



Clinical Trial System

DMLogic delivers process design software tools to support clinical trials.

DELIVERING DRUGS IN CLINICAL TRIALS

The exacting requirements of pharmaceutical manufacturing and shipping demand complex product tracking coupled with zero tolerance for error. Expiration dates, temperature sensitivity and special handling are just a few of the constraints inherent in pharmaceutical logistics. In their normal course of operations, pharmaceutical manufacturers usually ship their products to a few large distributors and retailers, with shipment visibility through the supply chain. But drugs in use for a clinical trials require a very different way of operating.

TRACING DRUGS WHILE PROTECTING THEIR IDENTITY

Though the pharmaceutical supply chain is, by its nature, complex, nothing matches the level of sophistication, detail and

accuracy needed to ship the drugs used in clinical trials. An overarching challenge is how to track the clinical trial drugs with pinpoint accuracy while eliminating any identifying characteristics.

Research protocol usually dictates a double-blind experimental design, where neither the person administering the drug nor the person receiving the drug knows dosages or which product contains the active ingredients.

Standard labeling must be removed along with all identifying traits of the drug. To ensure the right drug reaches the right patient, the product is branded with a unique "serial" number for tracking. Special drug packaging can include labels or boxes for patient returns and customized paperwork inserts. Some clinical trial packaging requires assembly, such as kitting injectable drugs

with a supply of syringes. Shipments can also be subject to temperature monitoring.

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EXPERIENCE COUNTS

The complexities of the clinical trials are such a large challenge to pharmaceutical companies that many choose to outsource the entire operation. One pharmaceutical company shunned the outsourcing option, referring to oversee its own trials. The company contacted the consultants at DMLogic to develop a system for managing the entire clinical operation, a system that would integrate trial shipments into its regular trade operation.



A key requirement was to use its current warehouse management system as the system of record. The decision was made because the warehouse was already a validated CFR Part 11 compliant system and would help make this transition seamless for workers.

EMPOWERING THE MANUFACTURER TO DO-IT-YOURSELF

Not a problem for the DMLogic team. The consultants knew the manufacturer's WMS intimately. DMLogic had done the implementation and the validation. Working closely with the manufacturer, DMLogic consultants conducted an in-depth analysis of the requirements. The need for assembled packaging and tailored paperwork forced the creation of a new solution that fit with the current WMS. The solution was to build a configurable decision tree system that allowed the manufacturer to "pick-and-choose" which

functions best met its own needs and the needs of each clinical trial.

The redesigned operation receives, picks and ships the serialized product with maximum efficiency and accuracy. Now the operation can easily customize this new module to accommodate the various process requirements from one clinical trial to the next.

The pharmaceutical company continues to praise the power of the new system and its applications in its operation, especially in handling the ever-changing requirements from wholesalers. By streamlining the clinical trial setup, including the time needed to train employees, the manufacturer received an added bonus: significant cost savings.

See our Lot Recall and ePedigree case studies to learn more about the solutions we have delivered to our pharmaceutical customers.

About DMLogic

DMLogic is a team of senior supply chain consultants with decades of experience solving challenges for our customers.

Our capabilities include warehouse management systems, material handling systems and process and facility design for distribution

Our experience includes pharmaceutical, automotive, electronics, retail, publishing and third party logistics.

Our team has provided solutions for Fortune 100 companies in the US and abroad, as well as for smaller companies in the US.

Our customers will attest: DMLogic builds partnerships for the long term, with a solid reputation for customer service and quality work.

DMLogic: a strong partner for companies looking to solve the complex challenges of managing their inventory.

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