

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

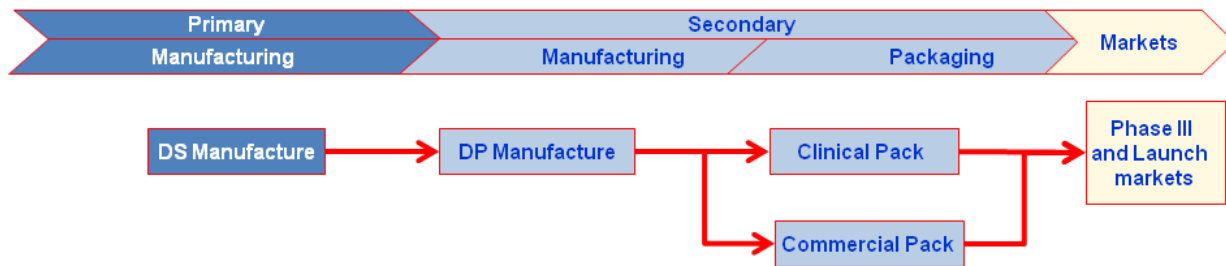
NEW PRODUCT INTRODUCTIONS

NDA can help you ensure the successful launch of new pharmaceutical products.

We have helped pharmaceutical companies launch new products with annual sales ranging from thousands of units for specialty products, to large scale commercial products with sales in excess of \$1bn.

We do this by working with you to develop and implement robust New Product Introduction Plans that;

- Manage the supply of Phase II and Phase III clinical trial materials to ensure clinical trials have sufficient product to meet demand.
- Identify and select suitable manufacturing partners for phase III and launch.
- Manage the Technology Transfer Process to new manufacturing partners and sites.
- Manage the implementation of new manufacturing technology and processes at manufacturing and supply partner's sites.
- Plan for the successful launch of new products by establishing pre-launch supply plans that provide sufficient product to meet launch and growth projections.



Typical Product Supply Chain - Phase III & launch

NEW PRODUCT INTRODUCTION CASE STUDY

ISSUE:

A pharmaceutical company with a product that was about to enter Phase IIb wished to establish a low cost supply chain using a mixture of in-house and external contract manufactures.

OBJECTIVE:

Identify suitable manufacturing partners to manufacture clinical trials materials and prepare for launch.

DELIVERABLE:

Suitable manufacturing partners for Drug Substance (DS) and Drug Product (DP) were shortlisted based on available technology, prior experience with the supply of clinical trials materials and commercial product, geographic location etc.

Expression of Interest (EOI) document issued to perspective manufacturing partners to give their suitability and interest.

Request for proposal (RFP) document written and issued to prospective manufacturing partners shortlisted from EOI returns.

Three finalist manufacturing partners identified from RFP. Audits and technical meetings conducted with finalists to review proposals and select successful partner.

Contract negotiated and awarded to the successful manufacturing partner.

Contact Us

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

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