OVERBROOK

Proper Laboratory Instrument Life Cycle Management

Aside from Your Team, Your Most Important Assets

By Ted Palashis
President, Overbrook Support Services

Key Words

Laboratory lifecycle, asset management, start-up phase, operational phase, expansion phase, maturity phase, exit phase, reconditioned instrumentation, refurbishment process, laboratory asset procurement, workflow, utilization, instrument reliability, comprehensive service plan, comprehensive harmonized service plan, diversionary cost ratio, short term growth, long term growth, organizational culture, workflow analysis, QA/QC reporting, service plan, accountability maps, market value, scarcity, tangible assets.

Abstract

Aside from the laboratory's personnel, its instrumentation is its most important tangible asset. As laboratory operations are extremely complex and instrumentation requirement profiles constantly change, the required skills to properly manage those assets cannot be underestimated.

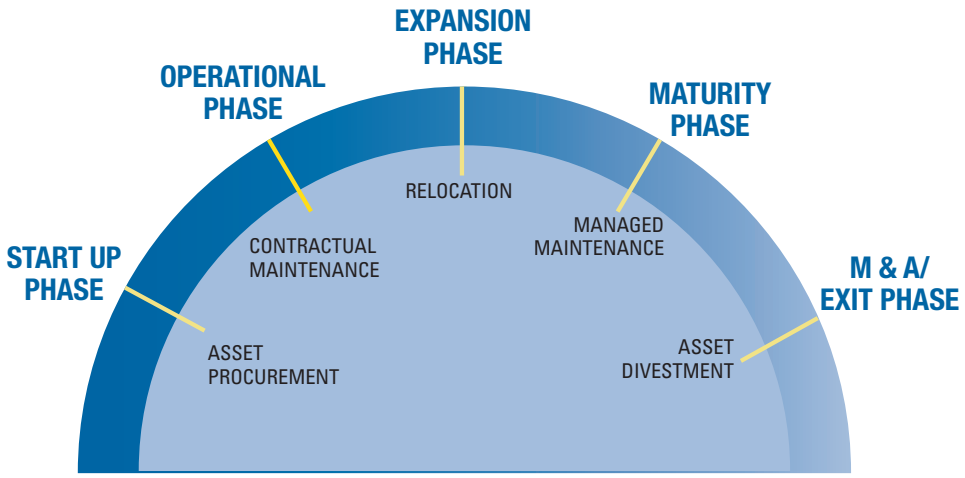
Making the proper decisions how a laboratory's instrumentation will be managed throughout their lifecycle can determine the success of the business and whether needed drugs, products, innovation and cures get to market. This paper discusses the lifecycle of the laboratory viewed as an arc of its maturity and the corresponding requirements to properly manage those assets.

The Laboratory Lifecycle

The Laboratory Lifecycle should be viewed as an arc of maturity of the business that encompasses five phases:

1. Start-up Phase
2. Operational Phase
3. Expansion Phase
4. Maturity Phase
5. M&A/Exit Phase

Though multiple asset management tasks and services can be deployed across all phases of the maturity of the lab, there are specific management tasks and services that generally correspond to each of these phases as they relate to instrumentation.



Start-up Phase

Outfitting of the laboratory

Outfitting the laboratory and the procurement of assets that are suitable to the scientific mission that are reliable, cost effective and effectively maintained by either the manufacturer or a qualified service provider is particularly critical in the start-up phase, as there is rarely much redundancy budgeted at this stage.

There are criteria that need to be considered in the selection of appropriate instrumentation. Those criteria should include items such as: known performance or maintenance issues, parts availability (i.e. do replacement parts need to be shipped from offshore—think trade restrictions) user friendly software and operation, required staff training to operate the instrumentation, compliancy adherence certification and the proficiency and willingness of laboratory personnel to perform routine ownership maintenance tasks.

Professional laboratory asset procurement specialists can offer expert market research, negotiating and logistical expertise.

Reconditioned assets

If start-up budgets are limited and if the science plan allows, reconditioned assets can be considered to preserve financial resources thereby increasing the chances of success of the start-up

Proper vetting of the origin of the reconditioned instrumentation, its refurbishment process and post-sale support are necessary factors in determining the success of the purchase and can result in substantial savings particularly with high value assets. *As a rule of thumb depending on the asset, a 30-40% savings off the cost of new instrumentation can be realized.*

Professional laboratory asset procurement specialists

Professional laboratory asset procurement specialists can assist in these tasks as well as offer expert market research, negotiating and logistical expertise to supplement in-house skills or provide them if in-house skills are unavailable.

Operational Phase

Instrumentation efficiency analysis

Once the laboratory is up and running and there is a general understanding of its routine analysis, volumes and sample workflows, an instrumentation efficiency analysis should be conducted to understand the “operational profile” of the laboratory.

This analysis is important to ascertain mission criticality of the laboratory's instrumentation in the context of its workflow (production vs. research applications), utilization (which assets get the most wear and tear), instrument reliability and the lab's experience of working with their service providers and the level and quality of support that was provided during and following the warranty period.

Comprehensive service plan

Based on this analysis, a comprehensive service plan, specific to the needs of the laboratory should be determined so that instrumentation can be properly maintained, and downtime minimized. The service plan should include a combination of varying levels of service, specific to those needs. Levels of service can include full contract maintenance services (production and mission critical instruments), qualification services (GxP instrumentation), time and materials and extended warranty support (R&D and other non-mission-critical instruments)

The plan should be comprehensive, harmonized and tailored to the operating profile of the laboratory and properly managed by capable, available in-house resources or outsourced.

Maintenance service responsibilities (following up with vendors, monitoring PM and qualification schedules, keeping track of inventory etc.) at this stage however, for reasons of perceived cost savings, often fall on either the individual scientists, the lab manager or facilities personnel which aside from the ad hoc nature of the approach, has its own diversionary cost implications which we'll discuss later in this article.

Expansion Phase

Expanding existing space, relocating to new facilities

Expanding its existing space or relocating to new facilities is a requirement of a laboratory with well-established business and science plans that have outgrown the limitations of its existing footprint and seeks to accommodate its increased sample volume and research capabilities.

The necessity of a well-organized and executed laboratory relocation cannot be overstated, as a failure to do so can directly affect burn rates, diverted labor, troubleshooting costs, quality control etc.

As labs move frequently, the aggregated effect throughout the industry has a substantial impact on productivity which in turn, effects the efficiency of needed drugs and products getting to market, R&D, healthcare and manufacturing in general.

A well-organized and executed laboratory relocation cannot be overstated, as a failure to do so can directly affect burn rates, diverted labor, troubleshooting costs and quality control.

Lab relocation plan

A well-organized and well-executed lab relocation requires an understanding of all the moving parts (the analogy is trying to change the wheels of a car as it's moving), identifying weak links in the chain of accountability, putting the right resources where they need to be and why excruciating attention to detail is absolutely required in properly managing and executing the move and follow up tasks.

A comprehensive harmonized service plan if already instituted can greatly minimize the disruption to lab operations, as maintenance activities and protocols already in place that are centrally coordinated can more easily integrate into the relocation plan.

Maturity Phase

Proper management of assets

In the Maturity Phase, the laboratory has reached a point in its life cycle where it needs to determine if it has the internal resources and expertise to properly manage its assets in a way that allows the lab to properly maintain a level of efficiency and cost effectiveness.

At this stage, the laboratory has moved from its earlier kinetic stages of growth challenges to managing its complex operations, infrastructure and science teams while maintaining peak productivity and profitability.

As the business has matured, laboratory operations have often developed ingrained ways of dealing with repairs, maintenance and the management of its assets. If done internally, as previously mentioned, the burden usually falls on facilities personnel, lab management or end users who usually do not have the engineering skills, bandwidth or expertise to properly maintain the laboratory's assets.

This approach usually results in critically overlooked maintenance activities, inconsistent coordination and monitoring of routine maintenance, qualification schedules and a lack of focus on the scientific mission of the laboratory.

Because of the uncoordinated nature of an unharmonized approach, underutilized assets that can often be redeployed to areas of the lab that could use the additional resources are often not on the radar screen and thus, not considered, resulting in overlapping capabilities and additional costs.

Underutilized assets, overutilized staff

A single underutilized asset on standby can cost hundreds of thousands of dollars between the unnecessary purchase of an additional asset and its accompanying maintenance contract costs.

A different dynamic holds true with lab personal but with the same result of additional expense. Overutilized staff, stressed bandwidth and the resulting effect on profitability and morale cannot be overstated. Also, diverted staff activities require additional resources and costs and a "diversionary cost ratio" needs to be taken into account.

Simply put—if a scientist is diverted from their job of doing research and running samples to managing instrumentation, the diversion cost is not a 1:1 ratio. Meaning, for every payroll dollar (plus carrying costs) that the scientist is not doing what they were hired to do, the dollar per hour diverted is not a dollar to dollar ratio, but at least 3:1. In some case, as high as 5:1 as the expectation is that that scientist is expected to generate a profit for the company of at least 3 times their cost.

A single underutilized asset on standby can cost hundreds of thousands of dollars.

This profit expectation either must be deducted from the P&L or compensated for by adding additional hires to make up for the diversion.

Outsourced asset management

Larger pharmaceutical, biotech and manufacturing companies as well as some 2nd tier laboratories have understood this dynamic and most outsource the managing of their assets to professional asset managers.

These services need not necessarily be reserved however for larger laboratories as 2nd and 3rd tier sized laboratories can also benefit from outsourcing these services to independent service providers with programs specifically designed for medium and smaller sized laboratories with services and cost scaling, specific to where the laboratory is in its life cycle.

Operational profile analysis

Regardless of the size of the laboratory, to coordinate a comprehensive, harmonized approach to properly maintaining and utilizing the laboratory's assets and to avoid operational inefficiencies, an operational profile analysis by someone qualified

should be conducted to adequately address the requirements of the laboratory and a comprehensive laboratory asset management program as a result of the analysis should be implemented to properly maintain the instrumentation.

At a minimum, the analysis should take into account the following:

- The laboratory's organizational culture and disposition towards asset maintenance
- Current, short and long term growth and science plans
- Utilization and workflow analysis of current assets
- Level of training of lab personnel
- Current personnel ownership diversion costs
- Proposed "instrument ownership" maintenance accountability
- Current and proposed expansion utility capabilities and limitations
- QA/QC reporting requirements
- Purchasing and inventory management
- Current vendor "service plan accountability maps"

If an outsourced asset manager is selected to implement and maintain the asset management program, factors in their selection should include the following:

- Engineering background
- Agnostic disposition of the management company (independent vs. manufacturer)
- Operational expertise (understanding of lab operations)
- Existing relationships with manufacturers
- On-site staff capabilities vs. remote support assistance
- Primary market focus (large, medium, small laboratories)
- Native engineering expertise (primary business focus)
- Infrastructure and reporting tools (software and internal infrastructure)
- Cultural fit to the laboratory

A well-executed, comprehensive, harmonized approach to managed maintenance of laboratory assets ideally positions the business for the next phase of the life cycle of the laboratory; a successful merger, acquisition or exit of the business.

If the outsourced asset manager and laboratory are properly matched, additional cost reductions and operational efficiencies will be realized due to the asset manager's relevant instrumentation experience, ability to effectively communicate "cross silo" within laboratory groups and business units and a comprehensive, harmonized understanding of how the laboratory operates.

A well-executed, comprehensive, harmonized approach to managed maintenance of laboratory assets ideally positions the business for the next phase of the life cycle of the laboratory; a successful merger, acquisition or exit of the business.

M&A/Exit Phase

Aside from a laboratory's relocation, the M&A/Exit Phase can be the most disruptive and challenging phase of the business in managing its assets due to a variety of factors. Incoming resources (both in terms of personnel and instrumentation) can create challenges due to overlapping capabilities and redundancies.

Repurposing, reselling or disposing of redundant assets

Proper management of highly valuable redundant assets by either having them repurposed within the organization or channeled for resale, can optimize resources and free up capital that can dramatically influence the financial calculus of a laboratory's overall value.

The steps in managing this process should include an initial determination if the asset can be efficiently repurposed within the organization. If repurposing of the asset is not desirable or feasible, certain criteria of salability to determine an asset's actual value need to be considered:

- Current market value due to the number of available assets on the used market
- Competition from new model technology improvements
- Scarcity in the market of the asset model or class (new or used) based on demand
- Transferability of software licenses
- Service provider options including installation and post installation support (making it easier on the buyer to consider purchase)

Knowledge, bandwidth and auction houses

As existing personnel resources may not have the depth of knowledge or bandwidth to take on the task internally, laboratories often choose the option of assigning the task to an auction house to resell its redundant assets.

Though beneficial in some cases for large pharmaceutical or manufacturing companies due to the sheer volume of equipment, auction companies usually don't have the required expertise nor is it within their operating model to optimize the value of individual high cost assets which make up the majority of value of the assets for sale.

A qualified laboratory asset management company can provide multiple options and management of the process in repurposing, reselling or disposing of redundant assets including a hybrid approach of managing the reselling/remarketing and auctioning of instrumentation. They can also arrange or directly provide the remarketing, sale, installation and post-sale support services that can greatly increase the value of redundant assets and relieve the burden of responsibility from lab operations.

In Conclusion

As laboratory operations are extremely complex and instrumentation requirement profiles constantly change, the required skills to properly manage those assets cannot be underestimated.

Making the proper decisions how these critical assets are managed throughout their lifecycle, can often determine the success of the business and thus whether needed drugs, products, innovation and cures get to market. ■

Mr. Palashis founded Overbrook Support Services, a leading privately-owned professional laboratory services and instrumentation company in 2001. The company focuses on essential laboratory instrumentation services throughout the lifecycle of the laboratory. Overbrook Support specializes in laboratory relocations, laboratory asset management, instrumentation engineering and procurement services and provides support to the life sciences, biotech, materials and environmental testing industries. Overbrook clients include EMD Serono, Quest Diagnostics, Sanofi Genzyme, Bureau Veritas and others.