

Driving the Pharmaceutical and Biotech Industries towards Excellence in Manufacturing, Supply and Quality

Adding Value Globally by:

- Developing and Implementing Supply Chain Strategies
- Improving Manufacturing and Business Processes
- Driving Quality and Compliance
- Establishing Advanced Manufacturing Capability
- Managing Clinical Supplies

As an International Consultancy, we deliver innovative solutions around the world to the pharmaceutical and biotech manufacturing sector.

Every individual in our team of consultants is a leader in their field and has more than 20 years of industry experience, so we understand the issues and challenges you face.

We pride ourselves on providing flexible and cost effective support to our clients, irrespective of the size of their organization and challenges.

NDA - Global Reach

Developing and Implementing Supply Chain Strategies

Through our understanding of the challenges and demands placed on the supply of pharmaceuticals and biologicals, we help you develop and implement manufacturing and supply chain strategies that establish the secure supply of new and existing products by:

- Planning the successful launch of new products.
- Conducting strategic sourcing reviews, rationalizing supply networks and outsourcing manufacturing.
- Managing the transfer of technology and products globally.
- Integrating suppliers and contractors into an efficient and cohesive supply chain.
- Delivering real and sustainable reductions in cost of goods.



Improving Manufacturing and Business Processes

Through the application of Six Sigma, Lean Manufacturing and Risk Management principles and tools, we can improve your manufacturing and business processes by:



- Increasing process understanding and manufacturing capacity without capital investment.
- Implementing and supporting Quality by Design (QbD) programs.
- Applying Process Analytical Technology (PAT).
- Improving process control and capability.
- Increasing manufacturing throughput, and reducing working capital.
- Identifying, developing and industrializing new and innovative product technologies.

Driving Quality and Compliance

In response to increasingly stringent regulatory requirements, we enable our clients to ensure compliance by:



- Implementing global quality management programs that help staff develop their understanding and commitment to quality.
- Providing comprehensive and professional quality assurance auditing, including support for GMP and PAI inspections by EC MHRA and the US FDA Inspectors.
- Ensuring Computer Related System (CRS) compliance and validation, including 21 CFR Part 11 and GAMP.

Establishing Advanced Manufacturing Capability

- We develop long-term facility plans that support business strategies and provide confidence that the right manufacturing capability will be available when required.
- By understanding your production requirements we can establish robust capacity plans, develop business cases for new capital investment, and install new capacity world-wide.
- We advise on the purchase of existing manufacturing sites as an alternative to constructing new facilities, using our extensive expertise in due diligence and contractual negotiations.



Managing Clinical Supplies

Through our deep understanding of the challenges facing global clinical supply we are able to:



- Develop and implement a global strategy to manage the supply of products for Phase II, Phase III & Phase IV clinical trials.
- Provide novel approaches to clinical supply packaging and labeling that assures the highest product control and integrity, and maximum patient compliance to the study regimen.
- Identify potential obstacles and solutions to the successful execution of a global supplies distribution plan, including import/export, QP release, specialized storage and shipping.
- Locate reliable and qualified contractors and vendors to assist with the sourcing and supply of all major dosage forms, including novel drug loaded devices.

Other Consulting Services

- Program and Project Management
- Packaging Technology
- Mergers and Acquisition Due Diligence and Integration Management
- Change Management
- Training and Education
- Equipment Engineering

Contact Us

To learn more about how NDA Consultants (Nick Davies & Associates LLC) can help you, please contact us:

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