WHITE PAPER

A Modern Framework for Integrated Laboratory Instrument Management (LIM)

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Introduction

Modern, automated labs are under immense pressure to improve operational efficiency, maximize ROI, monitor assets in real time, all while reducing waste and managing regulatory risk. Teams are expected to discover and produce at a pace once considered unthinkable. Service organizations are increasingly pursuing the realization of "Knight's Law" in laboratory operations (i.e., the output should double while costs fall linearly). This means not just growth, but that each scientist should be able to do almost double the work in the same amount of time, year over year. This can't be achieved by just purchasing the latest, bigger, and faster instruments, but requires automation and good asset management practices.

Too often, data-driven discovery is hindered by the inability to manage, monitor and utilize assets to their fullest, which leads to wasted/unused lab equipment. Optimizing the utilization of equipment and instruments in the lab is a key responsibility for lab managers, with great potential to reduce overall costs and compliance risk, while promoting productivity. After human resources and physical space, guaranteeing working instruments in the lab represents the next largest investment for most labs. Providing properly functioning instruments and equipment impacts both the capital budget (for new investments) and the operational budget (for repair, maintenance, calibration, and retirement). The key to success is closely managing the laboratory equipment lifecycle, from procurement through operations and into maintenance and retirement. In this paper, we describe the fundamental success factor for modern laboratories as a comprehensive Laboratory Instrument Management (LIM) framework. Using an approach that focuses on cross-functional collaboration and innovation, you can simplify, optimize, and transform your lab, ensuring you have the most productive mix of assets that are available, reliable, and performing the right tasks. Benefits of a robust Laboratory Instrument Management (LIM) program include:

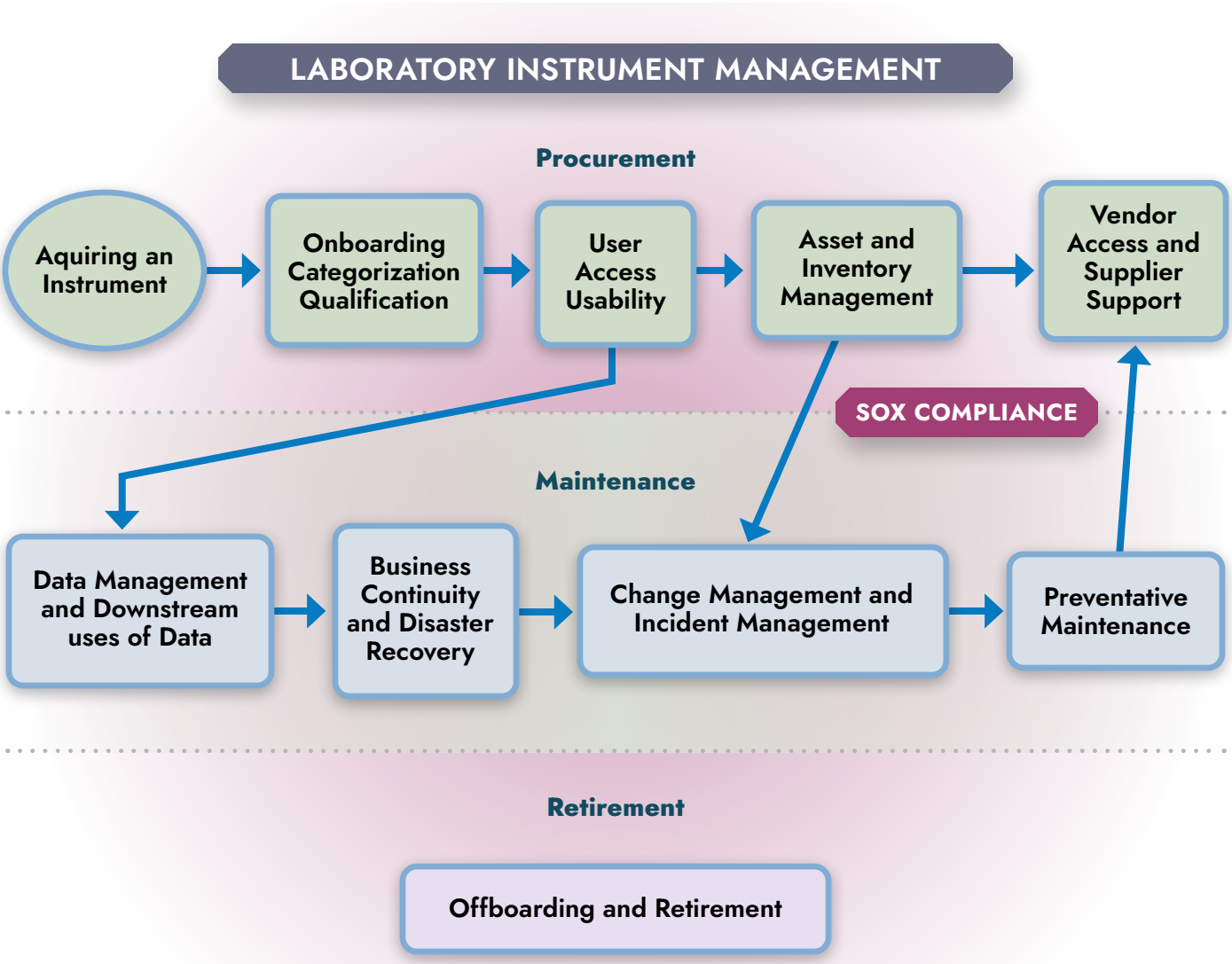
1. **Increased laboratory performance and equipment utilization**
2. **Lower repair costs and longer instrument life** (as fewer repairs are needed for a well-maintained instrument)
3. **Reduced interruption of services due to breakdowns and failures**
4. **Ability to provide accurate, timely information to Finance regarding Capital asset data for reporting purposes**
5. **Greater satisfaction for the scientists, operators and customers who rely on the data and equipment**

Stages: LIM Framework

Laboratories should have a well-organized instrument management program in proportion to the scale of the operation and according to the regulations that govern them. The program should at a high-level address procurement, maintenance, and retirement, including clear definitions of the cross-functional roles and responsibilities required. Written procedures for these processes must be documented and maintained over time, as equipment and software integrations change and new processes are embedded into the operating environment.

There are three key phases of the LIM framework: **Procurement**, **Maintenance**, and **Retirement**. Prior to the Procurement phase, there are a number of preparatory activities needed (defined as Phase 0: Preparation). Though Phase 0: Preparation is presented as an upfront activity, it is never too late to go back and align on roles, responsibilities and regulatory requirements.

FIGURE 1: LIM Framework



Phase 0: Preparation

During Stage 0, you lay the foundation for implementing an integrated LIM operation. This involves identifying both the people involved and the business processes that must be in place to support a compliant and efficient laboratory environment. The business processes must adhere to, and may be driven by, the pertinent regulatory requirements for your lab.

Define the team

The first step is to identify and document the cross-functional team who is responsible for laboratory instrument management. This likely includes representatives from Laboratory Operations, IT Engineering, Software/DevOps, Finance, Quality, EHS, Compliance, Facilities, and scientists. In addition, suppliers and vendors are often an important part of the infrastructure whose boundaries should be defined in relation to the internal team. Often, external vendors are used to perform instrument/software qualifications, maintenance, and custom validations focused on Data Integrity. With so many groups involved, individuals may not be sufficiently aware of upstream or downstream processes that impact the overall lifecycle of the equipment. Without documented roles and responsibilities, the team may be ill-prepared to handle the incoming lab instruments, resulting in confusion and delays to utilization of critical and costly equipment infrastructure.

With so many groups involved, individuals may not be sufficiently aware of upstream or downstream processes that impact the overall lifecycle of the equipment.

The team must make the time to document the nuanced duties that arise throughout the equipment lifecycle. A RACI (Responsible, Accountable, Consulted, and Informed) matrix can be helpful in establishing clear, delineated roles and defining their associated job responsibilities to empower departments to focus on and carry out their tasks while boosting their operational efficiency and eliminating confusion and redundancy. A template for the RACI matrix is provided in the Appendix.

Consider key regulatory requirements and policies

Next, you must identify key regulatory requirements that impact the lab operating environment. A list of common regulatory requirements and practices are shown in the table below. Assess the impact and define the key policies and procedures necessary to support compliance.

Regulation/Practice	Description	Impact Areas
Sarbanes-Oxley (SOX)	SOX implements reforms designed to improve financial disclosures which also impacts the security of information systems by requiring companies to create and maintain corporate record archives, including data access and retention procedures.	Laboratory instrumentation and data may be subject to SOX compliance
Analytical instrument qualification (AIQ) or Equipment qualification	Though not governed by a formal regulation, the foundation of all quality Analytical work is the qualification of the instrument. Ideally during the purchase and installation and before you use the instrument, you establish that the instrument is fit for use around the operating parameters that you test against.	Instrument and software qualifications (IQOQ, OQ ,and PQ), based on USP <1058> analytical instrument qualification (AIQ).
GxP	Ensures that regulated organizations observe specific and safe manufacturing and storage procedures that determine effective research standards for nonclinical laboratory trials and safe clinical trials involving human subjects.	Computer system validation (CSV) based on GAMP5 (risk-based approach and V model) and part/annex 11 compliance (electronic records and signatures) may be required to support GxP operations.

Regulation/Practice	Description	Impact Areas
CLIA	The Clinical Laboratory Improvement Amendments (CLIA) regulate laboratory testing and require that clinical laboratories be certified by the Center for Medicare and Medicaid Services (CMS) before they can obtain human samples for diagnostic testing.	Laboratory instrumentation and data may be subject to SOX compliance.
HIPAA	If you are managing patient lab samples and data, the information may be considered protected health information (PHI) and covered by the HIPAA.	HIPAA laboratory rules require that safeguards be implemented to verify the confidentiality, integrity and availability of lab results.

Based on the regulatory requirements, perform a gap analysis between relevant policies that are in place to support LIM and those that need to be created or refined. Note: Common policies and procedures are highlighted in subsequent phases.

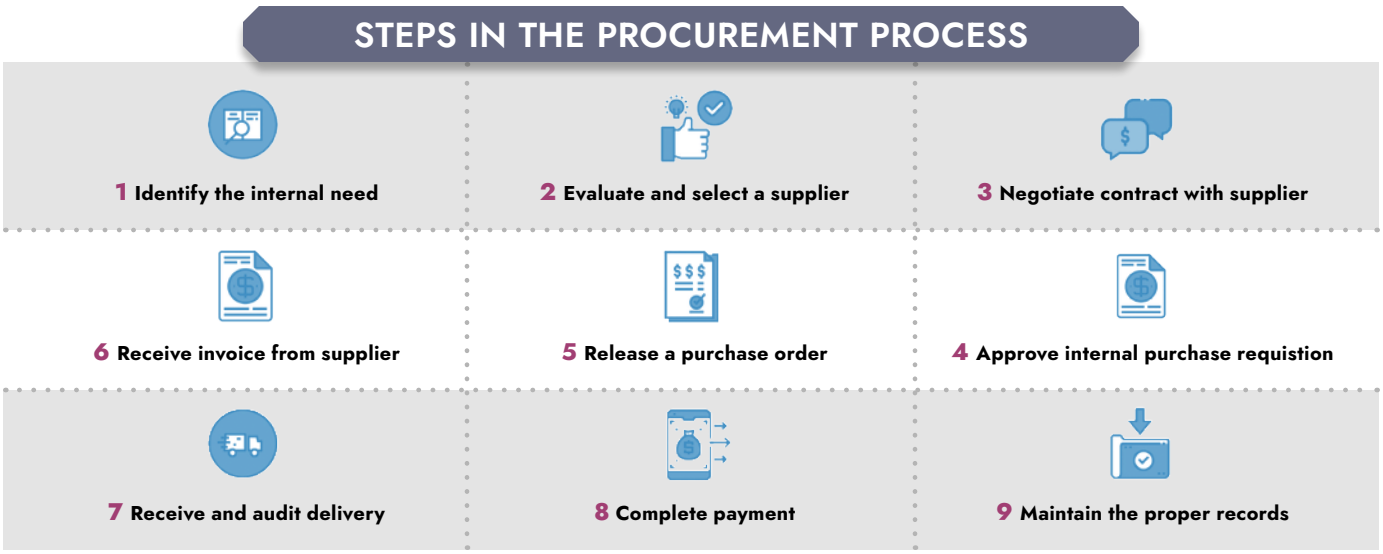
Phase 1: Procurement

Acquiring an Instrument

IT Engineering and DevOps teams should be involved early in the process to ensure the incoming equipment is compatible with (and can be easily integrated into) the existing laboratory infrastructure. Early involvement will ensure that additional resources to bridge the gap can be scoped and addressed in a timely manner before the equipment arrives at the facility. Having various stakeholders involved in the ticket approval process before the purchase is complete promotes collaborative efforts to smoothly onboard and operate equipment when they arrive.

Additionally, to minimize any mistakes and avoid additional costs, it is essential that each part of the procurement process be clearly defined and followed through with. The steps detailed below should be utilized to create a documented process flow to tailor to the laboratory's specific needs.

FIGURE 2: Procurement Process



STEP 1: Identify the internal need

This starts the procurement process flow within the organization. A department or business unit needs some instruments to operate. If multiple departments have the same need, procurement should consolidate their requirements to lower costs and increase visibility.

STEP 2: Evaluate and select a supplier

This step is all about identifying the list of potential suppliers for the required instruments. The evaluation process varies widely — it could be as simple as a quick web search to a structured RFP or RFI. The goals of this stage are straightforward — evaluate vendors based on price, quality, reputation, reliability, customer service, and any other relevant certifications. Procurement determines the best vendor after finalizing this analysis.

STEP 3: Write contracts with the selected vendor

At this point, the contracting process begins. It could again be quite straightforward, or it may require significant back-and-forth. In some cases, purchasers may choose to entirely bypass contracting; instead, they rely on a legally binding purchase order. The contracting team must look at the end-user license agreement, the payment terms, warranties, any indemnification clauses, and other legal aspects. If there are any implementation services as part of the contract, they'll want to ensure timelines, delivery schedules, the scope of work, etc. are well-understood upfront.

STEP 4: Approve an internal purchase requisition

This step essentially comes down to getting the go-ahead from the entity (department or business unit) that will finance the purchased items. They are not ordering anything at this point; they are simply getting internal approval to do so. Often, this approval involves discussing the request at the right cross-functional management level. Once this informal, but required, approval is granted, the formal process of submitting a Purchase Requisition (PR) can occur. The PR includes relevant details — purchaser and supplier info, related contracts, a list of requested items, prices, and terms — so that the department can approve or reject the purchase.

If multiple departments have the same need, procurement should consolidate their requirements to lower costs and increase visibility.

STEP 5: Legal review and release a purchase order

A legal review of the contract related to the PR then occurs, to ensure that all of the terms and conditions of any contract are acceptable. Legal review may involve rounds of negotiation with the supplier. Once legal approval has been obtained, the procurement department then creates and releases a Purchase Order (PO). This is where the actual purchase occurs. They will send the PO to the chosen supplier. It contains a PO number, detailed terms & conditions, delivery dates, etc.

STEP 6: Receive an invoice

The supplier will send an invoice with a full list of the items that were ordered, along with their prices and the due dates for the payments.

STEP 7: Receive and audit delivery

The supplier will provide the ordered goods and services in accordance with the terms of the contract. Typically, the receiving organization has a limited amount of time to audit the delivery and notify the supplier of any discrepancies such as missing items or quality issues.

STEP 8: Complete payment

Once the order has been verified, the Finance department will send a payment according to the terms specified in the contract.

STEP 9: Maintain proper records

It is a good business practice to store all documents from the original requisition through invoices in a single centralized location. It helps navigate any future audit. Analysis of this data helps track and optimize spending management.

New instrument purchases should include factors like remote monitoring, cloud-based software, and the ability to integrate with current infrastructure. Such factors enable scientists to adapt to shifting research focuses, stay updated on the progress of projects even when they aren't physically in the lab, and make it easier to share data and findings with other team members. During the search for new lab equipment it is essential to keep these factors in mind and consider both the short-term and potential long-term requirements of the instrument to make certain that you gain the most out of your investment

Categorization and Qualification

To comply with internal standards or industry regulations, instruments need to be validated periodically or with certain events. Equipment might also require qualification when purchased, when moved to a different location, after undergoing maintenance, or when a new method is implemented. Manufacturers' instruction will often provide recommended validation frequencies and processes, but it is the responsibility of the individual lab to validate to demonstrate suitability for the intended use.

It is recommended that organizations implement a standardized qualification process and develop a protocol template that can be used across all types of equipment to help speed up the qualification process. Having a well-defined protocol helps to ensure that all steps in the process are carried out consistently. This will make it easier and faster to validate instruments, as well as provide a reference document for future validations.

It is recommended that organizations implement a standardized qualification process and develop a protocol template that can be used across all types of equipment to help speed up the qualification process.

Instruments should be categorized broadly to facilitate standardization of the onboarding process by allowing execution of a standard set of processes against them. For example, a standard design for change management for a particular category of equipment can eliminate the guessing game of who needs to be involved in making and approving key decisions.

The wide range of activities (Analytical, Foundry, Codebase, Deployment, Testing) taking place in laboratories means that no single classification scheme can address the requirements of all laboratories. It is for individual laboratories to develop optimized schemes to meet their specific requirements. The recommended categories are

1. **Program Critical Equipment** is all equipment that is used to make measurements that are either reported or incorporated into results being reported to the customer. This should include computers that control or collect and process data from equipment that make measurements that are either reported or incorporated into results reported to the customer.
2. **Program Non-Critical Equipment** is all equipment that, although not used to make measurements that are either reported or incorporated into results that are reported to the customer, is used to ensure that such measurements or results are of high quality.
3. **Non-Critical Equipment** is all equipment not used to make measurements or produce results that are reported to the customer, nor used to assure the quality of the results that are reported to the customer.

Classifying instrumentation according to its complexity is yet another way to ensure that instrumentation of similar complexity is qualified to a level that is consummate with risks associated with the instrument. The scheme presented here is particularly useful in laboratories carrying out physical testing or calibrations.

- **Category 1** includes standard equipment with no measurement capability that is used to establish a reference standard. For instance, some standard weights are used to adjust balances and fixed-point temperature cells, such as the water triple point cell used to calibrate thermometers.
- **Category 2** includes standard equipment and instruments that are capable of measurement but are incapable of adjustment. Examples of equipment in this capacity include platinum resistance thermometers and float densitometers.

- **Category 3** includes commercial off-the-shelf equipment that is either:
  - Firmware controlled
  - Managed by software with limited functionality and internal to equipment
  - Capable of independent adjustment to conform to specifications
  - Does not include a computer with a full operating system that controls the system. Examples of equipment in this category include a precision thermometry bridge, pH meter, and laboratory balance.
- **Category 4** includes commercial off-the-shelf equipment with a computer and a full operating system driving the equipment, but which have no capacity for configuration, apart from that required to enable users to operate the equipment and to assign user privileges. Examples of equipment in this category include UV and FTIR spectrophotometers, and gas and high-performance liquid chromatography.
- **Category 5** includes commercial off-the-shelf computer-driven equipment with the capacity for configuration, with single or multiple terminals capable of controlling and/or monitoring and/or processing data from multiple sensors. Examples include a networked environment monitoring system or a networked instrument control, data capture, and processing system. It may also be necessary to clarify whether adding a new instrument to an existing network is a category 5, or some other category determined by the characteristics of the instrument if it was not connected to the network. There are several potential solutions to this type of scenario, probably the most universally applicable is to apply change control procedures and/or establish a process addressing the addition of new instruments and sensors to the respective network when it is first installed.
- **Category 6** includes all bespoke equipment.
- **Category 7** includes Workcells, which are collections of COTS (commercial off-the-shelf) instruments engineered to work as a single unit around a transport device, like a robotic arm.
- **Category 8** includes a system of Workcells which is a collection of Workcells.

All equipment with associated software should be allocated a software category according to the following criteria:

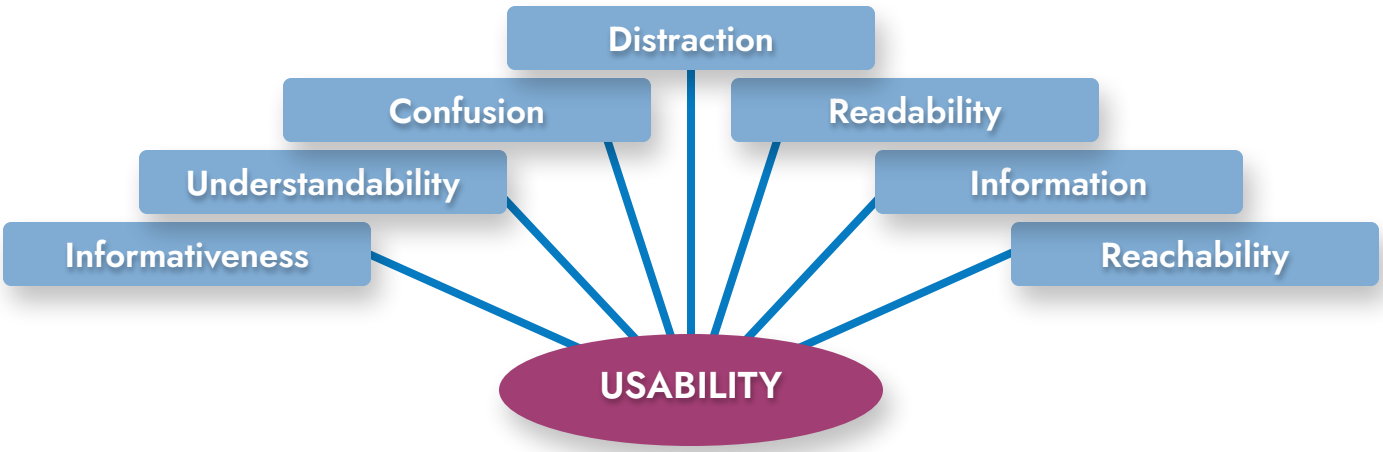
- **Category 1 Firmware:** This is software that is embedded into a piece of laboratory equipment (e.g., laboratory balances, pH meters or digital thermometers.
- **Category 2 Infrastructure Software:** This includes Operating systems, databases, and programming languages.
- **Category 3 Non – Configured Software:** This is software that can be installed and is capable of operation without modification. Included in this is the software that controls much of the analytical equipment used in the laboratory, such as spectrophotometers and chromatographs.
- **Category 4 Configured Software:** This is software that can be configured by the user to optimize its performance to meet the user's requirements. Included in this is software that controls networked equipment, and data collection and monitoring systems. Also included in this category are configured Excel spreadsheets not containing macros.
- **Category 5 Middleware:** This includes middleware, office software, statistical programming tools, spreadsheet packages, network monitoring software, anti-virus, backup, help desk, IT configuration management tools, and other network software.
- **Category 6 Custom Software:** This is software that has been developed and written for a specific organization and purpose. This includes applications that contain a configuration or scripting language which allows the user to modify a program's functions. This includes macros for Microsoft Office applications.

Instrument Usability

Usability refers to the ease with which participants can administer and interpret an instrument. The ISO (9241 ergonomics of human-computer interaction) defines five dimensions of usability: effectiveness, efficiency, level of engagement, error tolerance, and ease of learning.

Instrument usability should be prioritized in the procurement process. It is recommended that the following factors be considered before procuring an instrument:

FIGURE 3: Factors in Procurement



1. **Informativeness:** Information about the instrument use should be available and accessible
2. **Understandability:** Users should have a clear understanding of what the instrument does.
3. **Confusion:** There should be little possibility for confusion about which instrument to use and how to use the instrument.
4. **Distraction:** The instrument should be reliable, so it does not distract from the goal of its use.
5. **Readability:** The data produced by the instrument should be easily readable or readily available in human-readable form
6. **Information Density:** How much training and specific background knowledge is required to operate the instrument?
7. **Reachability:** How difficult it is for users to locate desired content within the web interface, taking into consideration temporal and spatial distance from the initial window viewport?

User Access

The development of an access management procedure is an important facet of onboarding a new instrument. It is essential for each user to have an individual account with a unique username and password; both entries are controlled by the software system policy requirements and local laboratory requirements. Each user might have a certain matrix of rights that allows the performance of accountable tasks and no more. The privileges may be defined by:

- **Training Level:** before assigning any access level the training must be finished first
- **Assignment Tasks:** each user is responsible for the appropriate use of his/her privileges.

A typical User Access flow might look like this:

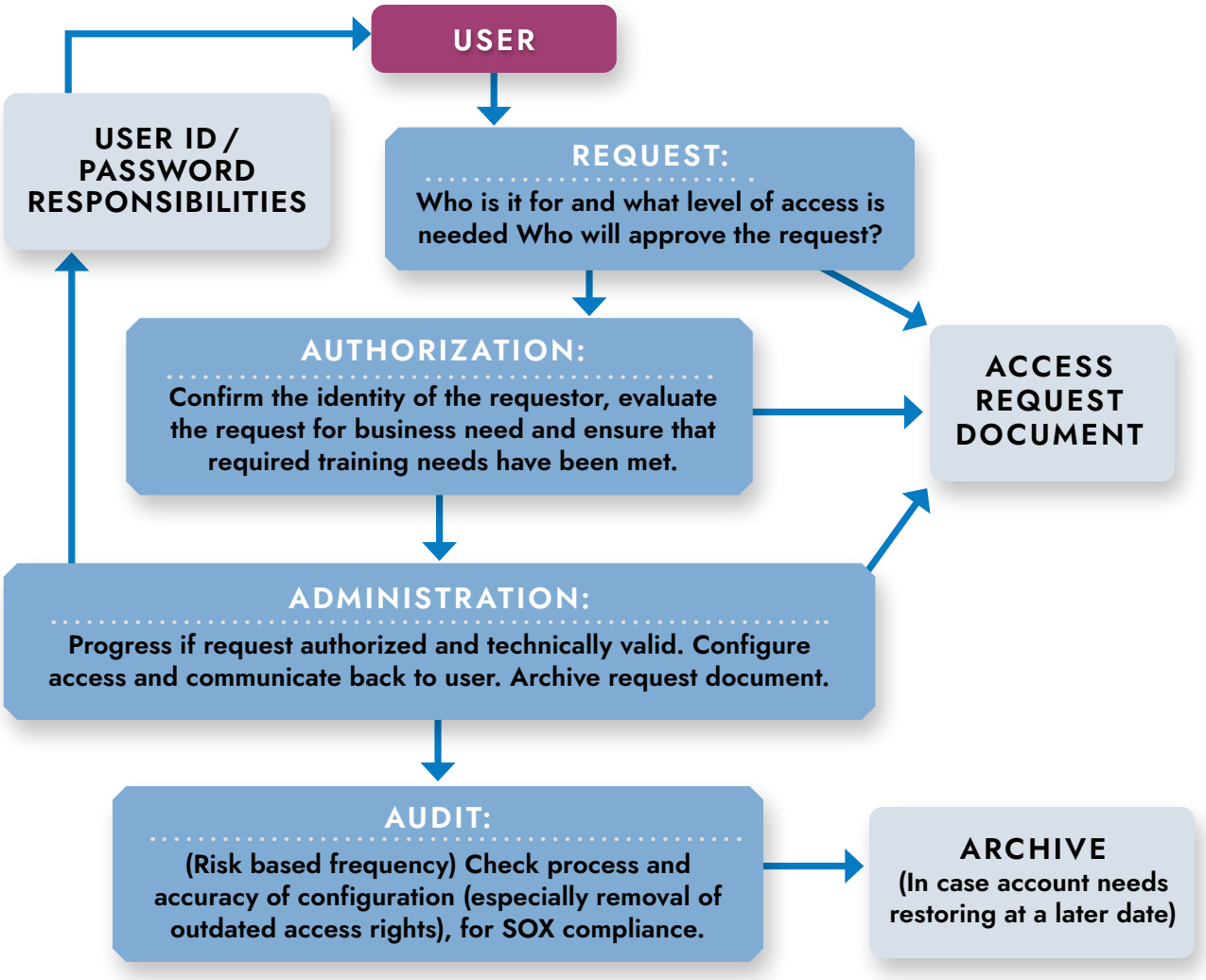


FIGURE 4: User Access Flow

Asset and Inventory Management

In order to optimize and inform instrument procurement decisions, it is important to have a solid assent management system in place for your laboratory. An effective asset management system will provide the following:

- **Real-time analytics** for accurate capital portfolio decisions
- **Performance analytics** to identify potential improvements.
- **Real-time snapshot** a view of asset health at any point in time.
- **Complete and up-to-date** information repository to support risk-based decisions relative to maintenance, capacity planning, instrument utilization, and execution
- **An updated summary** of safety-critical and production-critical instruments as well as their health statuses
- **Asset tracking and traceability** to meet environmental, health, and safety requirements

Vendor Access Management

As part of the instrument procurement process, it is recommended that organizations secure their data and identities from accidental leaks or malicious threats by implementing a system for vendor access management. Some of the main steps of this process include the following:

- **Assess Risk During Onboarding:** Tailor invitation processes, creation policies, and end date.
- **Ensure Governance with Sponsors** Assign sponsors and initiate access reviews to prevent orphaned account.
- **Protect Your Data** Block external file-sharing and require authorization for third-party data release.
- **Implement Least Privilege** Use just-in-time provisioning to provide no standing privileges access.

Supplier Management

Supplier management is a crucial aspect of any successful business, as it ensures that you are receiving the finest products and services from your suppliers at the best possible prices. Taking the time to form strong connections with your suppliers and manage their performance effectively allows you to keep your business running efficiently and avoid any potential obstacles. Key activities of supplier management include:

1. **Evaluating and selecting suppliers**
2. **Developing and maintaining supplier relationships**
3. **Negotiating contracts and pricing with suppliers**
4. **Managing supplier performance**
5. **Resolving issues with suppliers**

Other significant factors that are currently increasing the need for supplier management:

- **Increasing operational and geographical scale** that results in increasing need for local as well as global suppliers
- **The increasing complexity** of supply chains which leads to an increasing depth of the organization's supplier base
- **Augmenting risks in a supply chain** which can make organizations more likely to experience performance failure if their involved suppliers are not properly managed and evaluated
- **Managing supplier data** that gives organizations the opportunity to streamline vital supplier data in order to provide meaningful insights for the improvement of supplier management
- **Establishing long-term supplier relationships** that will enable suppliers and organizations to meaningfully collaborate and create synergies for maximized performance in the long-run
- **Leveraging supplier relationships** in times of reorganizations or external distress to ensure business performance doesn't fluctuate
- **An increasing competition** which means that organizations must identify and work to improve certain aspects of their business processes in order to gain a competitive advantage
- **Matching industrial and quality standards** of supplier performance so that organizations can achieve best-in-class performance

Best practices for supplier management includes the following key factors to effectively manage supplier support:

- Defining and communicating clear expectations to suppliers. This involves setting expectations for quality, delivery times, and cost.
- Maintaining open communication with suppliers. This ensures that both parties are always in accordance and are able to cooperate to address any issues that may arise.
- Building long-term relationships with suppliers. A more trusting and collaborative relationship can lead to higher-quality products and services.
- Continuously monitoring supplier performance. This helps to identify and address any potential problems before they become major problems.
- Establishing systems and processes to manage supplier contracts. This ensures that all contractual agreements are being properly followed and that both parties involved are being held accountable for their commitments.

Phase 2: Maintenance

Maintenance Plan

An overall maintenance plan be created, documented, and implemented for laboratory instruments that will include preventive maintenance procedures as well as provision for inventory, troubleshooting, and repair of equipment. Some of the first steps involved in the implementation of an equipment maintenance program include the following:

- Assign responsibility for providing oversight.
- Form written policies and procedures for equipment maintenance, including routine maintenance plans for all equipment. The plan should specify the frequency with which all maintenance tasks must be carried out.
- Create the format for records, write logs and forms, and put in place the necessary processes to maintain records.
- Train staff on the use and maintenance of the equipment and assure that all staff understands their specific responsibilities.

It is recommended to attach a label to the instrument stating when the next maintenance or service needs to be performed.

An SOP should be created that directs technicians to routinely calibrate Lab equipment for optimal performance and utilization. This is another area where clearly defined roles and responsibilities for equipment maintenance will enable departments to handle overlapping functions. It is essential that lab managers communicate regularly with these departments and ask for assistance when needed. Lab members must openly communicate with other departments (e.g., facilities management, EHS) as soon as equipment issues occur (e.g., equipment malfunction, bio-hazardous material spill).

Wherever applicable, labs must run periodic QA/QC checks on instruments and control charts of the results. Additionally, maintaining a predetermined calibration schedule and documenting these results keep the lab in compliance and always audit-ready. It is also necessary to put tags on equipment indicating whether it is in or out of service and to make sure to have backup equipment in case something malfunctions.

Preventive maintenance involves systematic and routine cleaning, adjustment, and replacement of equipment parts. Manufacturers usually recommend certain equipment maintenance tasks that should be carried out daily, weekly, monthly, or yearly. Following these recommendations will ensure that both the efficiency and the lifespan of the equipment are being maximized. This will also help to prevent:

- Inaccurate test results due to equipment failure
- Delays in reporting results
- Lower productivity
- Large repair costs

Maintaining a predetermined calibration schedule and documenting these results keep the lab in compliance and always audit-ready.

Change Management

When dealing with a laboratory that houses a wide range of equipment with various degrees of complexity and sophistication, it is important to take a risk-based approach to change management to engage the right stakeholders. To achieve this, implementing a risk assessment component to the change management process may be necessary.

It is recommended that IT Engineering, DevOps, and software teams be involved as applicable at the approval stage of the change ticket to either engage or inform the stakeholders on what changes are incoming and what is expected of them depending on which category of equipment is going through the change.

Incident Management

A laboratory event that takes place for two main reasons, either analyst error or instrument error, is known as a laboratory incident.

Types of analyst and instrument errors include (but are not limited to):

1. **Incorrect standard preparation**
2. **Error in mobile phase preparation or improper mixing of mobile phase**
3. **Improper baseline observed, running the sample set and improper integration observed, before the release of product/material**
4. **Incorrect HPLC/GC set up and run**
5. **Uncalibrated instrument used**
6. **Column leak, poor plate count, poor resolution**
7. **Connectivity failure between software and instrument**
8. **System failure during the analysis as a result of column high pressure/instrument**
9. **Calibration failure during quarterly/daily calibration procedure**

A documented incident management process for Lab Instruments should be implemented. A typical Incident management workflow looks like this:

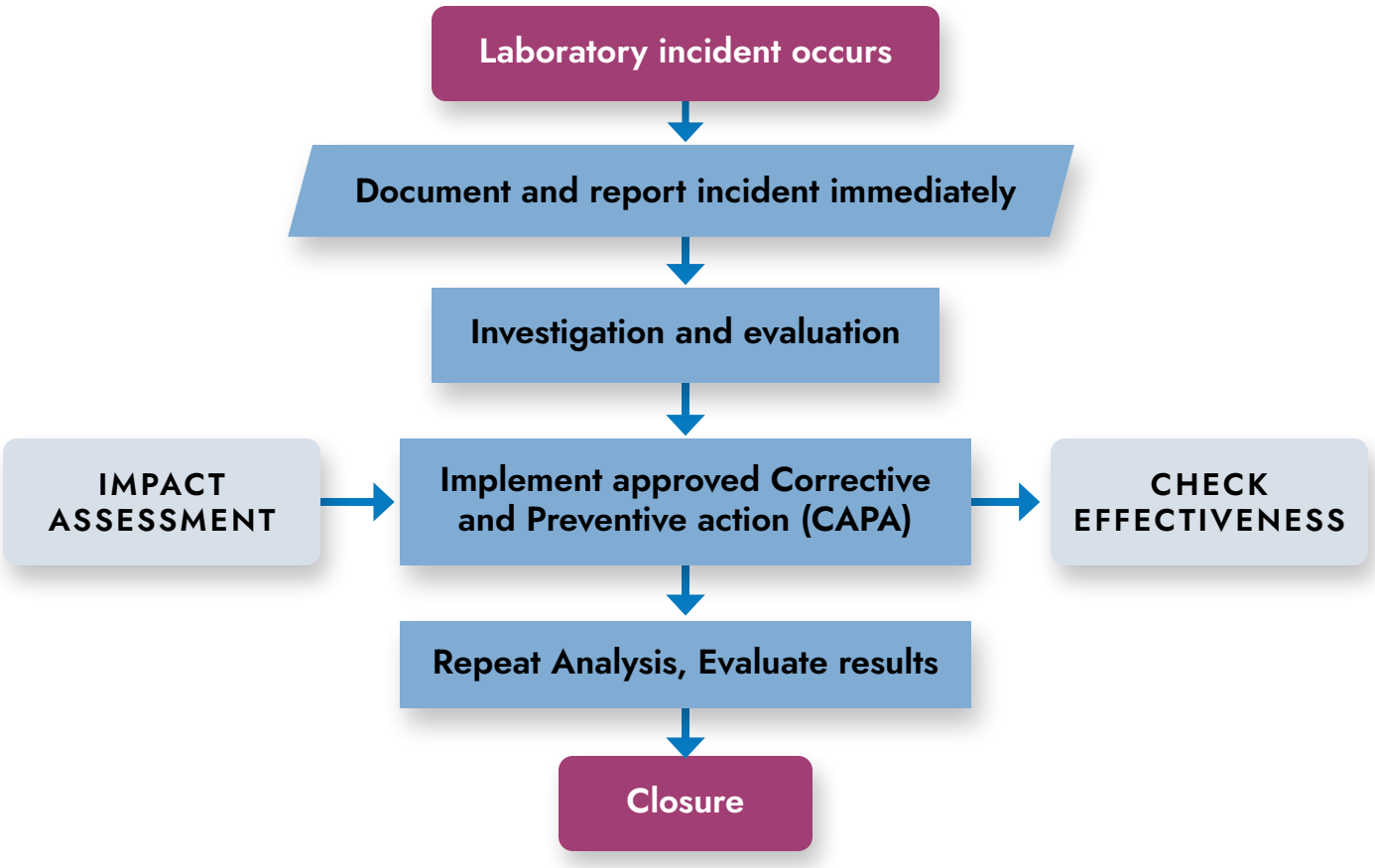


FIGURE 5: Documented Instrument Management

Business Continuity and Disaster Recovery

Business continuity (BC) and disaster recovery (DR) are closely related practices that allow an organization to continue operating after an adverse event occurs. When any organization faces an array of threats, from natural disasters to the latest round of cyber attacks, business continuity and disaster recovery (BCDR) is central to data recovery and resiliency.

Motivations for developing a data BCDR strategy may include protecting the availability and resiliency of services to customers, protecting revenue streams, satisfying the regulatory and compliance environment, etc. Data Protection, Backup, and Recovery processes should be governed by a Business Continuity and Disaster Recovery Policy or Plan.

A Business Continuity Plan (BCP) is a comprehensive set of plans to allow each business unit to resume business processes. Understanding the needs of employees during an unexpected incident is key. A good BCP is only possible with a good Disaster Recovery Plan.

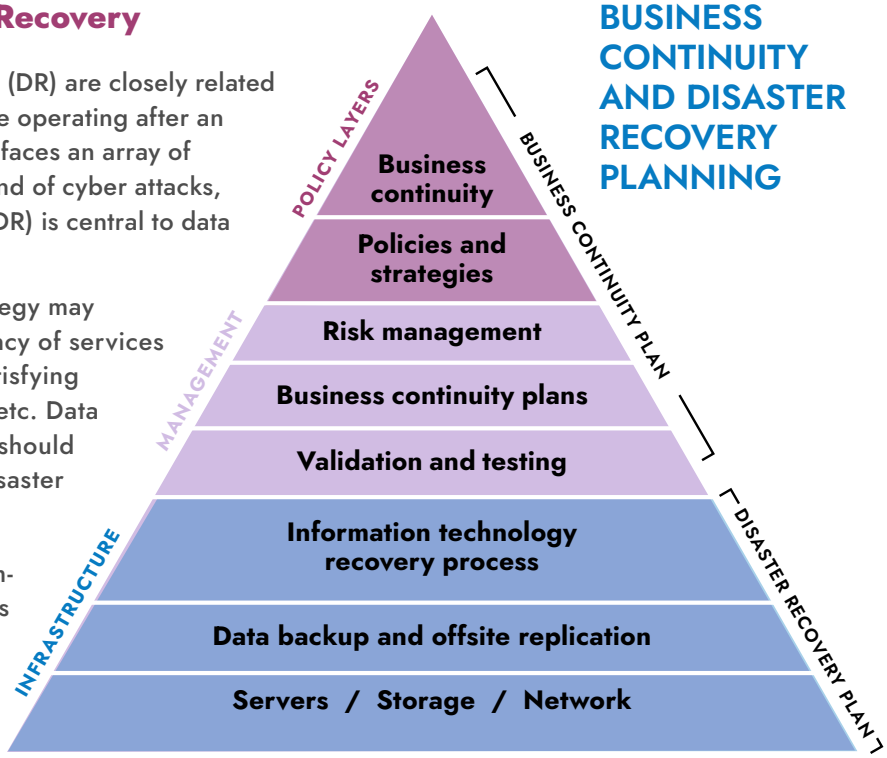


FIGURE 6: Business Continuity and Disaster Recovery Planning

A Disaster Recovery Plan (DRP) is a set of procedures and supporting documentation that enables an organization to restore its core IT services, such as applications and infrastructure, as part of an overarching business continuity plan.

Phase 3: Retirement

The decommissioning of an instrument at Ginkgo begins with creating a ticket with the Digital Tech Help Center Portal. The workflows then diverge in their own subprocesses depending on the type of instrument being offboarded, namely,

1. **Inactivation** of an instrument that is configured for Datastore
2. **Decommissioning** of an instrument that is NOT configured for Datastore
3. **Preparing** an instrument-connected lab computer for replacement

It is very important to have a policy and procedures for retiring older laboratory equipment. This generally occurs when the instrument is clearly not functioning and unable to be repaired, or when it is outmoded and needs to be replaced. Once it has been determined that a piece of equipment is no longer useful, it must be disposed of appropriately. Laboratories often neglect this final step, causing old equipment to accumulate, take up valuable space and oftentimes create a hazard. In order to properly dispose of equipment, salvage any usable parts, especially if the equipment is being replaced with similar equipment. Consider any potential biohazards, and carefully follow all safety disposal procedures.

A policy should also be in place for retiring/replacing Instrument-connected lab computers. Note that an instrument can be inactivated and its associated PC replaced if it is the only instrument that is connected to the PC. If a PC is connected to more than one instrument, however, all instruments that are connected to it need to be inactivated first before the PC can be replaced.

Conclusion

In today's highly competitive business environment, a robust Laboratory Instrument Management (LIM) program is essential for modern, automated laboratories. Laboratories should have a well-organized instrument management program in proportion to the scale of the operation and according to the regulations that govern them. Such a program will serve to reduce overall costs, service interruptions, and compliance risk, while improving both performance and productivity.

This paper has attempted to shed light on some key issues and recommended ways to document and streamline existing processes and implement new processes where none exist. The main aim is to invite the stakeholders to build upon these recommendations and guide the development of optimized future state work processes and selected process improvements

Laboratories should have a well-organized instrument management program in proportion to the scale of the operation and according to the regulations that govern them.

Key Recommendation

Create an independent Center of Excellence (CoE) for Lab Instrument Management that researches the latest equipment for compatibility, technology, ability to automate, and other key features and advises scientists on what to acquire instead of the scientists purchasing them ad hoc and the IT team having to reverse engineer them to integrate with Ginkgo infrastructure. The CoE must also have a member that supports the writing of Standard Operation Procedures (SOP) and Written Instructions (WI) for the key process of the Instrument Management framework. The CoE will also be responsible for continuous improvement of these SOPs and WI as they are being implemented in the day-to-day. The CoE must have a training wing that establishes training requirements for users who gain access to key instruments and maintain their training records. This independent entity will have to ensure the smooth transition of the equipment from one team to another throughout its lifecycle.

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Appendix

RACI Matrix

A RACI matrix is a tool that can be employed to identify various activities and stakeholders that need to be involved in collaborative efforts. It stands for Responsible, Accountable, Contributes/Consulted, and Informed. It is popularly used in project management but can be easily adopted and adapted to any area that manages a diverse group of actors and stakeholders.

A typical RACI matrix might look like this:

DELIVERABLE	STAKEHOLDER 1	STAKEHOLDER 2	STAKEHOLDER 3	STAKEHOLDER 4
Capital Acquisition Request (CAR)	R	A	C	I
User Access	I	C	N/A	R

Decision Making

Too much of what drains lab staff energy is really urgency, not importance.

Bain's RAPID tool, which loosely stands for Input, Recommend, Agree, Decide, Perform is another tool that can align and fast-rack the decision-making process involving multiple stakeholders with varying and competing priorities.

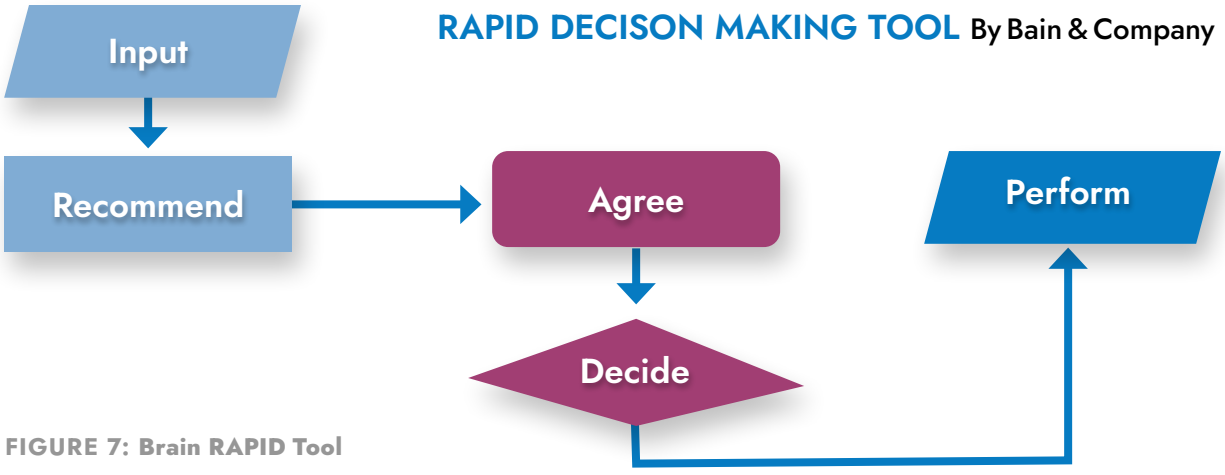

FIGURE 7: Brain RAPID Tool

The Eisenhower matrix can be another useful tool to distinguish between importance and urgency. It is a 2x2 grid of high and low importance and urgency. Complete high importance and high urgency tasks first. Schedule the high importance/low urgency work. Delegate the low importance/high urgency tasks, and delete the low importance/low urgency clutter around the lab. Ensure that the most important things are completed and that the lab is not losing valuable time chasing urgency.

THE EISENHOWER DECISION MATRIX

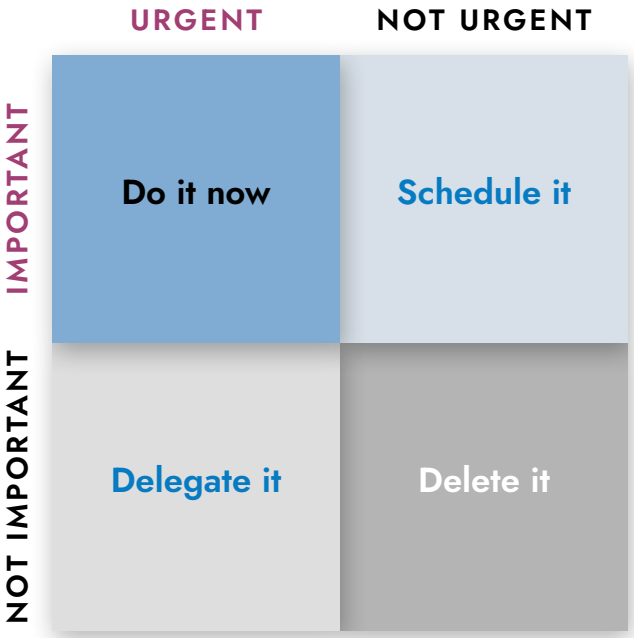

FIGURE 8: Eisenhower Decision Matrix

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