

Relocation Planning for Regulated (cGMP) Businesses

What is involved with relocating a regulated Life Sciences business? Answer: new facilities with a new layout, new equipment, training for new process flow and equipment, commissioning and decommissioning equipment, regulatory compliance in old and new facilities during the moves, regular communications with staff, public relations with community and customers, nonstop delivery of quality product to customers all during the entire process, new regulations and controls, emergency plans, changing dozens of contracts with vendors, providing décor and amenities for staff, use of considerable HR resources, a separate budget for the Relocation, regular meetings, reporting, solving unexpected problems, deadlines that must be met and unusual stress on staff due to extra work in addition to regular jobs.

In other words, it's the relocation of a **Complex Operating Business** with minimal risk and interference to revenues and production. I define a **Complex Operating Business** as having one or all of the characteristics below:

- Highly regulated (cGMP) or at a minimum, a GLP operation;
- Operations must continue uninterrupted seven days a week 24 hours a day;
- Shutting down existing operations in one location while starting operations in another is a complicated, COSTLY matter;
- Operations or product are at high risk with any disturbance.

The process flow should look something like this:



I view “Mission” and “Execution” as the two most important steps; of all the steps involved with relocation, these two steps are the ones that will have the most affect on the success of a relocation project. Other factors that make this all such a complex issue are:

- Fundamental Operating (Core) Business is at risk
- Cannot stop, slow or compromise production
- Quality has to be maintained
- Extra, new, unfamiliar work for staff
- Additional overlap staff required to assist during start up and shut down phases.
- Highly regulated business increases regulatory focus on new activities for relocation.
- Coming to grips with decisions required now for an event 1 to 2 or more years away.

What's the difference between a **“Move”** and **“Relocation”**? They are vastly different:

	Move	Relocation
What is involved?	Boxes, labels, moving trucks, packing and unpacking.	Relocating a highly regulated multimillion dollar business that operates 24 x 7, to new facilities without any interference to the quality or integrity of the product.
Tasks	Approximately 100 tasks	Probably over 1,000 tasks
Time Frame	Months	1 – 3 years of planning
Costs to execute	Around \$200k (for Life Sciences)	Over \$3 Million (including construction)
What is primarily at risk?	<ul style="list-style-type: none"> • Furniture, Fixtures and Equipment (FF&E) 	<ul style="list-style-type: none"> • Value of business • Integrity products

Following is a basic list of each relocation step and what may be involved. I realize that every cGMP or GLP operation can be unique and some more complex than others. Here's the list:

*Step 1: **Mission:*** Ensure that the Management Team understands the organization's strategic goals with the particular circumstances for each location. A Mission Statement for the Relocation Project should be developed that outlines the generalized goals and time frames for relocation.

*Step 2: **Concept Plan:*** The Concept Plan consists of:

Written Briefing: Based on a refined Mission Statement, the Concept Plan outlines the strategies for relocating the components of the operating business. The Concept Plan sees the business as an integrated whole and gives considerable thought to how the core business and supporting elements will relocate so as to minimize risk and avoid production interruptions.

Milestones: Showing major blocks of time for the planning and execution phases.

Budget: A budget is created for Relocation and approved by the corporation. The budget considers the extra amount of work that is ahead for staff, operating from several locations, training temporary and permanent staff on new equipment, orienting everyone to new processes and policies, temporary security and safety issues in multiple locations, moving standard office FF&E, moving product and specialized equipment, and decommissioning old facilities. Other issues outside of relocating the business must also be included in this budget. Those other issues include for example: multiple events for the staff and the community, décor for the building, and communications with staff, customers, suppliers and the community.

Organization: Functional Teams are created based on the Task Lists giving consideration to the core and supporting components of the business. Team leaders are selected and will be responsible for overseeing the creation of detailed plans and execution of those plans, and management of budgets for their team.

Step 3: Detailed Plans: Functional Teams are organized to suit the primary areas of responsibilities. They produce the Detailed Plans for their areas of responsibility giving consideration to cross functional relationships also called “dependencies.” There are additional detailed plans required by the Facility Quality Plan (FQP), such as security and safety plans, which further clarify operations during and after the relocation.

Step 4: Execute Plans: All Detailed Plans are implemented and vigorously supervised by leadership. Functional Team leaders report periodically on the status of their teams’ plans. Cross relationships (dependencies) are carefully monitored to ensure no unwanted delays. Team leaders are encouraged to reveal problems, instead of avoiding discussing difficulties they might be facing or anticipating.

A significant part of the execution step is monitoring the budget. Regular reviews should be made of where the project expenses stand. That review should clearly show what the budget allocation is, what has been spent to date and the total projected expense at the end of the project. Each Functional Team leader is held accountable for these three bottom line numbers.

Step 5: Move: The actual execution of the physical moves; can (and probably will) be multiple weeks of execution.

Step 6: Post Move: Following the move, tasks such as decommissioning, “punch out lists,” warranty issues and lessons learned are completed and the Transition Project is officially finished. A final budget review is completed comparing the original budget to actual costs.

Remember, people dislike change and there is a lot of change involved in relocation. Communicating with employees is important. Think about how you might feel if you came to work one day and nothing was the same:



Keep your employees informed throughout the process; let them see architectural concept drawings, maps, blueprints and most important written relocation plans. Solicit their input and provide solid feedback.

We have experience preparing detailed relocation plans and guidelines for complex organizations and can help you in preparing yours. Contact us at: www.facilities-management-solutions.com.

