



NUVALEZ
CONSULTING LIMITED

PHARMACEUTICAL CONSULTING

Excellence As Standard



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@nuvalezconsulting





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ABOUT NUVALEZ CONSULTING

After opening our doors in 2019, we have swiftly emerged as a key player in the life-science consulting industry, supporting a growing and returning list of international clients. We meticulously guide businesses through each critical step, offering expert insights and innovative solutions.

One of our unique strengths lies in our size; as a start-up we are small enough to integrate seamlessly with your team, and understand your specific needs. Yet, we're also large enough to offer a vast range of solutions and share a wealth of industry knowledge accumulated over 40 years of experience in the pharmaceutical sector.





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OUR SERVICES

SERIALIZATION & VALIDATION

Nuvalez Consulting is a leader in serialization services, recognizing its pivotal role in pharmaceutical supply chain management. Beyond meeting regulatory mandates like the DSCSA and EU-FMD, our expert team ensures product traceability and safety. Leveraging methods like EDI, we facilitate seamless information exchange with trading partners.

Specializing in validation consulting, our seasoned team supports pharmaceutical and biotech firms in meeting industry requirements, covering process and computer systems validation. Committed to enhancing operational efficiency and quality assurance, we offer comprehensive periodic revalidation, providing robust solutions for sustained compliance and product quality in the dynamic pharmaceutical landscape.

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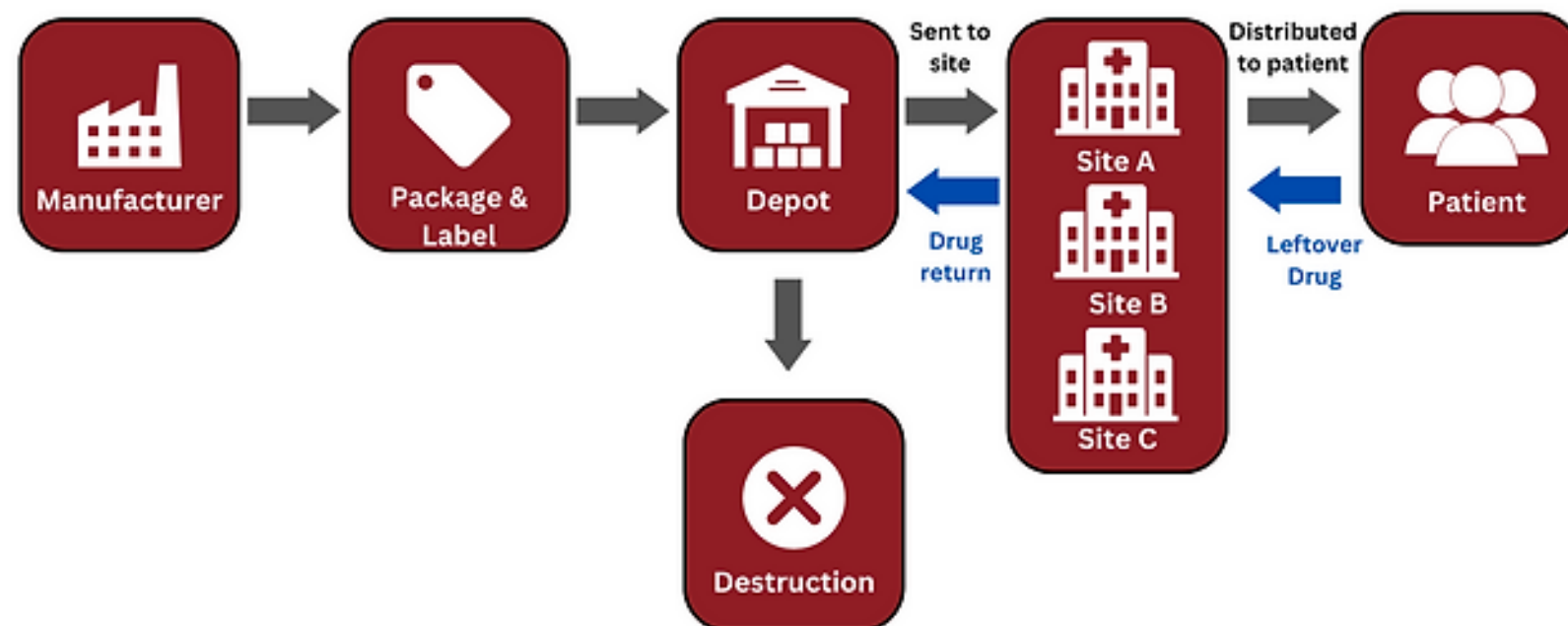
OUR SERVICES

DRUG SUPPLY MANAGEMENT

We understand that precision and attention to detail are paramount in the clinical trial drug supply process. Leveraging our expertise and innovative strategies, we offer a comprehensive range of services to ensure the seamless coordination and timely delivery of trial drugs. By partnering with us, our clients can conduct trials with maximum efficiency and confidence, ultimately advancing medical breakthroughs.



Clinical Trial Supply Chain





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OUR SERVICES

LAUNCH MANAGEMENT

Launching a pharmaceutical product in today's competitive landscape is a multifaceted challenge, demanding meticulous planning, precise execution, and strategic finesse.

Nuvalez Consulting recognizes that successful market entry is a pivotal moment for pharmaceutical companies, and we are committed to partnering with our clients to develop comprehensive launch strategies that maximize product visibility and establish a robust foundation for long-term success. Our experienced team's dedication to launch management is unwavering, and our approach is geared towards ensuring your seamless entry into the market.

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OUR SERVICES

QUALITY ASSURANCE

In the fast-paced and competitive landscape of today's business world, maintaining consistent quality in products and processes is non-negotiable. The key to building trust and confidence among customers and stakeholders lies in having a robust Quality Management System (QMS) in place. Nuvallez Consulting understands this fundamental principle and offers a comprehensive Quality Assurance consultancy service that empowers organizations to reach new heights of excellence.

Our Approach

We recognize that some clients may be at different stages of their journey. For pre-clinical and start-up clients, we offer complete lean and phase-appropriate Quality Management Systems. This tailored approach ensures that, whether you're just starting out or have an established presence in your industry, we provide the right tools and strategies to bolster your quality assurance efforts.





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OUR SERVICES DUE DILIGENCE

At Nuvarez Consulting we offer a comprehensive Due Diligence service on our website, catering to both Asset and Site Due Diligence needs. With a wealth of experience working alongside prominent companies such as Astra Zeneca, MSD, and J&J, our team is well-equipped to guide you through the intricate process of assessing potential investments. Our services go beyond mere expansion, focusing on seamless integration into your existing operational environment.

Whether you're an established enterprise or a budding investor, Nuvarez Consulting provides the expertise required to make informed and strategic decisions in the due diligence arena.

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OUR SERVICES

LOGISTICS MANAGEMENT

At Nuvalez Consulting, Logistics Management is approached with utmost precision and attention to regulatory compliance. Our dedicated team utilizes innovative strategies to oversee the seamless movement of drug substances and products, ensuring timely and secure deliveries, and enabling our clients to focus on advancing their critical research and development initiatives.

We take end-to-end ownership

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OUR SERVICES

ORPHAN DRUG SUPPLY MANAGEMENT

Orphan Drugs by their nature are low volume, high cost and considered critical demand. This can raise challenges with supply as it can be difficult to find the right supply base to cater for small and uncertain demand. However, NuVAlez Consulting are adept at managing Orphan Drugs and helping companies to choose and manage the right suppliers.

- Cross-Functional Alignment
- Global Expertise
- Agility & Flexibility
- Vendor Alignment
- Efficient Launch Timelines





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OUR SERVICES

AUDITS

Nuvalez Consulting delivers comprehensive auditing. Our skilled team conducts Internal, External, and Supplier audits, ensuring transparency, compliance, and operational excellence. With a meticulous approach, we identify opportunities for improvement and mitigate risks, fostering trust and growth in your organization. We work with a network of certified local auditors in the USA, Europe, India, UAE and China, eliminating any language barriers.





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OUR SERVICES

SALES & OPS PLANNING

At Nuvarez, we understand that effective Sales and Operations Planning (S&OP) is the cornerstone of a successful business. S&OP is a dynamic, forward-looking process that connects all key functions within an organization, aligning them towards common goals and objectives. It enables businesses to strike a delicate balance between demand and supply while adapting to changing market conditions.



OUR MANAGEMENT TEAM



Paul Kirwan
Co-Founder & CEO



Owen McGovern
Co-Founder & COO



Krista Hamilton
Business Development
Executive

PAUL KIRWAN

CO-FOUNDER & CEO

As a leader in supply-chain management, Paul brings over 3 decades of global expertise, currently serving as the Founder and CEO of Nuvalez Consulting Limited. Paul's journey in this field began with Mylan Pharmaceutical as a Global Supply Chain Manager, where he honed his skills in operational processes.

This foundation led Paul to executive roles at Aralez Pharmaceuticals and Nuvo Pharmaceuticals, where he oversaw global supply operations. His commitment to continuous learning, includes a Business Studies Degree with the Irish Management Institute. His career is characterized by a passion for streamlining operations, commitment to customer service, and a relentless pursuit of efficiency in supply-chain management.



OWEN MCGOVERN

CO-FOUNDER & COO

Owen McGovern, a distinguished professional in supply chain management, serves as Partner and VP of Operations at Nuvalenz Consulting. With a career spanning over two decades, he has contributed significantly to sectors such as clinical trials, serialization, operational excellence, and commercialization.

Starting in foundational roles, Owen's progression led to expertise in operational efficiency within the pharmaceutical industry. In his role at Nuvalenz Consulting, he excels in managing diverse client needs, showcasing adept problem-solving and delivering impactful results. Prior to Nuvalenz, his entrepreneurial venture in supply chain consulting highlighted his capacity for independent leadership. Owen's academic background includes computer programming and specialized training in supply chain management.



KRISTA HAMILTON

BUSINESS DEVELOPMENT EXECUTIVE

Krista Hamilton, an accomplished professional in supply chain management, serves as a Supply Chain Consultant and Business Development Executive at Nuvarez Consulting. With a career spanning three decades, she excels in operations, clinical trials, and supply chain risk mitigation. Krista's role at Nuvarez Consulting demonstrates her expertise in guiding life science companies through product launches. In leadership positions at B. Braun Medical Inc. and Auxilium Pharmaceuticals, she showcased proficiency in implementing planning processes and managing diverse supply chain activities.

Her academic background includes an MBA in Operations from Cornell Johnson Graduate School of Management. Renowned for cost-effective solutions, Krista stands as a distinguished leader in supply chain and operations, contributing significantly to Nuvarez Consulting's success.



KENNETH FORD, PH.D

CMC CONSULTANT – EXTERNAL

Kenneth Ford, Ph.D., is a seasoned pharmaceutical leader with over two decades of invaluable expertise in product development, scale-up, submissions, and technical operations support. Armed with a Ph.D. in Chemical Engineering from Lehigh University and an MSCEP from the Massachusetts Institute of Technology, Kenneth's academic prowess is complemented by a wealth of practical experience. Throughout his career, he has showcased his exceptional leadership abilities as evidenced by his roles as Vice President of Manufacturing at Lyndra Therapeutics, Senior Director at Novartis and Takeda, and Senior Director at Shire Pharmaceuticals. With a track record of spearheading numerous successful projects, including the approvals and launches of multiple pharmaceutical products such as Xiidra®, Gardasil®, and RotaTeq®, Kenneth Ford continues to be a driving force in the pharmaceutical industry, shaping the landscape of product development and manufacturing with his unwavering commitment to excellence and innovation.



PAULA ADAMS

QUALITY ASSURANCE CONSULTANT – EXTERNAL

Paula Adams brings over 15 years of extensive experience as a Quality Professional within FDA regulated industries. With a comprehensive background in the manufacture, testing, and quality management of drug products, biologics, and medical devices, Paula possesses a deep understanding of quality systems throughout the product lifecycle. Her expertise allows her to approach problem-solving holistically, identifying true root causes and implementing effective corrective actions. Over the course of her career, Paula has played pivotal roles in implementing quality systems for both manufacturing and laboratory settings. Additionally, she has led numerous quality remediation and continuous improvement initiatives, demonstrating her commitment to maintaining high standards of quality and compliance. With her background spanning Quality Control, Quality Assurance, and Manufacturing, Paula excels in conducting thorough internal and external compliance audits, as well as evaluating audit results and responses with precision and expertise.





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