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Relocation Strategy for Mission Critical Lab Equipment for GLP / GMP Regulated Facilities

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PerkinElmer precisely.

1 Introduction: Relocation Processes

Running a laboratory in a GxP compliance environment is complex. Moving that lab – with a minimum of downtime while protecting your compliance standing – adds another layer of difficulty.

Relocation processes to be addressed:

- Planning, scheduling and coordinating
- Preparing the inventory
- Identifying each instrument and its parts
- Preparing regulatory documentation (pre-verifying, qualifying, validating)
- Disassembling instruments
- Ensuring the safe handling of all chemicals and lab samples
- Managing transportation or disposal of all hazardous materials
- Handling all packing and moving
- Re-installing all lab instruments and holistic testing
- Performing any qualifications / validations, as needed, post-move
- Addressing any obstacles in a move, such as moving oversized equipment.

2 OneSource Relocation Case Study

Primary Objective: Lab Equipment Move / Re-Commissioning for 44 Labs at $2.5b Hospital Products Manufacturer

- **PerkinElmer is main contractor, providing in-house:**
  - Pre- and post-calibration & qualification
  - Custom qualification protocol development
  - Equipment and accessory labeling
  - Dismantling, packing, setup, and qualification
  - Sample handling (-80, -20 ºC) & Restricted Standards
- **Manage moving company & chemical waste management company**
- **3 categories of equipment, plus chemicals, across 44 labs**
  - 300 pieces General Lab Apparatus
  - 150 Analytical Systems (1000 items)
  - Process Equipment (requiring specialized moving equipment)
- **Custom Qualification protocols developed for Analytical System**

Hospira

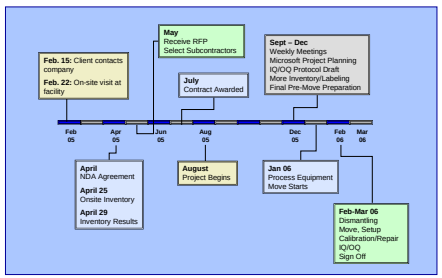
3 Special Concerns for GLP/GMP Facilities

Protecting Your Regulatory Compliance Requires:

- Pre- and post-calibration verification of lab equipment
- SOPs for decommissioning and recommissioning
- SOPs for handling critical samples and chemical waste management
- SOPs for multi-vendor service & PM – IQ/OQ/PQ qualification
- GLP/GMP training and understanding for regulatory procedures
- Good Documentation Procedures (GDP) – training & execution

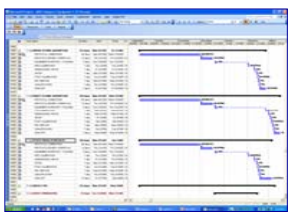
4 Relocation Timeline: Feb. 2005 – April 2006

- **Feb 15 –** Client contacts company; on-site visit scheduled
- **Feb 22 –** On-site visit
- **April** – NDA agreement / initial inventory list received
- **April 25-28 –** Onsite inventory of all equipment, accessories, chemicals
- **April 29 –** Client provides up-to-date inventory of site
- Moving and chemical waste management vendors contacted
- **May –** Receive RFP
- Select moving and chemical waste management vendors
- **June –** Submit RFP
- **July** – Awarded contract
- **Aug. 1** – Project starts
- **Feb. to April 30 –** Move dates
- **April 30, 2006 –** Sign Off on project. Continue working relationship with additional tasks not included in the contract.



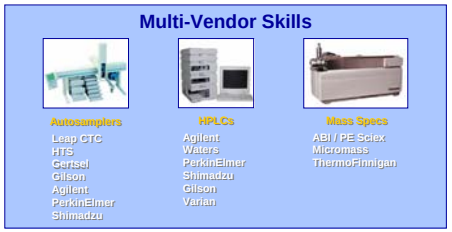
5 Strategy: Pre-Move Planning

- **Weekly / Biweekly Meetings (onsite and phone conferences):**
  - **Corporate Team:** Project Manager, Facility, Engineering, QA, Compliance, Scientists, Construction Manager
  - **PerkinElmer Team:** Onsite Project Manager, Scientists, Customer Service Engineers, Support Staff
  - **Subcontractors:** Moving, Chemical Waste Management
  - PerkinElmer internal support meetings
- **MS Project Schedule**
  - Equipment move
  - Lab content move
  - Personal items move
  - Sample handling
  - Other events



A Relocation Typically Requires 4 to 6 Months of Planning

6 Strategy: Multi-Vendor Skills

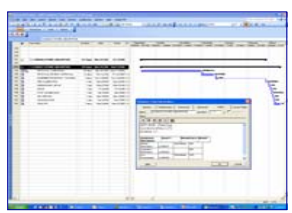


Efficient relocation requires skills in servicing instruments from a variety of instrument manufacturers

Our Multi-Vendor Expertise

- **BASF** - Complete lab equipment dismantling, move, commissioning, qualification (LCMS, GCMS, FTIR and other lab equipment)
- **Synta Pharmaceuticals** - Complete lab equipment dismantling, move, commissioning, qualification (including LCMS, Genomic/Proteomic), 4 moves in 2006
- **Rockefeller University** - Complete HTS lab equipment dismantling, move, commissioning, (LCMS, LH, MLD, Imaging, G.L.E), 3 Day
- **J&J** - Repair and calibration (HPLC,GCMS and other lab equipment)
- **Wyeth** - GMP manufacturing site, (service HPLC and other lab equipment)
- **Merck** - Maintain 4 Sites (HPLC, GC and other lab equipment)
- **Schering –** Maintain 4 Sites (HPLC, GC and other lab equipment)

7 Strategy: Scheduling



Employ Microsoft Project to Manage:

- Inventory verification
- Meetings
- Labeling / tagging of equipment
- Equipment relocation (each item assigned a move date, chosen to mesh with client's needs and move phases)
- Personal items and drawer contents move
- Creation of IQ/OQ protocols / calibration procedures
- Decommissioning, move, setup, post-calibration, repair, qualification
- Chemical move and sample handling
- Large equipment move

8 Strategy: Compliance Skills

The ability to perform Qualification / Validation on a variety of instruments from various manufacturers while maintaining the document paper trail for each instrument so as not to harm GMP/GLP status.

In addition, providing the harmonized document templates that ease maintaining and auditing of each instrument.

Our MV Validation / Qualification / Calibration Expertise

- **Duke Medical** - Custom validation of >100 systems, plate readers / washers, flow cytometry, luminometers, refrigerators, freezers
- **Bayer** - GMP manufacturing labs, validation of lab, pilot and production scale separation systems and DNA synthesizers, incubators
- **Biogen Idec** - GLP labs, validation of Tecan Genesis, Beckman Biomek, CMS, HPLC, plate readers, UV-Vis spectrophotometers

9 Strategy – Skills, Capabilities & Resources

- Availability of trained service engineers on a global basis
- Availability of resources for large-scale projects
- Training program and facilities for multi-vendor services
- Solid infrastructure to support the relocation project and associated tasks
- Network of qualified subcontractors for move and chemical handling
- Compliance skills to work on projects that require regulatory understanding
- Past experience and know-how for managing the entire project

10 Summary: Essential Strategies

- **Plan, plan and plan some more**
- **Use appropriate management / scheduling tools**
- **Verify accuracy at every step (inventory & labeling)**
- **Know compliance requirements and create the necessary documentation for each instrument**
- **Communicate - at every level**
- **Plan for the unexpected and be flexible**
- **Choose a service provider with the technical multi-vendor capability and resources to handle the job**