Verta Life Sciences | Molecule to Market Consulting.
Supporting Life Science Companies; Develop, Manufacture, Register, Launch, and Supply their Products.

LOGISTIC SERVICE PROVIDER SELECTION AND SUPPORT CASE STUDY

Verta 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.

In the last two years alone we have helped companies register and launch 5 new products.

We do this by working with you to;

- 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.
- Manage the scale up and manufacture of registration batches.
- Write Regulatory CMC Module 3 sections.
- Design commercial packaging and select packaging partners and sites.
- Design artwork for Packs, Patient Instructions and create registration artwork copy.
- Establish a commercial supply network and ensures serialization in place for launch.
- Select the most appropriate Logistics Service Provider to support commercial supply.

- Plan for the successful launch of new products by establishing pre-launch supply plans that provide sufficient product to meet launch and growth projections.

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:

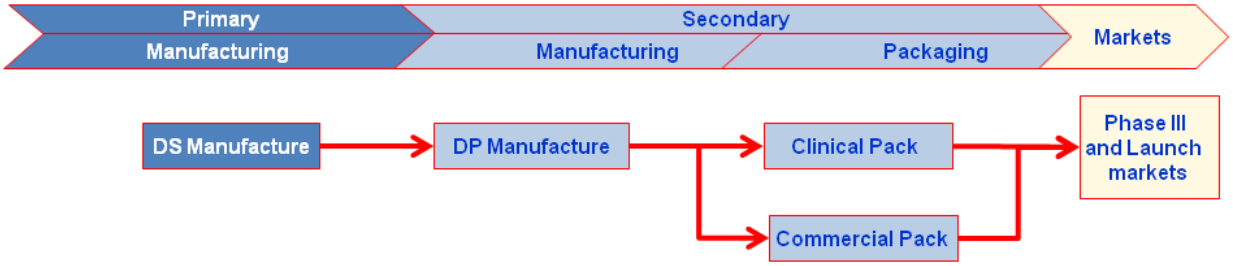
Suitable manufacturing partners for Drug Substance (DS) and Drug Product (DP) were shortlisted based on available technology, prior experience with the supply of clinical trials materials and commercial product, geographic location etc.

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

Request for Proposal (RFP) document then written and issued to 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.



Typical Product Supply Chain - Phase III & launch

Contact Us

To learn more about how Verta Life Sciences can help you, please contact us:

Email: experts@Vertals.com
Head Office: Verta Life Sciences, LLC
3737 Glenwood Ave,
Suite 100
Raleigh, NC 27612
USA
US Phone: +1 919-787-1921
Free phone: +1 888-565-3179

Website: www.Vertalifesciences.com
EU Office: Verta Life Sciences
Unit 1782, PO Box 92,
Cardiff, CF11 1NB
UK
UK Phone: +44 (0)2921 25 0830