their way to revolutionize drug development, medical diagnostics, and health care delivery—not only in the private sector,[2] but also at the federal Food and Drug

Total Product Life Cycle for Medical Devices

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Medical Device Safety is the Foundation for Total Product Life Cycle

The FDA's Medical Device Safety Action Plan outlines a vision for how the FDA can continue to enhance its programs and processes to assure the safety of medical devices throughout their life cycle, to provide for the timely communication and resolution of safety issues, and to advance innovative technologies that are safer, more effective, and that address unmet needs.

A team-based approach to medical device safety and effectiveness for premarket review, postmarket surveillance, and compliance

Historically, the Center for Devices and Radiological Health (CDRH), the center in the FDA that regulates medical devices, was organized largely according to the stage of the product's life cycle —premarket review, postmarket surveillance, and compliance— rather than holistically by the type of product being regulated. Although that organizational structure allowed CDRH employees to become specialized by function, it did not always promote the type of collaboration and communication that is proving essential to the continuously evolving innovation of medical devices. In 2019, CDRH reorganized to

Contains Nonbinding Recommendations

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 4, 2024.

The draft of this document was issued on April 3, 2023.

For questions about this document regarding CDRH-regulated devices, contact the Digital Health Center of Excellence by email at digitalhealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov. For questions about this document regarding CDER-regulated products, contact the Center for Drug Evaluation and Research at 301-796-8936 or by email at druginfo@fda.hhs.gov. For questions about this document regarding combination products, contact the Office of Combination Products by email at combination@fda.gov.

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LINKS TO FURTHER FDA DOCUMENTS

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Key URLs for Further Reading:

FDA Draft Guidance on AI in Regulatory Decision-Making Draft Guidance Document:
https://www.fda.gov/media/167973/download

Artificial Intelligence and Medical Products:
https://www.fda.gov/about-fda/cdrh-transparency/total-product-life-cycle-medical-devices

AI in Drug Manufacturing
https://www.fda.gov/media/165743/download?attachment

Using AI in Drug Development
https://www.fda.gov/media/166704/download

AI/ML in Drug Lifecycle Duke Workshop Summary:
https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1100&context=dlj_online

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KEY INSIGHTS FROM RELATED GUIDANCES

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CROSS-CENTER COLLABORATION (FDA CENTERS)

CBER, CDER, CDRH, AND OCP FOCUS AREAS:

Foster Collaboration: Engage with stakeholders, academia, and global regulators.

Develop Standards: Promote harmonized AI regulatory standards.

Support Research: Encourage monitoring and evaluation of AI performance.

Advance Regulation: Provide policies supporting innovation.

AI IN DRUG DEVELOPMENT (FDA AI/ML DISCUSSION)

AI enhances drug discovery, clinical trials (e.g., recruitment, dose optimization), and postmarket safety surveillance.

Emphasis on data quality, bias minimization, and adaptive model maintenance.

DRUG MANUFACTURING (CDER DISCUSSION PAPER)

Applications of AI in process design, control systems, and trend monitoring.

Importance of cloud computing, data integrity, and cybersecurity in manufacturing.

EXPERT WORKSHOP ON AI/ML (DUKE UNIVERSITY & FDA)

Discussed applications of AI in precision medicine and clinical endpoint assessments.

Challenges include data access, security, and dataset shift

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CONCLUSION

Shaping the Future of Drug Development with AI

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AI'S GAME-CHANGING ROLE:
Transforming every stage of drug development, from discovery to post-market regulation, with enhanced efficiency and innovation.

GUIDANCE AS A ROADMAP:
The FDA Draft Guidance provides a structured, risk-based approach to ensure that AI applications prioritize safety, quality, and effectiveness.

THE POWER OF COLLABORATION:
Progress relies on strong partnerships between regulators, industry experts, and researchers to tackle challenges such as data integrity, transparency, and equitable access.

A VISION FOR THE FUTURE:
Responsible adoption of AI can simplify complex processes, accelerate drug development, and deliver groundbreaking therapies to patients worldwide.

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ABOUT US

Dr. Hotha's Life Sciences LLC is a Global biotech consulting firm specializing in comprehensive pharmaceutical and life sciences solutions. With more than two decades of expertise, we partner with clients to guide them through the entire drug development lifecycle—from early discovery to market entry. Our proficiency spans therapeutic areas, focusing on small and large molecules, ADCs, Oligonucleotides, and Peptides, ensuring successful outcomes for drug substances and products.

OUR MISSION

At Dr. Hotha's Life Sciences LLC, we transform complex challenges into clear, actionable strategies. Our mission is to simplify CMC drug development by providing bespoke solutions for regulatory submissions, including INDs, NDAs, and ANDAs. We are dedicated to delivering fast-to-clinic and fast-to-market strategies that maximize quality, accelerate project timelines, and meet stringent regulatory standards.

Complexity to Clarity Together
With a strong focus on early-phase to late-phase projects, Drug substances, and Drug products, we offer end-to-end consulting services that guide our clients through every development phase—from initial discovery to regulatory submission.

Our Approach:

Partner: We believe in solid collaborations. By partnering closely with our clients, we build tailored strategies that align with your unique goals and challenges.

Plan: We provide strategic planning that encompasses the entire development lifecycle. Whether navigating complex regulatory environments or optimizing lab operations, we ensure that your project is equipped for success.

Prosper: With our expertise and guidance, you can bring life-saving therapies to market faster, achieving sustainable growth and long-term success.

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Author Biography:

Kishore Hotha, PhD, MBA

President, Dr. Hotha's Life Sciences LLC

With over 20 years of experience in the biotech, CDMO, and pharmaceutical industries, Dr. Kishore Hotha specializes in end-to-end CMC development operations. As the founder of Dr. Hotha's Life Sciences LLC, he provides strategic consulting in complex small molecules, ADCs, Oligonucleotides, and Peptides, supporting clients from discovery through regulatory submissions.

Dr. Hotha has led high-performing global teams, implemented scalable systems across international sites, and managed over 80 client projects. His contributions include supporting 90+ regulatory submissions (INDs, NDAs, ANDAs) and delivering 45+ successful commercialization. Known for his ability to navigate complex CMC challenges, he has transformed strategies to meet fast-to-market demands while enhancing R&D capabilities.

A prolific author with over 80 publications, Dr. Hotha also serves on editorial boards and frequently speaks at international conferences. His PhD in Analytical Chemistry and MBA in Project Management empower him to deliver innovative, results-driven solutions that advance drug development and commercialization.

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