

GOOD PRACTICE GUIDE:

Asset Management

Data Integration

Impact on
Risk Management

Identification of Assets

Organizational Plans
and Objectives

Alignment with
Business Drivers

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GOOD PRACTICE GUIDE:

Asset Management

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Preface

The pharmaceutical industry is a heavily regulated, asset-intensive industry with structured quality management systems and supporting business processes. Often it is difficult to determine how to best integrate the business processes and quality management system so that they work together to support the strategic objectives of the organization.

The ISO 55000 series of international standards for asset management (ISO 55000 [1], ISO 55001 [2], and ISO 55002 [3]) was first published in 2014 by the International Organization for Standardization (ISO) [4] and introduced the fundamentals of asset management and the supporting asset management system. These fundamentals, when integrated into the broader governance and risk framework of a pharmaceutical organization, can contribute tangible benefits and leverage opportunities. An effective asset management system translates the organization's objectives into asset-related decisions, plans, and activities using a risk-based approach.

Effective control and governance of assets, physical and non-physical, by organizations is essential to realizing value through managing risk and opportunity in order to achieve the desired balance of cost, risk, and performance. The regulatory and legislative environment in which the pharmaceutical industry operates, with a focus on GMP, is increasingly challenging. The inherent risks that many assets present are constantly evolving.

The asset management system helps pharmaceutical operations to align the needs of stakeholders to the business. Whether it is the patients who need the drug products, the manufacturers who produce it, the regulators who ensure the products are safe, or the investors who fund the operations, all stakeholders should have confidence that the operation will support their needs.

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Table of Contents

1	Introduction	7
1.1	Background	9
1.2	Purpose and Objectives	9
1.3	Scope	9
1.4	Benefits	10
1.5	Key Concepts/Terms	12
2	Asset Management – Determination of Organizational Plans and Objectives	15
2.1	Introduction	15
2.2	Understanding the Organization and Its Objectives	15
2.3	Business Drivers	17
2.4	Understanding the Stakeholders	18
2.5	Setting the Scope of the Asset Management System	19
2.6	Organizational Context	20
2.7	Leadership, Behavior, and Change	25
3	Asset Management System – Setting Policy and Strategy	27
3.1	Introduction	27
3.2	Asset Strategy	28
3.3	Asset Management Policy	28
3.4	Strategic Asset Management Objectives	31
3.5	Strategic Asset Management Plan (Asset Management Strategy)	34
3.6	Strategic Financial Planning	36
3.7	Determination of Strategic Risk and Opportunities	39
3.8	Performance Evaluation	42
4	Asset Management Plans – at the Operational Level	49
4.1	Introduction	49
4.2	Alignment with Organization Strategy	50
4.3	Development of the Operations Asset Management Plan	51
4.4	Determination of Resources	58
4.5	Asset Operation	61
5	Asset Management Maturity – Journey to Operational Excellence	63
5.1	Introduction	63
5.2	Asset Management Maturity Level – Awareness	65
5.3	Asset Management Maturity Level – Developing	67
5.4	Asset Management Maturity Level – Implementing	69
5.5	Asset Management Maturity Level – Optimizing	71
5.6	Performance Evaluation and Improvement	73

6 Appendix 1 – Asset Management Policy: Additional Information..... 83

7 Appendix 2 – Strategic Asset Management Plan (SAMP): Additional Information..... 91

8 Appendix 3 – Asset Management Plan: Additional Information..... 99

9 Appendix 4 – References 107

10 Appendix 5 – Glossary 109

10.1 Acronyms and Abbreviations 109

10.2 Definitions 111

1 Introduction

1.1 Background

The assets of pharmaceutical, biotechnology, and medical device companies represent a substantial investment. Globalization, shifting labor markets, and sustainability concerns provide increased pressure to improve performance.

Decisions to invest in assets, which can take years to deliver, need a good deal of foresight and are rarely taken overnight or impulsively. The decision needs to be informed by good data. An effective asset management system has access to this critical decision data to proactively help with the decision-making process. Too often in the industry, a proposal is made where an asset could be the answer and time is inefficiently spent in mobilizing a team to prove the hypothesis is correct. An asset management system provides quick access to the data showing whether the right asset is required.

As assets age, technology evolves, industry trends change, and expectations rise, it often becomes more difficult and more expensive to maintain assets to meet changing performance goals and to efficiently meet the economic and regulatory requirements for which they were designed and constructed. Given the competitive global economic climate of the pharmaceutical industry, most organizations are not expected to significantly increase their operating budgets. This situation, if left unchecked, can result in a loss of availability and operational capability of assets over time.

Globalization, shifting labor markets, and sustainability requirements have upset the profitability equation. These factors require organizations to start looking for areas to recalibrate quickly in order to stay competitive. In the face of a changing profitability equation, leadership continues to ask the following:

- What part of the cost equation can be reduced or eliminated? How can spending be decreased and still make the numbers?
- How can the risks that the assets come with be reduced, particularly for the large assets? Examples of these risks include not having the assets work when needed to or finding that they are non-compliant at inspection.
- How can a bigger return on capital be gained? How can the organization be more agile with deploying and maintaining assets?

Unfortunately, the levers to change the equation are often inflexible. Maintenance is often constrained by the work order process and dependent on parts availability. Production yields cannot be changed quickly and easily. Procurement can only administer so much control over material prices. Manufacturing processes or asset reliability can be difficult to change quickly. In global organizations, performance may differ from region to region as asset deployment practices are different geographically. In the end, the equation often comes down to the sheer physicality of asset management, i.e., the heavy things that are hard to change such as supplies to account for, products to manufacture; plants to manage, and equipment to maintain.

Asset management has traditionally been treated as a function instead of a management system. It was once seen as a limited set of tactics for justifying capital expenditure for replacing existing aged assets with new assets, independent of an organization's business strategy and other functional areas.

In January 2014, the ISO [4] released a set of standards (ISO 55000 [1], ISO 55001 [2], and ISO 55002 [3]) that *"relate to a management system for asset management, which is referred to as an 'asset management system' throughout the three standards."* [1]

ISO 55000 [1] provides an overall framework for establishing an organization's asset management system that integrates the following factors:

- *“the nature and purpose of the organization;*
- *its operating context;*
- *its financial constraints and regulatory requirements;*
- *the needs and expectations of the organization and its stakeholders.”*

ISO 55000 [1] also states the following:

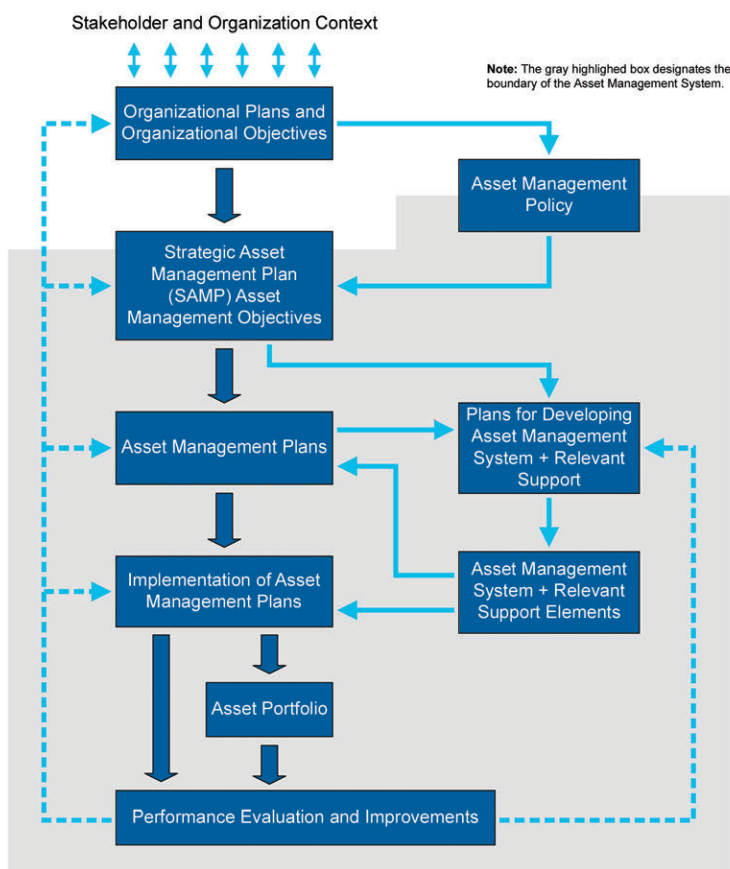
“An asset management system impacts the whole organization, including its stakeholders and external service providers, and can use, link or integrate many of the organization's activities and functions that would otherwise be managed or operated in isolation. The process of establishing an asset management system requires a thorough understanding of each of its elements and the policies, plans and procedures that integrate them.”

ISO 55000 [1] is not specific to a particular industry; it provides a structured approach for any asset-intensive organization to help establish a framework for developing, managing, and sustaining an asset management system.

Figure 1.1 illustrates the relationship between key elements of an asset management policy.

Figure 1.1: Relationship Between Key Elements of an Asset Management System (from ISO 55000 [1])

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1.2 Purpose and Objectives

This Guide provides an overview of the discipline of asset management based on the ISO 55000 series of standards [1, 2, 3]. This Guide demonstrates how ISO 55000 [1] and other global best practices in asset management can be adapted for use by the pharmaceutical, biotechnology, and medical device industries. The intention of this Guide is to help organizations to establish an asset management system that enables them to realize increased value from their assets, both physical and non-physical.

The goals of this Guide include the following:

- Identify best practices in strategic asset management as outlined in ISO 55000 [1]
- Break down traditional organizational silos (i.e., isolated entities) by identifying how all departments participate in and contribute to an integrated asset management system
- Enable organizations to compare their asset management approach to best practices
- Provide recommendations, examples, and resources to help organizations in the development or improvement of their asset management system

1.3 Scope

The scope of asset management as it applies to this Guide is determined by the organization. This Guide can be applied to entire organizations, specific plants or business units, critical manufacturing lines, or specific equipment. It can also cover specific types of assets, both physical and non-physical.

This Guide references existing internationally recognized standards and guidance documents, including ISO 55000 [1], Global Forum on Maintenance and Asset Management (GFMAM) [5] The Asset Landscape Second Edition (March 2014) [6], and The Institute of Asset Management (IAM) [7] Asset Management – an anatomy (December 2015) [8].

This Guide is not intended to duplicate content in other ISPE Good Practice Guides or internationally recognized standards and guidance documents. This Guide references other Good Practice Guides as appropriate.

In the past, disciplines have become very narrow in focus. While specific functions have been successful in meeting their own needs, the overall goals of the organization may not necessarily have been met. For example, the responsibility of one function may be to reduce costs on a project, but by doing so lifecycle costs have increased.

Asset management is a process of coordinating all activities of the organization to ensure it realizes maximum value from the assets. This realization of value normally involves balancing costs, risks, opportunities, and performance benefits over the life of the assets or process. By having all stakeholders involved, risk is reduced, and quality and compliance are built into the process while optimizing total cost of ownership. This will lower the likelihood of supply chain failure leading to drug shortages caused by equipment failure.

In general terms, the lifecycle of the asset or process begins when the organization identifies a new therapy or device to meet the needs of a patient. This would progress through planning for Research and Development (R&D), production, acquisition and commissioning of plant and equipment, operation of the equipment in daily operation, and eventually decommissioning.

1.4 Benefits

ISO 55000 [1] states:

“An asset management system provides a structured approach for the development, coordination and control of activities undertaken on assets by the organization over different life cycle stages, and for aligning these activities with its organizational objectives.”

The pharmaceutical industry faces many challenges, for example:

- Drug shortage avoidance
- Embracing rapidly evolving technology
- Rising customer expectations
- Continuous improvement of operating and R&D cost controls; competitive pricing
- Global shift toward international harmonization (ICH [9]); regulatory compliance
- Changing political, economic, scientific, and social trends
- Shift toward more collaborative business models
- New supply chain models
- New R&D and information technologies
- Requirement to effectively handle ever-growing volumes of data
- Biosimilars entering the market

Pharmaceutical organizations, by establishing an asset management system based on ISO 55000 [1], will be better equipped to face industry challenges by ensuring informed decision-making based on value creation through effective asset management while balancing performance, costs, and risks. An integrated risk-based decision-making process enables organizations to more effectively address asset and financial risks while balancing long-term financial plans with short-term financial needs and medium-term activity plans.

Organizations do not need to fully implement an asset management system based on ISO 55000 [1] before they start realizing the associated benefits in such areas as improved cross-functional communications, integration and alignment within the organization, improved cost controls based on lifecycle considerations, process improvements, value-based asset decision-making, strategic planning, and long-term sustainability.

The following benefits of an asset management system are highlighted in ISO 55000 [1]:

- Implementing an asset management system can create “...benefits, or quick wins, in areas such as risk reduction, [cost avoidance,] opportunity identification or process improvement...”
- “The process of creating an asset management system brings new perspectives to the organization and new ideas on value creation from the use of assets. These new perspectives can also stimulate improvements in other organizational functions, such as purchasing, finance, human resources and information technology.”

- *“The creation of an asset management system is usually cross-functional and based on life cycle considerations; this can provide a focal point for addressing the issues of functional integration of the organization and life cycle planning.”*
- *“Top management benefits from new insights and cross functional integration.”*
- *“An asset management system provides an ideal framework for the identification, understanding and integration of the many technical standards, codes, guidelines and best practices that affect the organization’s assets, and support the implementation of asset management.”*
- *“An asset management system supports energy management, environmental management and other activities related to sustainability.”*
- *“Financial functions benefit from improved data and linkages.”*
- *“An asset management system touches many parts of the organization:*
 - *the organization’s human resources function may work with its asset management system on the development of competency models, training programs and processes for coaching and mentoring; these developments benefit both functions;...*
 - *communicating with employees, suppliers and contracted service providers about the asset management system can result in improvements in the quality of asset information; it will also increase awareness amongst individuals, inside and outside of the organization, of their role in asset management decision making and the value of the activities they are undertaking;*
 - *the asset management system can stimulate creativity and innovation by supporting people who understand the importance of asset management and are motivated to work towards achieving the asset management objectives.”*

Implementing an effective asset management system provides numerous other benefits to organizations, such as:

- Simply acquiring the right assets for the organization
- Reducing the organization’s risk profile which results in improved safety performance by reducing the risk of injury and catastrophic events
- Improved control of assets which contributes to improved customer and regulator confidence and lower insurance premiums
- Standardization of equipment and processes which reduces costs of spare parts, materials, and training
- Improved understanding of asset performance and benchmarking performance across the organization
- More effective management of outsourced services
- Balanced allocation of operational and capital expenditures across the organization and individual sites
- Delivery of value based on Return on Net Asset (RONA)

1.5 Key Concepts/Terms

Alignment of Technical Register and Financial Register

By linking the financial information of assets to the technical systems, information can be shared to ensure effective decision-making (e.g., for capacity expansion plans or developing recapitalization plans).

Asset

An asset is defined in ISO 55000 [1] as follows:

“An asset is an item, thing or entity that has potential or actual value to an organization.”

An asset can be physical, such as a pump. An asset can be non-physical, such as a control system or data stored in a system. Careful consideration needs to be given to the non-physical assets; they are easily overlooked but have a large impact on the operational and compliance aspects of the pharmaceutical industry. This concept should be applied throughout this document.

Asset Management versus Management of Assets (Managing Assets)

- Asset management is a complex topic approached at many levels and applied to many functions or departments. Both the **management of assets** and **asset management** are necessary to enable organizations to extract maximum value from their assets. It is a common assumption that asset management focuses on the things that are done to assets, which can make conversations confusing and unproductive.
- The ISO 55000 series of standards [1, 2, 3] provide an overview of asset management, its principles and terminology, and the expected benefits from adopting asset management. An asset is something that has potential or actual value to an organization; and **asset management** is the “*coordinated activity of an organization to realize value from assets.*” [1].
- The ISO 55000 series of standards [1, 2, 3] provide common concepts, language, and requirements for an asset management system. In doing so, they address both the activities performed directly on the assets (**management of assets**) and the objectives of the organization to exploit those assets (**asset management**).
- **Managing the assets** needs to be specified and executed in the context of the organization's purpose and business plans (into which their asset management thinking and strategies should feed). The activities that directly impact the assets (for the purposes specified in the business plan) are often referred to as lifecycle activities or managing assets and are included within **asset management**.
- However, assets often support more than one function and more than one functional unit within the organization. Not all asset management activities can be formalized through an asset management system; for example, aspects such as leadership, culture, motivation, etc. are not managed through the asset management system, but are part of **asset management**. The **management of assets** is primarily governed by the asset management system.

Data Integration

Some asset data comes from control systems that are often isolated from other information systems. Integration of this data through the asset management system provides new asset information, leading to improved organizational decision-making. This information can also be used for process improvements and to enhance regulatory compliance.

Impact on Risk Management

Implementation of an asset management system recognizes holistic risks, not silo risks (i.e., risks from isolated entities); overall, this can lower risk in many elements of an organization's operation. Impacted aspects could include better regulatory compliance due to reducing deviations from assets, increased operational efficiency due to having assets ready when needed, better cost management due to having predictable spend profile for assets, and a safer work environment for employees by having predictable and reliable operation of assets.

Identification of Assets

Assets provide value to the organization. Each asset or asset system that is acquired by an organization provides a function or service that has been identified as needed by the organization. By identifying and managing these assets, an organization can achieve maximum value from its investment in these assets. All assets, both physical and non-physical (non-tangible), should be identified (e.g., software or control systems that require consistent investment).

Organizational Alignment/Line of Sight

Assets are owned by the organization, not by a department. An asset management system supports a long-term, sustainable approach to decision-making based on many complex factors, not a one-dimensional view. Using this collaborative model ensures alignment of all stakeholders that operate and maintain assets.

Total Cost of Ownership

Total cost of ownership should be addressed in the asset plans and acquisition of structures or equipment. Good asset management ensures that the long-term operational costs (Operating Expenses (OPEX)) that are affected during the construction or capital planning phase of a project (Capital Expenditures (CAPEX)) are balanced to ensure a cost-effective, predictable drug supply is sustained.

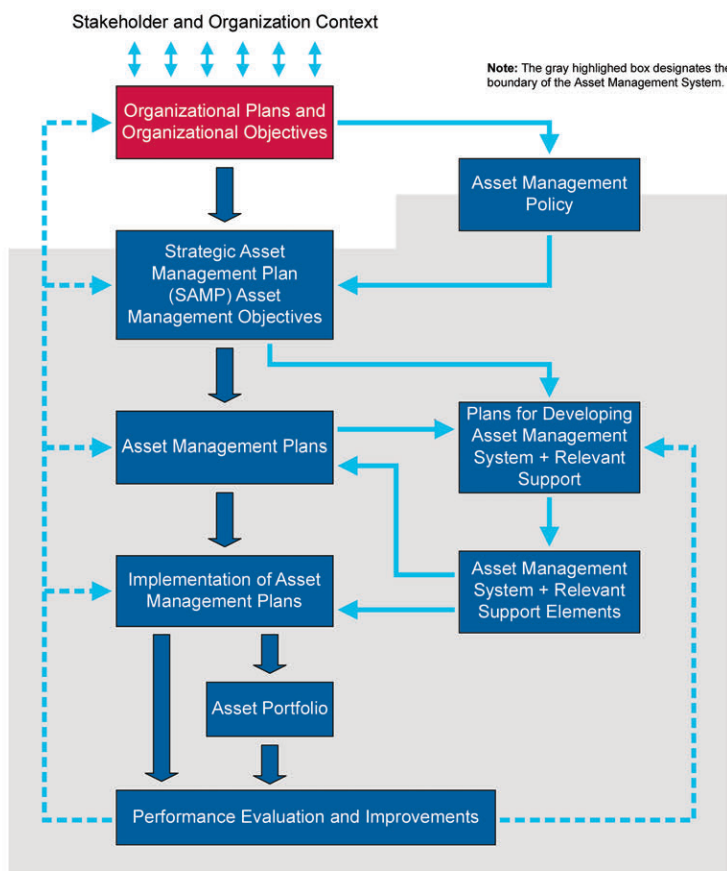
2 Asset Management – Determination of Organizational Plans and Objectives

2.1 Introduction

This chapter focuses on the organizational plans and organizational objectives. Figure 2.1 illustrates the relationship between organizational plans and objectives and the other elements of an asset management system.

Figure 2.1: Key Elements of an Asset Management System – Organizational Plans and Objectives (from ISO 55000 [1])

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2.2 Understanding the Organization and Its Objectives

Synchronizing the asset management system to the organizational objectives is key to an organization's performing well and reaching its goals in a timely, efficient manner. Understanding the organization's short, medium, and long-range objectives is important in aligning the asset management system's performance to meet the needs of the organization.

It is important to understand both the timeframe relative to the objectives as well as to understand the maturity level of the organization. For example, an organization that is launching a novel drug for an unmet need would have significantly different needs than an organization that is making a biosimilar or an organization that is adding another manufacturing stream to a well-established product line.

Coordinating the asset management goals with the organizational goals is an important foundational element in deploying and maintaining a successful asset management system. There may be disruptions in the process over time (such as negative audit findings or missed earnings estimate), but the organization's asset management direction and timeline should be well defined. It is for these reasons that it is important to perform a periodic review of the asset management system to assure ongoing alignment with organizational objectives.

2.2.1 Asset-Related Factors that Inform Organizational Objectives

2.2.1.1 Organizational Maturity Level

Different organizations have different maturity levels, ranging from well-established and predictable legacy firms to start-ups experiencing spurts of growth while still working to develop effective work processes. A company in those early stages would not have been through a series of asset lifecycles for the organization's varied investments. A mature company would be expected to have a defined process for asset lifecycle management.

2.2.1.2 Time Horizons

Time horizon considerations are factors that drive an organization's objectives. If the organization is in the process of taking a product into pilot manufacturing before scale-up, then the asset lifecycle might only be a few years. If the organization is making a product with no competition on the horizon, then the timeframe could be in excess of ten years. With patent exclusivities and looming competition, time horizons can be well understood and defined.

2.2.1.3 Asset Management Cadence

Compliance, profitability, and cost pressures all contribute to an organization's objectives and are important elements in determining the direction of an asset management program.

2.2.2 Integrated Management System Approach

ISO 55000 [1] recognizes that the asset management system rarely functions in isolation from the other management systems that are active in the operating environment of an organization. An integrated management systems approach is therefore strongly advocated.

In the pharmaceutical industry, there are a number of management systems that should be considered for integration. For the manufacturing function, the overarching management system is GMP to protect the patient and supply chain management to ensure that medicines are always available. In the R&D function, the processes associated with drug discovery and development, such as Good Laboratory Practice (GLP), are the defining management systems. Furthermore, the pharmaceutical industry often has particular health, safety, and environmental challenges such as containment of potent compounds. An organization's Health, Safety, and Environmental (HSE) management system enables the successful identification, monitoring, and mitigation of these challenges, supported through secure asset-related controls.

2.3 Business Drivers

A key principle of an asset management system in the pharmaceutical industry is recognition that pharmaceutical assets, in the form of buildings, services, equipment, and infrastructure, are primarily enablers to the core business objectives of providing exceptional patient outcomes through discovering, developing, and supplying safe effective medicines. That recognized, few of the activities associated with R&D and manufacturing can be accomplished without safe, compliant, and operable assets.

In the lifecycle of an organization, there are changing business drivers. Historically, asset management was defined in terms of how to perform maintenance in the best way possible in a predictable environment; this is no longer the case. When making decisions about investments in assets, there needs to be alignment with the overall business strategy and good cooperation between asset management and strategy teams to ensure appropriate maintenance and infrastructure strategies are enacted.

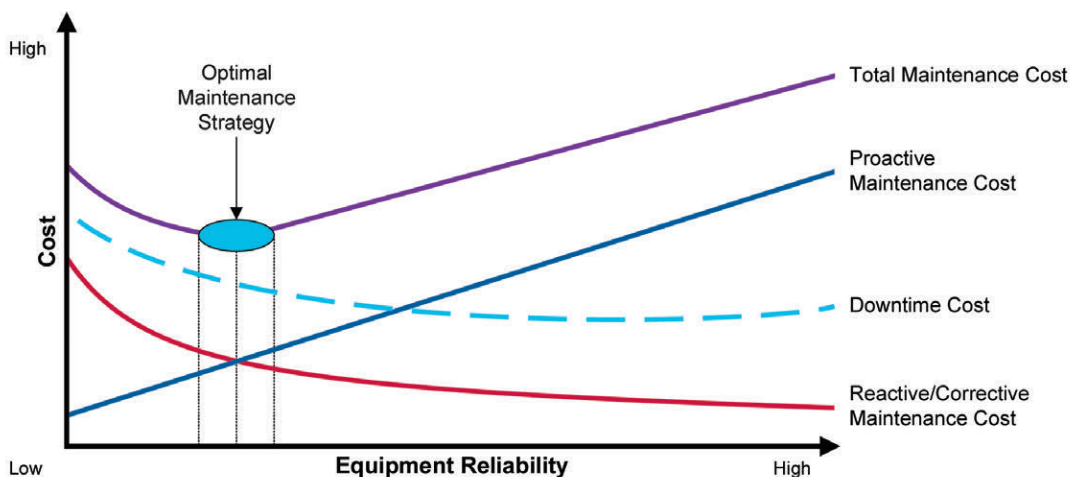
Total Cost of Ownership (TCO) calculations indicate that the majority of recurring costs become locked in at the design phase. In the early stages of product launches, maximizing asset availability, minimizing downtime, and working out any issues using a repeatable process are critical to meeting launch schedules. A well-developed and executed asset management plan can significantly reduce or even eliminate the disruption in the early stages, thereby saving significant amounts of money in resources, reducing waste of product, and accelerating time to market. This is a key business driver for asset management and is significantly undervalued by most organizations. When emphasis is on time and being under budget for new asset implementations, TCO aspects are typically not given priority. However, this can significantly increase the cost of the Operate and Maintain (O&M) phase of the asset lifecycle.

After an asset is through the resource heavy start-up phase, there is typically a more predictable environment. R&D processes, market volume, and sales forecasts are more accurate. When market volume starts to peak, asset performance is an important business driver. The focus becomes maximizing the value from assets, which includes maximizing production output and repeatability and securing R&D laboratory availability. During this phase, focusing on measures such as Operational Equipment Effectiveness (OEE) is important to monitor and adjust, as necessary, through problem solving.

Asset management plans should continue to drive behaviors throughout the entire lifecycle of the asset, focusing more on the lifecycle horizon rather than the operational day-to-day activities. As an organization settles into driving asset performance through continuous improvement and meeting production schedules, cost cutting can become a focus. Companies often consider reducing Preventive Maintenance (PM) costs through sourcing less expensive parts or making outsourcing versus insourcing decisions for many aspects of the manufacturing process. These and many other cost cutting measures are reviewed and analyzed in an effort to maximize value out of the value stream. However, this outcome is rarely the case. Some argue a “run to failure” strategy could be more cost-effective; however, industry practice demonstrates that “run to failure” costs significantly more than planned, predictive, and condition-based maintenance strategies. These maintenance strategies can all be part of a balanced asset management plan.

Next, an end-of-life decision needs to be made on the product as patents expire and competitors and treatment alternatives appear. The focus is now on cost cutting until the end-of-life and decommissioning is reached. A risk-based review on whether to delay or even skip PM schedules can be helpful, though this will affect the time left to end-of-life. Certain compliance activity will need to be retained.

Figure 2.2 shows cost over the life of an asset and where the most impact to the business can be affected. These higher impact areas can have significant effects on business drivers. The asset management plan should address negative impacts if the wrong areas are chosen as a focus area and positive impacts if the higher cost potential areas are chosen.

Figure 2.2: Optimum Balance of Planned versus Reactive Maintenance

The overall benefits of asset management include improved financial performance by improving the return on investments. Informed asset investment decisions can enable the organization to balance costs, risks, opportunities, and performance. Managing risk to reduce financial losses can also improve HSE and social impacts. This can lead to reduced insurance premiums and eliminating potential fines and penalties. These are a few business drivers that asset management can impact. Refer to Section 2.2 (Benefits of asset management) of ISO 55000 [1] for a comprehensive list.

During the lifecycle of assets, external events can occur that negatively impact the business, e.g., acquisition or sale of the organization, audit findings, safety or environmental events, or market forces such as decreasing price targets driven by major customers such as insurers or government health plans. To help mitigate these risks, the asset management plan needs to undergo periodic reviews and possible revision based on business needs. This ensures that the asset base, both current and planned, meets the overall business strategy. For example, there would be no benefit in building biologics research facilities if the business strategy is to focus on small molecules.

2.4 Understanding the Stakeholders

ISO 55000 [1] recommends that the asset management system should recognize and respond to the internal and external environment in which it operates and, in particular, be fully aware of the demands of key stakeholders with which it will interact, integrate, and serve.

Stakeholders in the asset management system range from the patients who may have no treatment alternatives, through to the employees, and all the way to company stockholders who are focused on financial performance.

Aligned to the patients' rights to receive safe medicines are the expectations of the healthcare regulatory authorities. These agencies inform the design, start-up, and operation of assets through setting compliance expectations in the statutory requirements and guidelines of the GxPs.

In addition to the patients, the other key stakeholders in the business are the investors, whether shareholders or private owners. Unlike many other industries, the wider financial business case for capital and revenue investment is often not based on immediate asset lifecycle costs; this is particularly relevant when set against the overall expenses of in-house drug development. However, significant delays to the launch capability of a manufacturing plant can markedly impact the organization's profitability. Furthermore, failure in an established asset's ability to deliver the required capability (e.g., supply chain capacity or compliance shortcomings) can have severe tangible and intangible financial impacts.

The process of managing stakeholders consists of communicating with them while managing their expectations and concerns for meeting their needs, addressing issues, resolving conflict situations, and achieving project goals. The most critical aspect is thinking broadly about the stakeholder community. Plant neighbors and surrounding communities rely on responsible corporate stewardship for noise and pollution reduction. Investment also follows reputation; that is, businesses can fail on reputation alone. Employees rely on a safe, fulfilling work environment that benefits the organization and the community. Regulatory bodies range from a local conservation committee approving building permits to healthcare regulatory agencies (such as ANVISA [10], EMA [11], MHRA [12], and FDA [13]); these all have roles as stakeholders. Stakeholder management is a critical component to the successful delivery of any project, program, or activity.

The stakeholders and their concerns impact decision timeframes, and their expectations are part of the input into the asset management system; as these standards change, a good asset management system can help the business to respond quickly. For example, periodic inspections of elevators and fire systems by regulatory bodies are usually more than an inspection of condition. There is an expectation that these assets are being managed properly and maintained throughout their lifecycle. This information can be extremely beneficial when asset replacement or rebuild decisions are made and placed into annual operating plans.

To ensure success, all significant investment projects should include a stakeholder engagement strategy that contains a detailed plan of action for communicating and collaborating with key stakeholders.

2.5 Setting the Scope of the Asset Management System

There are several factors to consider when determining the scope of the organization's asset management system. Scope is dependent on the organizational objectives, which should be based on value creation or maintaining existing value.

A common misconception is that setting up an asset management program is an all or nothing proposition. ISO 55001 [2] states the following:

"The organization shall determine the boundaries and applicability of the asset management system to establish its scope. The scope shall be aligned with the SAMP [strategic asset management plan] and the asset management policy."

This statement allows for flexibility in the application of asset management. The scope can be narrow or broad based on the asset management policy.

When an organization commits to an asset management system approach, it usually already owns existing assets. These assets are likely to be in a range of conditions with varying ranges of operating life and remaining life; this makes the asset management system more important as there are varying degrees of risk to the success of the business. Consideration should also be given to assets that may support the operation but are not in the immediate area, such as process utilities.

Pharmaceutical companies have the advantage of complying with GMPs to assist in setting the scope of an asset management system. Assets identified as GMP are usually associated with the high value activities aligned with organizational objectives.

Once the scope is defined, all assets need to be identified to build the asset portfolio. The assets in the portfolio are usually tracked in a Computerized Maintenance Management System (CMMS) or Enterprise Asset Management (EAM) system.

The business functions that are required to support the asset portfolio also need be identified; all relevant stakeholders within these functions need to be notified. This includes outsourced resources and so cross-organizational considerations need to be addressed, e.g., alignment of corporate principles and values.

After an asset management system is in place, the organization may update the scope based on changes in the needs of stakeholders, market conditions, regulatory requirements, or objectives. These changes are generally communicated by updates to the asset management policy.

2.6 Organizational Context

Organizational context is the relationship between asset management and the other elements of the business. In order to determine what is required for the asset management system, an organization needs to first determine the circumstances or context under which they operate, i.e., operational limitations, strengths, weaknesses, opportunities, threats, and stakeholder relationships. Understanding an organization's context and stakeholder's needs provides the basis for an organization to determine what is critical, urgent, and valuable. Organizational context helps to determine the content of the asset management system.

Organizations need to consider the internal and external factors that impact their operating context. Internal factors include the condition and intended use of facilities, current asset portfolio, organizational capabilities (resources, leadership, culture, competencies, flexibility, etc.), and lifecycle stages for organizations, facilities, systems, assets, and products. External factors include current and future demand for products and services, regulatory requirements, public policy, public relations, the organization's reputation, and industry trends. The factors that determine an organization's context are unique and need to be fully understood to develop the right asset management system framework to enable an organization to create the maximum value from their assets.

The remainder of this section provides examples of external and internal stakeholders and the various lifecycle stages that impact organizational context.

2.6.1 External Stakeholders

Table 2.1 provides examples of how external stakeholders, regulatory authorities, impact aspects of asset management.

Table 2.1: Examples of Regulatory Impact on Asset Management

Regulatory Area	Example	Asset Capability Impact
Environmental	Toxicity effects on fish in the surrounding environment	Outfall effluent monitoring and control
Animal Welfare	Stress to animals from temperature excursions	Design and operation of vivarium HVAC systems
Safety	Exposure of workers to highly potent compounds	Design and operation of containment systems

2.6.2 Internal Stakeholders

Table 2.2 provides a summary of the internal stakeholders that need to be involved for an asset management system to be successful.

Table 2.2: Internal Stakeholders Relevant to the Asset Management System

Stakeholders	Interest
Operations/Production	Right assets for the right productivity
Maintenance Function	Maintenance appropriate to the risk of the assets
Equipment Supplier or Manufacturer	Service to the assets
Critical Utilities Operations	Right assets for the right productivity
Facilities Management	Manage a level of service for the asset, and renovation planning
Scientific Equipment Maintenance	Maintenance appropriate to the risk of the assets
Energy and Utilities Function and Providers	Whether the resilience models meet the business risk
Asset Information Management	How all data on the asset is collated and presented
Quality Assurance Function	Right quality from the right asset
Research Scientists	Right assets for the right research
Finance	Predictability on costs
HSE Function	Whether the asset has inherent problems
Human Resources	Current training plans and any future requirements
Unions	Particularly applicable in some countries as unions are the sole representative of staff wellbeing

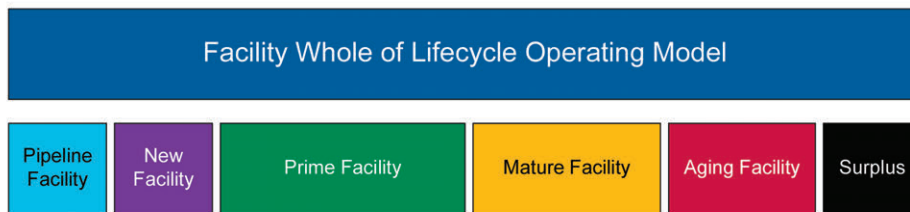
2.6.3 Organization Lifecycle

The phases of an organization lifecycle are:

- Start-up (survival)
- Growth and expansion
- Maturity
- Acquisitions/mergers
- Decline

2.6.4 Asset Lifecycle of Facilities

The asset lifecycle of facilities can be shown graphically using the Facility Whole of Lifecycle Operating Model, as presented in Figure 2.3. This model and the following descriptions can be used to identify the current status of a facility and to project strategy changes that will be necessary as a facility transitions to later stages.

Figure 2.3: Facility Whole of Lifecycle Operating Model**2.6.4.1 Pipeline Facility**

Pipeline facilities are in the process of being delivered to the end-user. The timeframe that a facility is considered to be pipeline is from concept through to start-up before handing the keys over to the inhabitants and end-users.

2.6.4.2 New Build Facility

New build facilities are recently delivered facilities that may still have items covered by warranty or guarantee. These facilities may have outstanding commissioning issues that need to be resolved. Capacity exists for future development. Characteristics of new build facilities include:

- Improving facility performance as start-up issues are overcome
- Potential minor investment to optimize use
- Current workplace strategy
- New technology
- Normalizing operational costs

2.6.4.3 Prime Facility

Prime facilities have well-developed inventory and a positive atmosphere; they are desirable to the inhabitants. These facilities set a standard for similar use facilities and have capacity for further development. Characteristics of prime facilities include:

- Typically 2–15 years old
- Optimum facility performance
- Modest ongoing investment required to sustain infrastructure
- Effective workplace strategy
- Current technology
- Efficient operational cost

2.6.4.4 Mature Facility

Mature facilities are functional, but some of the contents need investment to keep ahead of obsolescence. These facilities may have undergone refits and refurbishment, and there is limited opportunity to further develop the facility. Minor refurbishment may be needed in some areas. These facilities are close to the end of its original design life. Characteristics of mature facilities include:

- Typically 15–25 years old
- Disrupted facility performance
- Significant tactical investment required to replace/update infrastructure
- Potential modernization of workplace required
- Increase in underlying operating costs due to the age and condition of the facility

2.6.4.5 Aging Facility

Aging facilities are functional and have undergone significant changes since construction. These facilities do not have the capacity for further development and are limited by the little opportunity to develop. Most of the installation is now obsolete and the infrastructure may also need significant investment to bring it to current standards. These facilities may have exceeded expected life of the original design. Characteristics of aging facilities include:

- Typically over 25 years old
- Potential poor facility performance
- Plan for major renovation or disposition
- Outdated workplace
- Significant increase in underlying operating costs

2.6.4.6 Surplus Facility

Surplus facilities are no longer performing a business function. For a surplus facility, condition-based asset strategies may not be justified since many systems are placed in a layup or inactive status (e.g., boilers, process equipment, etc.).

A facility can be removed from service and made surplus in any stage of asset life. The financial costs of both deactivation, ongoing maintenance in layup, and of reactivation or disposition should be considered when placing a facility in surplus.

Table 2.3 defines the general conditions that may be encountered during each stage of the facility lifecycle. This table can be used as a baseline for comparison.

Table 2.3: Typical Facility Lifecycle Stages

	Workplace	Typical Age (Years)	Services	Maintainability	Condition
Pipeline	Idea	0	To be determined	Standardized	Architectural
New	Learning	0–2	New	Some obstacles	Issue Management
Prime	High Performance	2–15	Customized	High effectiveness	Excellent
Mature	Need refurbishment to keep operational	15–25	Lean	Some equipment needs to be replaced to keep ahead of obsolescence	Wear and tear but good
Aging	Outdated	25+	Basic	Difficult to find spares	Outdated
Surplus	Any	Any	Any	Any	Any

2.6.5 System and Asset Lifecycle

The phases of a system and asset lifecycle are:

- Design
- Procurement
- Construction and installation
- Commissioning
- Qualification
- Operation
- Improvement
- Refurbish
- End-of-life (find different use, scrap, recycle, etc.)

2.6.6 Product Lifecycle

The typical phases of a product lifecycle are:

- R&D
- New patent
- Product launch

- Growth
- Mature
- End of patent/generic
- End of product life

2.7 Leadership, Behavior, and Change

ISO 55000 [1] describes the role of leadership in asset management in terms of organizational accountability. This includes setting the direction for asset management through the following:

- Ensuring endorsed policies and strategies for asset management are in place
- Ensuring alignment of asset management objectives with those of the business
- Securing adequate resources to deliver these objectives via the asset management system

Leadership sets the strategy for the organization by providing clarity and focus. Leadership, culture, and maturity are the key determinants for developing high performing organizations when implementing an asset management system. High performing organizations are supportive of more than one cultural type and leadership style.

Developing a successful asset management system is directly linked to behavior. The challenge for leadership is in how to translate, align, and implement asset management aspects (fundamentals, strategies, objectives, values and plans) throughout the organization, thereby creating “line of sight” (i.e., organizational alignment).

2.7.1 Organizational Design - Maximizing Asset Value

The design of an organization is directly linked to its ability to be successful. There are many ways that an organization can be structured and there is no single “right” structure for an organization. However, there are many structures that can prevent an organization from being successful. These structures are linked to the culture that results from the individuals and the groups that make up the organization. These concepts are discussed further in Chapter 5 in terms of the significance of the organization being one that does not operate in silos.

A key factor that needs to be taken into consideration when developing an organizational structure is the need for the organization to be flexible or dynamic. Certain organizations need to be able to evolve and adjust rapidly. For example, technology-based companies often need to be able to keep up with the rapid rate of change of their products, just as pharmaceutical companies need to be able to get a product from conception to commercialization. The organizational structure would need to allow for the scale-up of new products to supply both clinical and commercial needs.

Leadership provides a foundation that supports the culture, and thus the practices, supporting asset management. One way that leadership can effectively establish an organizational model is to map out responsibilities. Ensuring clearly defined roles and responsibilities lays the foundation for understanding organizational needs. Once these have been developed and an estimated workload within each role has been defined, the organizational scale-up can be laid out. The number of positions needed to fill the organizational need is defined by the estimated workload of the articulated roles and responsibilities. Decisions on the extent of outsourced provision can also be addressed.

Leadership can leverage a map to understand how the roles that support asset management will be accomplished. Some of these roles will support many responsibilities while others will be dedicated to only one responsibility. The mapping of responsibilities can force decision-making regarding the level of service that the organization will get from these roles. In addition, it also allows the organization to hold individuals accountable and know that all asset management responsibilities have been accounted for, thus maximizing asset value for the organization.

As organizations continue to demand higher value from their assets, the organizational design needs to evolve in order to achieve the objectives of the asset management system. This in turn supports the achievement of the business objectives. The organizational design needs to be flexible; changes over time ensure that the organization is structured to deliver on their strategic objectives and deliver maximum value.

2.7.2 Roles, Responsibilities, Relationships, and Interfaces

In order for an organization to succeed, there needs to be clear lines of accountability; this requires roles, responsibilities, relationships, and interfaces to be defined. There are different methods that can be used to establish lines of accountability within an organization. Two common tools for mapping out business process roles, responsibilities, relationships, and interfaces are:

- SIPOC Diagram – Suppliers, Inputs, Process, Outputs, Customers
- RACI Matrix – Responsible, Accountable, Consulted, Informed

Every business process has inputs and outputs. The SIPOC diagram can be used to map out all relevant elements of a process in a simple diagram or table format. Typically, a team is responsible for defining the business process and breaking down the process into its various subprocesses. The SIPOC diagram organizes the defined business process into a logical flow from suppliers and inputs to the process to outcomes and customers of the process. The SIPOC diagram defines the following:

- Who supplies inputs to the process
- Specifications for the inputs
- Who the customers are for the process
- Requirements of the customers

Once a business process has been clearly defined, a RACI matrix can be used to identify the roles and responsibilities required. The business process task can be broken down into specific roles, responsibilities, relationships, and interfaces. The roles associated with each task can be separated into four categories: responsible, accountable, consulted, and informed. The RACI matrix is designed to assign tasks, activities, responsibilities, accountability, and decision-making, and to clarify expectations on the level of participation. The RACI matrix ensures all tasks are owned by a role. When roles are not clearly defined, there can be misunderstanding and duplication of effort. For example, some individuals may think they are responsible and/or accountable for a task when they are actually in consulting or supporting roles. The RACI matrix helps stakeholders in a business process understand cross-functional roles and responsibilities. It also provides a better appreciation of the roles performed by other functional areas.

3 Asset Management System – Setting Policy and Strategy

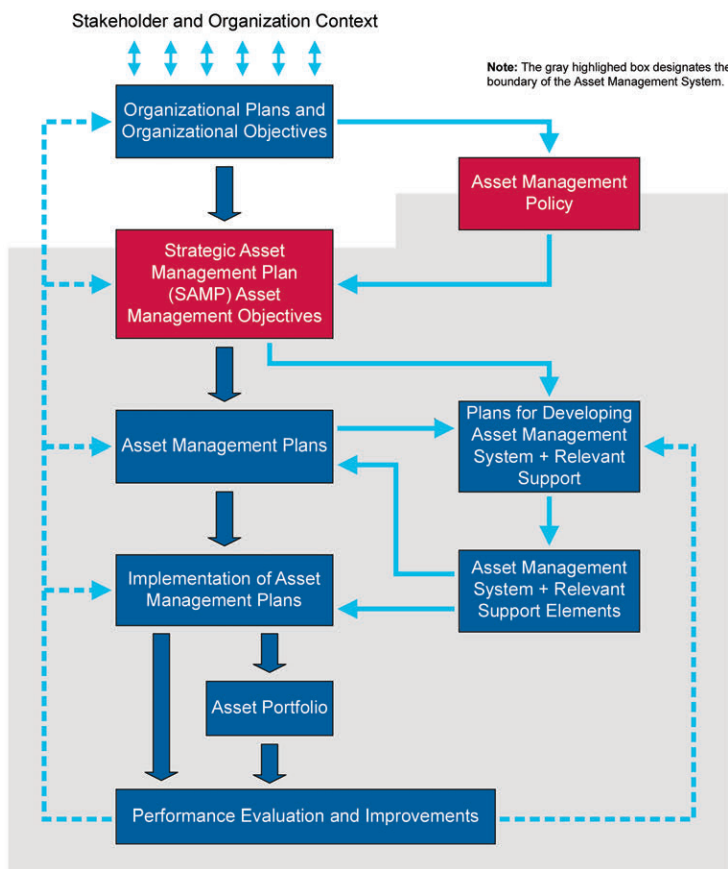
3.1 Introduction

This chapter focuses on the elements of strategic asset management planning and, in particular, on how the delivery of requirements can be supported through establishing an asset management policy and Strategic Asset Management Plan (SAMP). This chapter emphasizes the characteristics of pharmaceutical asset management that should be considered in a policy and SAMP.

Figure 3.1 illustrates the relationship between the policy, SAMP, and other elements of an asset management system. Fundamentally, the strategic objectives cascading from the business systems need to inform the requirements of the organization's asset base through an asset strategy.

Figure 3.1: Key Elements of an Asset Management System – Policy and Strategy (from ISO 55000 [1])

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3.2 Asset Strategy

The asset strategy records how an organization's asset base needs to be adapted and sustained to deliver the business plans. This adaption may require the investment of capital and revenue resources. Stakeholders in the organization should expect to have early warning of these strategic investments and provide scrutiny to ensure that these investments offer real value-adding opportunities for the business.

In most organizations, irrespective of their level of maturity in asset management, an asset strategy of some form exists. The asset strategy sets out what is to be done with the organization's asset base over time, whereas the asset management strategy (as described in Section 3.5, also referred to as SAMP) records how this is to be achieved in-line with the commitments of the asset management policy (as described Section 3.3).

The asset strategy should capture those elements of the strategic business plan that are specifically enabled by the organization's asset base. The strategy typically summarizes the changes required for the assets over a period of five to ten years, indicating when the capability would be required and the expected duration of the change. From this strategy, the forward investment or divestment profile can be agreed with leadership and the finance function.

Established assets should also form part of the asset strategy so that ongoing revenue commitments can be identified. In the case of aging assets, there may be a need for additional expenditures to counter an anticipated increase in asset failures.

Asset strategy considerations for pharmaceutical organizations may include, for example:

- New technology platforms being introduced into R&D
- New product launch plant
- Implications of outsourcing to Contract Development and Manufacturing Organization (CDMO)
- Exiting a therapeutic area and the potential need to repurpose a building
- Consolidation/rationalization of assets from mergers
- Infrastructural enhancements required to treat effluent from a newly introduced product

3.3 Asset Management Policy

3.3.1 Asset Management Policy Development

The asset management policy is a concise statement of commitment by an organization (or function within an organization) that records the principles by which it will govern its assets, consistent with the overall organizational business plan. As such, the policy should describe the general approach to be taken to asset management and the scope of application.

To create a meaningful and effective asset management policy within the pharmaceutical industry, it is essential to understand the following:

- Perspective of stakeholders, including:
 - Senior business stakeholders, such as the asset owners (e.g., operations, finance management)
 - Impacted stakeholders, such as the Quality Assurance (QA) and HSE functions

- External stakeholders, such as regulatory bodies, shareholders, and patient groups
- Flow of accountability and scrutiny through the organizational structure of the business
- Scope of the asset portfolio to which the system will be applied (e.g., plant level, site level, or companywide)

The asset management policy should be endorsed by the senior leader who has direct overall accountability for the physical asset portfolio scope to which the policy applies.

Quality management systems commonly follow the Plan, Do, Check, Act Cycle¹, as illustrated in Figure 3.2. The approved policy is the base document that sets the direction and ambition for delivering the required customer outcomes, sets clear lines of accountability and communication, and also introduces the control mechanisms to ensure alignment to the policy.

Figure 3.2: Example of Plan, Do, Check, Act Cycle

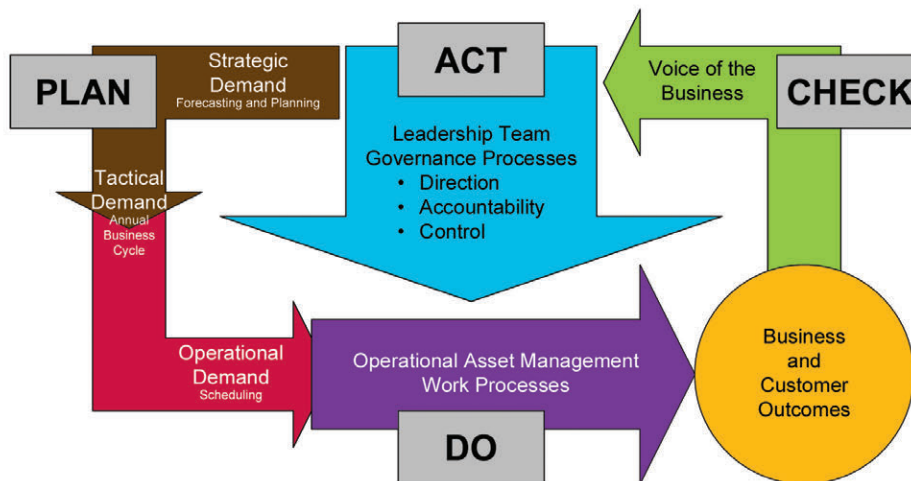
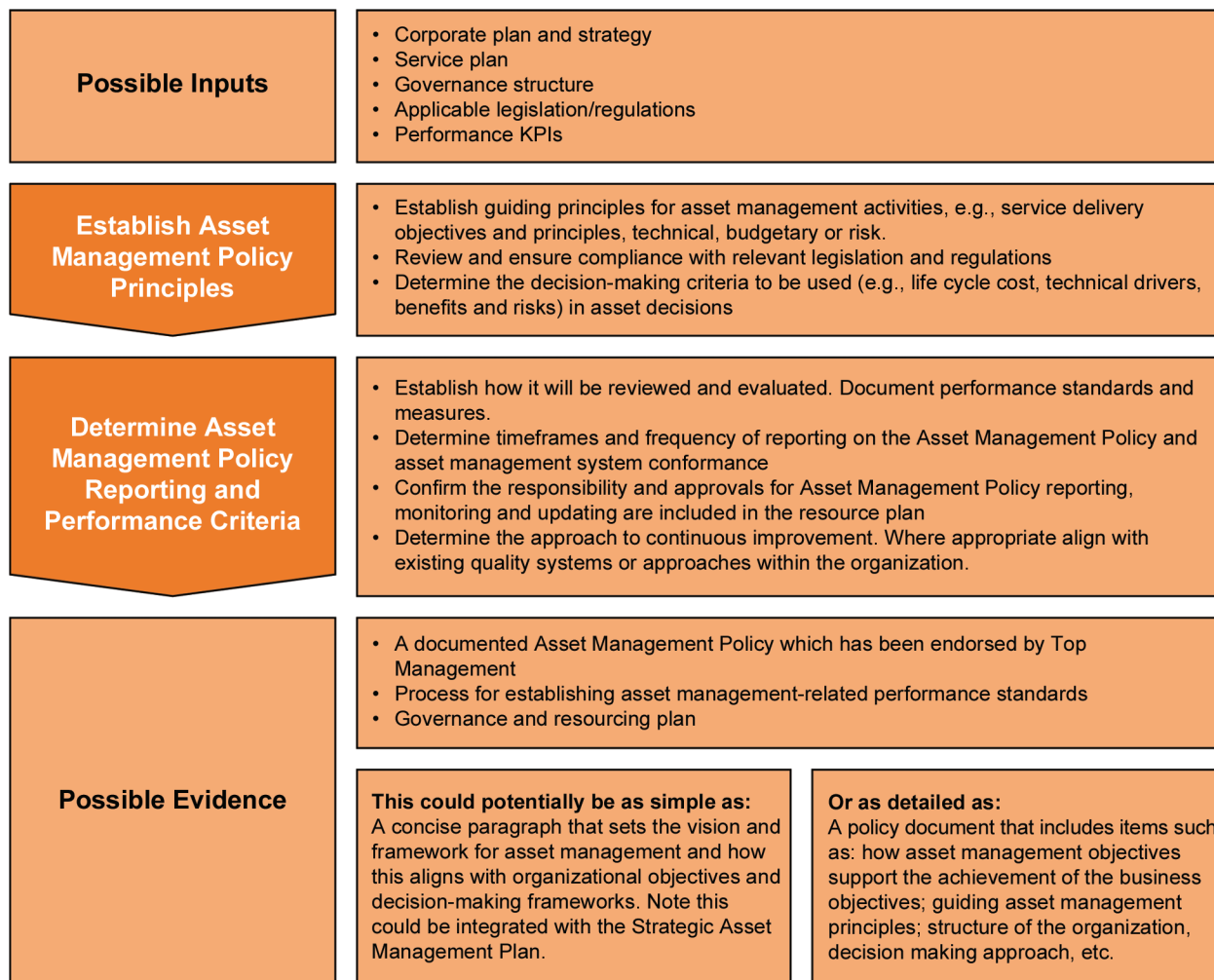


Figure 3.3 provides an example of a high-level workflow used to develop an asset management policy and outlines considerations to be made in developing the document.

¹ Based on the Shewhart Cycle for learning and improvement, also known as the PDSA (Plan, Do, Study, Act) Cycle, as described by Deming [14].

Figure 3.3: Example Approach for Developing an Asset Management Policy [40]

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Refer to The IAM [7] Subjects 1, 2 and 5: Asset Management Policy, Strategy, and Plans [15] for information on best practices in compiling asset management policies.

3.3.2 Asset Management Policy Contents

The asset management policy document may include the following sections:

- General statement of purpose
- Vision statement and aims of the organization
- Strategic asset management objectives (as described in Section 3.4)
- Asset management framework drawing
- Scope, in terms of asset base and organizational functions bound by the policy

- Policy statements
- Revision notes
- Senior leadership endorsement statement

The asset management policy may include the following example policy statements specific to pharmaceutical R&D and manufacturing:

- Commitment to clinical trial volunteer and patient safety through ensuring that assets fully comply with GMPs relevant to the territories in which manufactured product is sold. This may include a statement on GMP training and competency assurance for individuals working within the asset management strategy.
- Commitment to safeguarding the health and safety of scientists and process and maintenance operators by ensuring asset-related controls against exposure to highly active/potent pharmaceutical agents and other processing substances.
- Commitment to ensuring supply chain security or R&D productivity by providing the necessary level of plant and equipment availability.
- Commitment to working collaboratively with other core management system stakeholders (including as appropriate Quality Assurance, operations, finance, HSE, facilities management) to realize overall business objectives.
- Commitment to managing the effective investment of capital and delivery of new asset capability in-line with business plan timeframes, e.g., product launch milestone dates.
- Commitment to developing a facility and environment that attracts new talent into the organization.

3.4 Strategic Asset Management Objectives

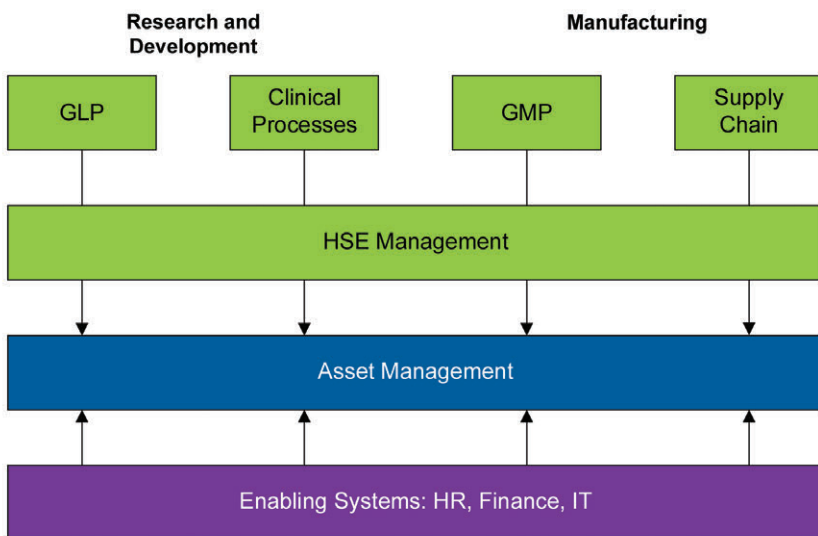
3.4.1 Organizational Context

Asset management objectives need to be informed by, and integrate, with the overarching business objectives of the organization and to fulfill the principles set out in the asset management policy. As discussed in Chapter 2, the business objectives are based on the primary management systems for the pharmaceutical industry, GMP, supply chain management, processes associated with drug discovery and development, and HSE.

Realization of asset management objectives requires the support of key enabling functions. The recruitment of high-caliber technicians and engineers is essential for the operation of the asset management system. Recruitment typically falls within the Human Resources (HR) management system. Financial governance of in-year and longer-range revenue and capital budgets falls within the finance management system.

The resulting cascade of organizational goals is illustrated in Figure 3.4.

Figure 3.4: Cascading Organizational Goals



3.4.2 Asset Management Context

The strategic asset management objectives provide the intermediate level of detail that allows the overarching business objectives to be translated into tangible asset management strategies, and ultimately into operational asset management plans and activities. They form the “line of sight” from the business direction and strategy through to an individual engineer working within the asset management system.

Well-formed objectives help ensure that there is a high degree of confidence that day-to-day activities carried out to secure and improve the capability of a physical asset are aligned to the needs of the business, operationally, tactically, and strategically.

Thus, the objectives can inform both in-year budgets and provide the basis for forecasting and agreeing on longer-range investment needs.

Table 3.1 provides examples of how business objectives can be translated into related asset management objectives.

Table 3.1: Examples of Business Objectives with Corresponding Asset Management Objectives

Business Objective	Asset Management Objective
Moving into a new therapy area	Build/acquire/commission new laboratories with the requisite research capability
New product launch	Perform an assessment of manufacturing capacity within in-house supply chain, with possible capital allocation for a new build or expansion
Organization-wide cost reduction regime	Reduce maintenance effort through a risk-based criticality and value assessment
Attracting new talent into the business	Ensure vibrant and productive workspaces are provided and sustained
Outsourcing end-of-life product to CDMO	Decommission and sell/demolish surplus manufacturing assets

3.4.3 Asset Management Objectives

The asset management policy should establish asset management fundamentals and provide the framework for aligning the SAMP with strategic business objectives. Asset management objectives need to be guided by the SAMP and drive asset management practices.

The following are areas that should be considered when establishing asset management objectives:

- Risk management and decision-making criteria
- Regulatory compliance
- Asset management structure, roles, and responsibilities
 - Identify stakeholder needs and requirements
 - Specify levels of service – customer and technical
 - Use of SIPOC tool to establish the asset management structure by defining suppliers, inputs, processes, outputs, and customers for all critical processes (refer to Section 2.7.2)
 - Use of RACI matrix to clarify roles and responsibilities, which helps eliminate duplication of effort and provides an alignment of personnel to key steps identified in the SIPOC (refer to Section 2.7.2)
- Asset financial management
- Preparation of asset management plans
- Commitment of resources required to deliver asset management
- Asset management reporting requirements
- Continuous monitoring and evaluation of asset management processes
- Implementation of improvement plans for asset management processes

ISO 55001 (Section 6.2.1) [2] states the following regarding asset management objectives:

“The asset management objectives shall:

- *be consistent and aligned with the organizational objectives;*
- *be consistent with the asset management policy;*
- *be established and updated using asset management decision-making criteria;*
- *be established and updated as part of the SAMP;*
- *be measurable (if practicable);*
- *take into account applicable requirements;*
- *be monitored;*