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CASE STUDY

Successfully Executing a Tech Transfer in a Week

Challenge

- Multiple blockbuster products ($3 Billion USD/year) were coming off patent, and the Sponsor company needed to rebuild its flagship site to manufacture the next blockbusters without losing market share
- Scope: Five product lines including pouches, solid oral dosage (RM dispensing to unit dose final packaging) in multiple configurations
- Timeline: 3-days (including weekends) to shut lines down, clean equipment, crate equipment, ship 750 miles to the new site, install, qualify, and resume production with new staff
- Regulatory strategy meeting with FDA for site change, supply chain, validation master plan, staffing plan, training plan, analytical transfer
- Inventory controls to move raw materials, equipment, staff, and procedures from one site to another

Solution

- Create a work breakdown for every task, assign responsibilities
- Identify each item on the critical path and define to the minute each item. All protocols are pre-approved before execution
- Brainstorm solutions, including changing all connections to quick disconnect, crates were pre-built, contingency trucks, staff
- All equipment was decommissioned and recommissioned to ensure
- Train team at sender site with training plans and side by side hands-on learning of all tasks
- Every item that can be done before "transfer" is completed so that only critical tasks remain
- Dry run movements with scale models to ensure equipment can be moved into place
- Layout of equipment, components, and personnel with exact location before disconnecting from the sender site

Results

- FDA approved the changes
- Sending and receiving sites were aligned with a plan before execution
- All raw materials were available and released prior to transferring 100 pieces of equipment
- All personnel (warehouse, operations, QA, QC, engineering) trained before the 3-day tech transfer started
- All equipment (mfg, pkg, QC, warehouse) transferred without damage or failure. The contingency plan wasn't touched
- All qualification protocols were executed without deviation
- All product was released and approved for distribution without a reduction in efficiency

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

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