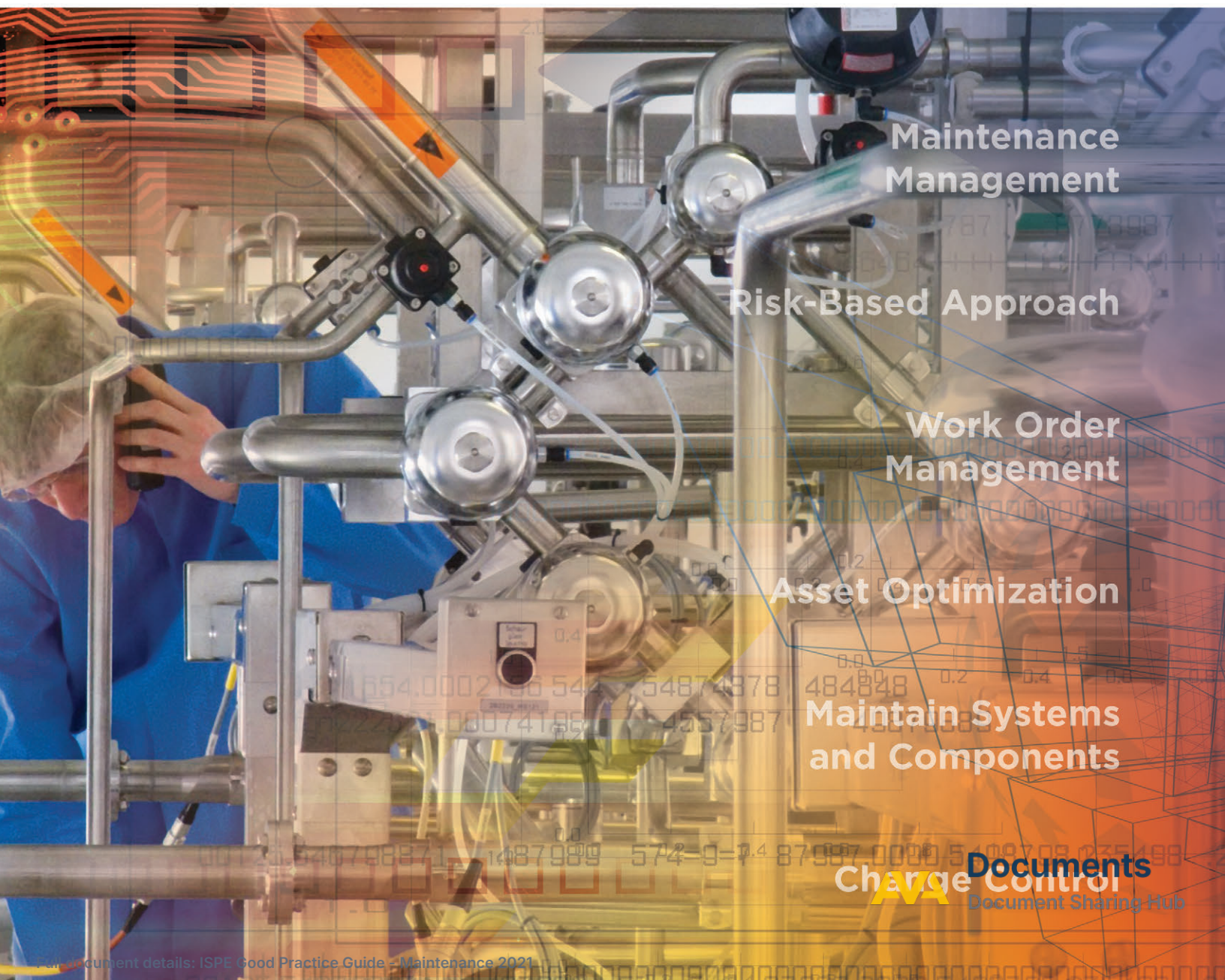




GOOD PRACTICE GUIDE: **Maintenance**

Second Edition



**Maintenance
Management**

Risk-Based Approach

**Work Order
Management**

Asset Optimization

**Maintain Systems
and Components**

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GOOD PRACTICE GUIDE: **Maintenance**

Second Edition

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Preface

Maintenance can impact both the quality of products and the compliance of pharmaceutical processes. Maintenance Programs have long been recognized as critical to the success of the operations they support.

This Guide focuses on achieving cost-effective compliance with existing regulations and associated guidance. It describes current established good practice and seeks to provide a practical and consistent interpretation of the required elements of a pharmaceutical Maintenance Program, while offering maximum flexibility to enable widespread adaptation and encourage innovation.

This Guide focuses on maintenance in GMP areas and is intended to be used as a tool for the development, implementation, and execution of a Maintenance Program in a pharmaceutical manufacturing environment.

Since the first edition of this Guide, the ICH Q9 risk-based approach has been widely adopted worldwide. This edition reflects alignment with the risk-based approach with respect to maintenance and the industry as a whole. Updates to this edition include consolidating basic and good practices categories, adding clarification on terminology for users, and updating examples.

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1 Introduction

1.1 Background

Maintenance Programs have long been recognized as critical to the success of the operations they support. Maintenance has the potential to affect both the quality of products and the compliance of pharmaceutical processes.

Many pharmaceutical organizations have realized the importance of maintenance, and this has resulted in an increased focus on maintenance processes. This had led to the escalation of requirements being imposed on maintenance operations. In many cases, these increased requirements resulted in added cost and slower execution. In more recent years, the risk-based approach described in ICH Q9 [1] has been applied to Maintenance Programs.

Key themes and practices have become prevalent with respect to Maintenance Programs, e.g.:

- The pharmaceutical industry is using more condition-driven Maintenance Programs based upon operating data derived from Predictive Maintenance (PdM) technologies, rather than performing maintenance on a calendar basis. PdM practices are mature and have been in use in other industries for many years.
- Lean manufacturing concepts and self-directed work teams, borrowed from other industries, affect how maintenance services are delivered.
- Reliability-based techniques, which focus on asset functionality, failure modes, and criticality in the design of Maintenance Plans. Wireless sensors and connected real-time monitoring are becoming more and more prevalent and provide critical information to the user. Smart building techniques are changing the way that facilities are maintained.
- The movement to outsourcing or out-tasking more of maintenance activities adds a level of complexity to Maintenance Programs. A number of organizations are utilizing an Integrated Facilities Management (IFM) model which requires a paradigm shift in the way these services are managed and utilized.

1.2 Purpose

Maintenance practices and trends, coupled with the adoption of the ICH Q9 risk-based approach and the deployment of new technologies, have brought pharmaceutical industry professionals together to update this Guide. This *ISPE Good Practice Guide: Maintenance (Second Edition)* seeks to:

- Help ensure the quality and compliance of maintenance operations and the products impacted by maintenance
- Provide guidance on the latest trends in the maintenance, repair, and improvement of facilities and systems to ensure that organizations are afforded flexibility without impacting the quality of the products
- Recommend a systematic approach aimed at the continual improvement of maintenance operations
- Recommend flexible, standard practices for maintenance professionals that can be applied globally
- Recognize the continuing impact of outsourcing services to third parties and the impact of technology in the production processes
- Control the escalation of non-value generating requirements and cost

This Guide seeks to provide a practical and consistent interpretation of the necessary elements of a pharmaceutical Maintenance Program, while offering maximum flexibility to enable widespread adaptation and encourage innovation.

The practices defined in this Guide aim to address the escalation of cost that results from increasing requirements on pharmaceutical maintenance operations.

This Guide has been developed with the philosophy that the quality and compliance of a Maintenance Program takes precedence over cost elements.

1.3 Scope

This Guide is intended to be used as a tool for the development, implementation, and execution of a Maintenance Program in the pharmaceutical manufacturing environment. This Guide focuses on maintenance in a GMP environment.

Individual systems or equipment and their components may have a potential impact on product quality.

In this Guide, the term GMP, when applied to systems, equipment, or components, indicates a range of practices and controls that can be used to satisfy the requirements and manage potential risk to product quality to an acceptable level. The need and extent of these practices and controls will be based on risk.

This Guide uses the term non-GMP when applied to components, systems, or equipment, as determined through the application of Quality Risk Management (QRM), that do not have an impact on product quality.

Note: The *ISPE Baseline® Guide: Volume 5 – Commissioning and Qualification (Second Edition)* [2] describes a QRM approach (based on ICH Q9 [1] and ICH Q8 [3]) for the classification of systems and equipment based on its potential impact to product quality. Direct impact systems have an impact on product quality (GMP), and systems that are not direct impact do not have an impact on product quality (non-GMP). In addition, the Baseline Guide applies the risk assessment process for identification of the Critical Design Elements, within the direct impact systems, that is used to identify and document the quality impacting components.

The term maintenance, as used in this Guide, is intended to include the various types of maintenance performed on systems, equipment, and facilities.

Good Engineering Practice (GEP) is the foundation upon which a successful Maintenance Program is built. When considering the application of the Maintenance Program to GMP versus non-GMP elements, a risk-based approach that takes into account product quality, novelty, and complexity should be considered to scale level of effort and cost. Refer to *ISPE Good Practice Guide: Good Engineering Practice* [4].

This Guide does not address calibration or cleaning programs. For further information, see *ISPE GAMP® Good Practice Guide: A Risk-Based Approach to Calibration Management* [5] and *ISPE Guide: Cleaning Validation Lifecycle – Applications, Methods, and Controls* [6].

To avoid replication of materials and issues already addressed in other Guides, reference is made to related ISPE Guidance Documents for a complete discussion of the support issues affecting Maintenance Programs and the operations which they support. This Guide is intended to be complementary to the *ISPE Good Practice Guide: Equipment Reliability* [7] and the *ISPE Good Practice Guide: Asset Management* [8].

1.4 Benefits

This Guide provides professionals in the pharmaceutical industry with guidance on the approach to the maintenance of pharmaceutical facilities, equipment, and systems. This Guide is intended to be flexible to permit organizations to develop solutions to maximize performance and minimize the total cost of asset ownership.

1.5 Objectives

This Guide has been prepared to help pharmaceutical maintenance professionals develop and implement Maintenance Programs in accordance with GMPs. It is intended primarily for industry professionals in the US and Europe; however, many of the concepts are considered to be applicable in any pharmaceutical environment, irrespective of the size or location of the organization.

This Guide is intended to facilitate pharmaceutical maintenance, and as such, it does not attempt to address applicable codes, standards, and policies beyond the GMPs, which need to be considered in the development and execution of a Maintenance Program.

1.6 Key Concepts

This Guide introduces the concept of a range of maintenance practices organized into two categories:

- Maintenance Good Practices
- Maintenance Best Practices

Maintenance Good Practices parallel the GEPs and GMPs described in other ISPE Guidance Documents [4, 9].

- Maintenance Good Practices should be performed on equipment, systems, and facilities to ensure a level of reliability and asset performance as determined by the organization. Maintenance Good Practices are recommended for systems, equipment, and components where risk assessment indicates that patient safety and product quality could be impacted.
- Maintenance Best Practices are those practices that go beyond Maintenance Good Practices and typically are applied only for business purposes. Maintenance Best Practices incorporate program refinements, optimization, and advanced maintenance approaches, capabilities, and methodologies.

This Guide supports a risk-based approach to the determination of which category of maintenance practices should be applied to a system or its components. Risk management should be part of the analysis performed prior to an asset being placed in service and in many cases will involve the maintenance unit. The maintenance unit should apply its Maintenance Program and develop Maintenance Plans according to the risk assessment. An overview of the ICH Q9 [1] risk-based approach is described in Chapter 11 (Appendix 3).

The concepts and definitions used in this Guide build upon those from other ISPE Guidance Documents [7, 8, 9].

1.7 Structure of the Guide

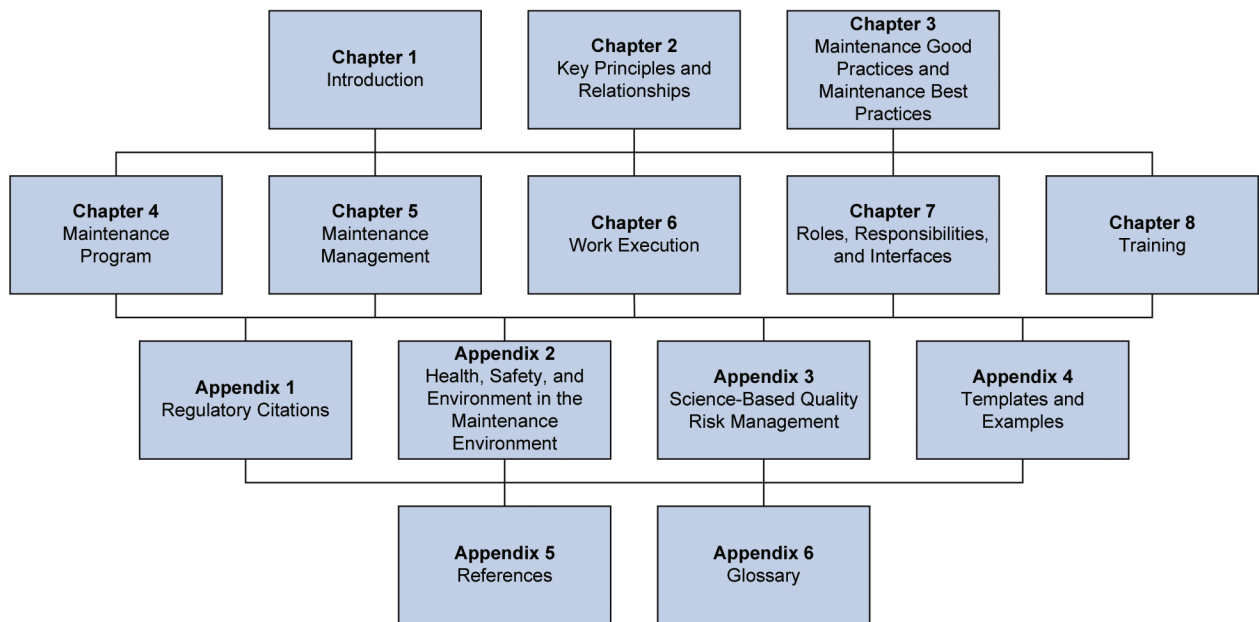
This Guide is divided into three main parts:

- Chapters 1 through 3 describe the philosophy and provide details of the key concepts of this Guide, introducing the two categories of maintenance practices described in this Guide: Maintenance Good Practices and Maintenance Best Practices
- Subsequent chapters elaborate on each of these categories of maintenance practices and consider:
 - Maintenance Program, its elements, and regulatory requirements
 - Work order management, including: Work Requests (WRs), Work Orders (WOs), planning and scheduling, WO completion including calibration work orders, and emergency work

- Roles and responsibilities involved in executing Maintenance Good Practices
- Training to ensure that personnel performing maintenance have the technical and procedural knowledge necessary to ensure patient safety and product quality
- Appendices provide information on regulatory citations, Health, Safety, and Environment (HSE), science-based QRM, and examples and templates which may be useful to the reader

The chapter structure is shown in Figure 1.1.

Figure 1.1: Chapter Structure



2 Key Principles and Relationships

2.1 Introduction

This chapter outlines philosophies and regulatory concepts for maintenance operations in a pharmaceutical manufacturing environment, regulated by the FDA [10], EMA [11], and other regulatory agencies for Active Pharmaceutical Ingredients (APIs) and finished pharmaceuticals. Regulatory concepts are outlined for both the development and execution of a Maintenance Program. In pharmaceutical manufacturing operations, there is a direct dependency upon systems to operate within tolerances in order to achieve drug product quality. Maintenance activities are directed at ensuring system performance, and thus, drug product quality. The Maintenance Program should help to ensure that the equipment is continually maintained in a qualified state and is suitable for intended use.¹

See also Chapter 9 (Appendix 1) for regulatory citations.

2.2 Philosophy

The process to establish regulatory concepts should start with the development of a list of all the elements of a Maintenance Program for a pharmaceutical manufacturing facility. These elements may range from strategic (Maintenance Strategy, organization, etc.), to tactical (work order execution, spare parts application, etc.). Each of these elements should be reviewed in the context of the GMP requirements.

This Guide focuses on those elements of maintenance where GMP requirements apply. In addition to the GMP requirements, a comprehensive Maintenance Program should address other drivers for performing maintenance, such as:

- Health and safety
- Environmental protection
- Business continuity

It is expected that many of the recommended practices described in this Guide will contribute toward meeting or exceeding other requirements of a Maintenance Program. It should be noted that requirements based upon drivers, other than GMP requirements, may result in additional controls or activities that extend beyond the Maintenance Good Practices recommended in this Guide.

2.3 Maintenance Practices

The GMP requirements permit flexibility and provide scope for innovation and improvement. The regulations are not intended to prescribe exactly what needs to be done for any particular activity, including maintenance. In general, the regulations require that maintenance is performed and documented to ensure affected operations consistently produce drug product that meets predefined specifications. However, how maintenance is performed is subject to change, depending upon an organization's philosophies, requirements, and capabilities.

Maintenance Good Practices are aimed at ensuring drug product quality and operational compliance, and are intended to meet the requirements of GMP. Maintenance Good Practices are also aimed at ensuring that operations do not experience unexpected downtime or system failures.

¹ FDA Guidance for Industry on Process Validation: General Principles and Practices [12] states that "activities undertaken to demonstrate that utilities and pieces of equipment are suitable for their intended use and perform properly" is referred to as qualification.

Maintenance Best Practices are practices that go beyond Maintenance Good Practices and involve tools and analysis typically aimed at optimization and increasing asset performance and lifecycle. Maintenance Best Practices go beyond GMP requirements.

The practices described in this chapter are part of Maintenance Good Practices, unless specifically noted otherwise, and subsequent chapters of this Guide elaborate on these two categories of maintenance practices.

2.4 Maintenance Program

2.4.1 *Establishing a Maintenance Program*

A Maintenance Program is a written document establishing the requirements for performing and controlling maintenance activities and should be approved by stakeholders. Maintenance Programs normally include sections on:

- System inventory and risk assessments
- Criticality analysis for key assets
- Reliability Centered Maintenance (RCM) plan
- Computerized Maintenance Management System (CMMS)
- Bar codes and Radio Frequency Identification (RFID) tags
- Change management
- Roles and responsibilities
- Documentation requirements
- Critical spare parts identification and storage requirements
- Turnover process for new facilities and equipment
- Training for client and partner/subcontractor staff
- Preventive Maintenance (PM) plan

Maintenance Programs should encompass management processes and controls, such as how new systems are brought into the Maintenance Program and who has the authority to approve and make changes.

The Maintenance Program's inventory of systems that require maintenance facilitates the determination (or confirmation) of system impact via a risk assessment. In most cases, the risk assessment is completed, and Maintenance Plans are established in conjunction with the maintenance unit during the Commissioning and Qualification (C&Q) phase and prior to putting the asset into service.

Maintenance Programs should document the rationale for determining when Maintenance Good Practices apply.

Maintenance Programs should have a process for handling unplanned maintenance activities. Typically, the program should detail how unplanned work should be evaluated for impact on drug products and how approvals and documentation should be managed. Unplanned activities, e.g., an equipment malfunction, by definition may require some degree of immediate judgement and action.

Organizations may apply common Maintenance Programs across their manufacturing sites. When a significant issue arises at one site, it should be addressed at all sites where there is potential for the same issue to occur. (Note: this is not a regulatory requirement.)

2.4.2 Maintenance Plans

Maintenance Plans contain tactical maintenance tasks performed to:

- Maintain systems (and their components) in proper working order
- Monitor performance in order to detect abnormalities or conditions that might lead to failure

Maintenance Plans are prepared in accordance with requirements established in the Maintenance Program. These tasks are usually time based or condition performance based, depending upon the asset, process requirements, and the organization's capabilities. Maintenance Plans are usually considered as PM WOs although they may be considered as other practices, e.g., corrective WOs.

Maintenance Plans can be established and performed on a system level or a component level. Instructions for maintenance can apply to several systems or be specific to a particular system or component (such as an individual equipment item).

Tasks outlined in the Maintenance Plan should be described in sufficient detail to ensure proper and consistent work implementation by persons qualified to execute the work. Maintenance Plans should include a predetermined frequency or trigger to execute the work to ensure asset performance.

Maintenance Plans and their frequency of execution are typically developed from various inputs including:

- Equipment manufacturer's original recommendations
- Experience with similar equipment
- Review of historical data (trending)
- Process requirements
- Risk assessments
- Complexity and novelty of equipment

For the execution of Maintenance Plans, a Maintenance Management System (MMS) can provide scheduling and documentation capabilities that assist maintenance management. Manual systems tend to be used in smaller sites and can be equally effective from a regulatory perspective. Most CMMSs (Computerized MMSs) are hybrids in that they produce a paper document (i.e., WO) that becomes the record of maintenance. When the record of maintenance and the schedule for maintenance are managed and recorded using a paper copy outside of the CMMS, the CMMS may not require software validation or hardware C&Q, as these are typically the only two maintenance system functions that have GMP regulatory impact. If the CMMS is used to maintain the record of maintenance or the schedule for maintenance, it should be in compliance with 21 CFR Part 11 [13]. For further information, see *ISPE GAMP® RDI Good Practice Guide: Data Integrity – Key Concepts* [14].

2.4.3 Change Management

The Maintenance Program should include procedures or reference to procedures for addressing change management. Throughout the lifecycle, there will be times when nonroutine repairs, modifications, and/or replacements will be necessary, creating the possibility of impact on process parameters (and ultimately drug product). The process for assessing, executing, and documenting these events or changes to systems should be established in the Maintenance Program. Organizations may refer to their quality organization's change management process.

When changes are implemented, some degree of testing and/or verification is required to ensure that the original equipment/component qualification status has not been impacted. The need to perform routine repairs, adjustments, and the like, within pre-established tolerances that have no impact on the process or drug product, should be considered when developing a change management program.

Refer to *ISPE PQLI® Guide: Part 3 – Change Management System as a Key Element of a Pharmaceutical Quality System* [15].

2.4.4 Roles and Responsibilities

The regulations are flexible regarding how the maintenance unit organization is structured and how specific roles and responsibilities are defined and performed; this is critical when third-party providers are utilized to perform this work. For GMP systems and equipment, the roles and responsibilities of maintenance staff should be documented. The regulations specifically state that assignment of responsibility for maintenance and maintenance scheduling shall be included in the written procedures for maintenance. It is also an expectation that roles and responsibilities be established for an overview of the maintenance activities, including processes such as:

- Writing maintenance procedures
- Authorizing changes
- Review and approval of work processes
- Response to deficiencies
- Training
- Documentation

Where maintenance personnel are engaged in these activities, their roles and responsibilities should be documented. In addition, where there is a review and approval of a process or procedure, it should be independent and unbiased.

Table 2.1 outlines the typical roles and responsibilities of stakeholders of maintenance activities with respect to the key elements of a Maintenance Program.

Table 2.1: Typical Roles and Responsibilities for Maintenance Activities

Maintenance Activity for GMP Systems and Equipment	Integrated Facilities Management (IFM) Provider or Subcontractor if Present	Maintenance Unit (Client Representative)	Subject Matter Expert (SME)	System Owner	Quality Unit
Maintenance Program	Prepare	Approve	Prepare and Approve		Approve
Risk Assessments	Prepare	Prepare and Approve	Prepare and Approve		Approve
Maintenance Plan	Prepare	Prepare and Approve	Prepare and Approve		
Change Control	Prepare	Prepare and Approve	Prepare and Approve	Approve	Approve
Deferred Maintenance		Prepare and Approve	Prepare and Approve		
Training Program		Prepare and Approve			Approve
Training Plans	Prepare	Prepare and Approve	Prepare and Approve		
Deficiencies		Prepare and Approve	Prepare and Approve		Approve (Process only)*
Spare Part Application (Like-for-like)	Prepare	Assess and Approve	Review		Approve
Spare Part Application (Not Like-for-like)	Prepare	Assess and Approve	Review	Approve	Approve
*The Quality unit should approve deficiencies that have the potential to affect Critical Process Parameters.					

2.4.5 Maintenance Documentation

2.4.5.1 Procedures

There are several approaches that organizations use in the application of procedures to maintenance processes. Organizations may develop governing procedures which provide a framework for maintenance practices, within which the maintenance unit is able to create plans, instructions, check-sheets, task lists, etc., to carry out the maintenance work. Alternatively, organizations may use specific procedures that are associated with an individual work process, e.g., the PM for a particular filling line might have a PM procedure specific to the line. There also might be hybrid approaches to maintenance procedures. The key difference between using governing procedures or specific procedures lies in where the approvals are conducted: within the maintenance unit or outside of the maintenance unit. Typically, the Quality unit approves governing procedures and the Maintenance Program; however, Maintenance Plans, instructions, or check-sheets, etc., would be approved and managed locally within the maintenance unit. The Maintenance Good Practice approach is to use governing procedures in the form of the Maintenance Program (which should be approved by the Quality unit) and to supplement these with Maintenance Plans that are developed, managed, and approved internal to the maintenance unit.

2.4.5.2 Deficiencies

When deficiencies are encountered on systems or equipment that may impact product quality and patient safety (GMP systems or equipment) during the performance of maintenance activities, they should be reported, investigated, and documented in a timely manner. If the deficiency is identified as an equipment or component failure that does not affect a Critical Process Parameter and has no potential impact to drug product quality (i.e., risk to meeting a Critical Quality Attribute (CQA)), then the deficiency can be reported, investigated, documented, and corrected within the authority of the maintenance unit. If the deficiency has affected a Critical Process Parameter, it should be reported to the Quality unit and the System Owner. Subsequently, the necessary course of action should be determined and typically would include an investigation, corrective measures, and reporting requirements.

Note: The *ISPE Baseline® Guide: Volume 5 – Commissioning and Qualification (Second Edition)* [2] designates Critical Design Elements as the engineering and automation design elements used to implement design controls (Critical Aspects) to ensure documented Critical Process Parameter operation. Examples of engineering design features include components, instruments, and materials of construction. Critical Design Elements are identified and documented based on technical understanding of the product CQAs, process Critical Process Parameters, and equipment design/automation.

2.4.5.3 Continual Improvement

Although not a specific regulatory requirement, continual improvement and innovation is encouraged by the FDA. [16] The regulatory requirement to investigate an abnormal event or occurrence with respect to maintenance activities is applicable where drug product may be impacted. Organizations may trend maintenance activities as a means of achieving a higher level of asset performance (Maintenance Best Practice). It should be noted that review and trending of maintenance activities is not a regulatory requirement. When a failure is experienced on a GMP system or equipment, however, the expectation is that any corrective action taken would be applied to similar systems where the same possibility of failure might exist, including other relevant locations within the organization. This should not be interpreted to mean that maintenance procedures on similar systems at all locations of an organization should be identical. Although there might be business reasons for harmonizing maintenance processes across an organization, this is not a regulatory requirement, nor is it always practical or appropriate.

2.4.6 Equipment

The US FDA 21 CFR Part 211.67 states “...records shall be kept of maintenance, cleaning, sanitizing, and inspection.” [17] The capability to track the maintenance activity on a specific piece of equipment in a manufacturing process for a drug product is important to demonstrate that proper controls exist. GMP systems or equipment should have a documented status at all times. When maintenance is being performed, a tag or identifier should be used to display clearly that the equipment or room that is undergoing maintenance is out of service.

Equipment that is used for producing a drug product should have a unique identification to distinguish it from other similar equipment. The use of a unique equipment identification scheme also provides a way to establish and track maintenance activities.

Maintenance activities may affect the cleanliness of GMP systems or equipment. Maintenance activities may also affect the performance of the equipment; a proper verification of operations is recommended.

Maintenance activities should be performed in a way that addresses drug product contamination and exposure concerns. Consideration also should be given to the tools, equipment, and materials that maintenance personnel use in the execution of their work.

It is recommended that if possible, all documentation should be performed electronically in the validated CMMS to ensure that the work is performed and recorded in the most efficient and effective manner.

2.5 Spare Parts and Materials

When parts and materials (lubricants, etc.) are applied, there should be some verification that the qualified state of the system has not been affected. Spare parts and materials management is not a specific requirement of the regulations. However, before a part is installed, its suitability for an application should be determined. Criteria should be established to determine whether a part is identical (i.e., functionally equivalent) or requires some additional evaluation or change control. The criteria should include defined roles to assess and implement part and material replacements.

When new equipment is installed, the Bill of Materials (BOM) should be established as part of the turnover package so that this information can be captured and stored in the CMMS system. A Best Practice is to have these items tethered to the CMMS system equipment ID for reference in the planning, scheduling, and ordering of parts for a work request or routine PM.

The Maintenance Good Practice approach to spare parts and materials application is to establish criteria for identifying spare parts and materials as like-for-like.

The maintenance unit should develop a procedure to determine if spare parts and materials are like-for-like. This procedure should be approved by the Quality unit. When parts or materials are deemed like-for-like, they can be installed as identical or functionally equivalent and do not require further documentation, beyond noting the installation on a WO.

If parts or materials are deemed not to be like-for-like, this constitutes a change that should be documented through the established change control process for GMP systems or equipment. Testing and requalification requirements should be established in advance of any part application. Appropriate testing should be conducted to ensure the equipment is working properly and is suitable for its intended use.

2.6 Training

A training program should be established as part of the Maintenance Program. The training program should determine the roles and responsibilities for:

- Training
- Training content
- Training delivery systems
- Evaluation of training
- Subcontractor training and qualification
- Role-based training based on job title and function
- Documentation practices

Training records should be housed in a validated Quality Management System (QMS) and include the training records of the organization's employees, contracted staff that performs work on validated equipment and systems, and all subcontractor employees who are working on GMP-related activities.

The Training Plan is the schedule of courses or learning activities that should be accomplished for a given period. Training is required for GMPs and job function. The basic skills that personnel bring to a job are normally confirmed during the hiring process. For instance, a trade qualified electrician is assumed to have the basic skills set for that trade, and therefore documentation to that effect is not usually required by the regulatory authorities.

An important concept of GMP training is that personnel should understand how their duties may impact drug product quality.

All of the organization's employees, contracted staff, and subcontractors performing work on GMP-related equipment and systems should be included in the organization's role-based training system. A training curriculum needs to be established that clearly spells out the training program required for anyone assigned to a specific role or job description.

Refer to Chapter 8 for more information about training.

2.7 Culture

It is important to establish a culture for maintenance that is collaborative in nature, where clear lines of communication are established, SOPs are developed for the various processes, and all work performed follows the SOPs irrespective of whether it is executed by an employee or a subcontractor. The establishment of quality agreements for key services should serve as the model for which the roles, responsibilities, and approvals of work performed are addressed.

2.8 Maintenance Key Relationships

The Maintenance department must have a relationship with production operations, IT, quality, finance, purchasing, engineering, and all subcontractors including IFM providers, contractors, and vendors. These relationships can be the difference between having a successful operation or one that has issues with performance. Touch points and overlaps between functions need to be identified and a working relationship between departments established to avoid conflicts and confusion as to who is responsible for a given area or issue.

2.8.1 Safety

Safety should be built into the Maintenance Plans and not be performed as an afterthought. The safety SOPs should be integrated into the site's Maintenance Plans. As part of the PM and Corrective WO Management Plan, Job Hazard Analysis (JHA), Lockout/Tagout (LOTO) Plans, and Confined Space among others must be included in the work order planning and execution. The training on the HSE SOPs should be part of the employee's and subcontracted staff's training curricula and housed in the QMS.

Refer to Chapter 10 (Appendix 2) for more information about HSE in the maintenance environment.

2.8.2 Quality Management System

A Best Practice is for an organization to have a computerized QMS to track quality issues related to the performance of maintenance and calibration activities. These systems typically house training records and role-based training curricula, Quality and HSE SOPs, Corrective and Preventive Action plans, and related documentation. In addition, employee CVs, and subcontractor certifications and CVs are stored in the system as well.

2.8.3 Operations Management

The operations team adds requirements for product contact and GMP production equipment. These include the establishment of SOPs for a variety of areas including equipment access, removal of equipment from service, any unique cleaning or sanitization requirements, test runs to prove the equipment is calibrated and set up properly, and change control procedures related to a room, equipment, and/or system.

2.8.4 Equipment Reliability

The use of reliability maintenance tools and techniques is becoming more and more commonplace. Organizations can consider installing sensors that provide real-time monitoring of equipment and conditions including the addition of accelerometers, corrosion probes, current and voltage monitoring, and related types of sensors. The goal is to reduce unplanned failures and to ensure that equipment problems are promptly addressed.

See also *ISPE Good Practice Guide: Equipment Reliability* [7].

2.8.5 Physical Asset Management

The maintenance of the physical plant including support systems, walls, floors, and ceilings as well as the utility systems maintenance can lead to a more reliable and repeatable facility. One of the keys to this program is to have a PM program that is robust enough to keep the physical plant in a safe, clean, and reliable manner.

2.8.6 Risk Management

For critical production and utility related equipment, a strategy to consider is to utilize a technique such as a criticality analysis to identify the hierarchy of what the criticality of each piece of equipment is and how it fits into the overall plant operation. Once this is established, a PM program based on risk and criticality can be established for the facility.

3 Maintenance Good Practices and Maintenance Best Practices

3.1 Introduction

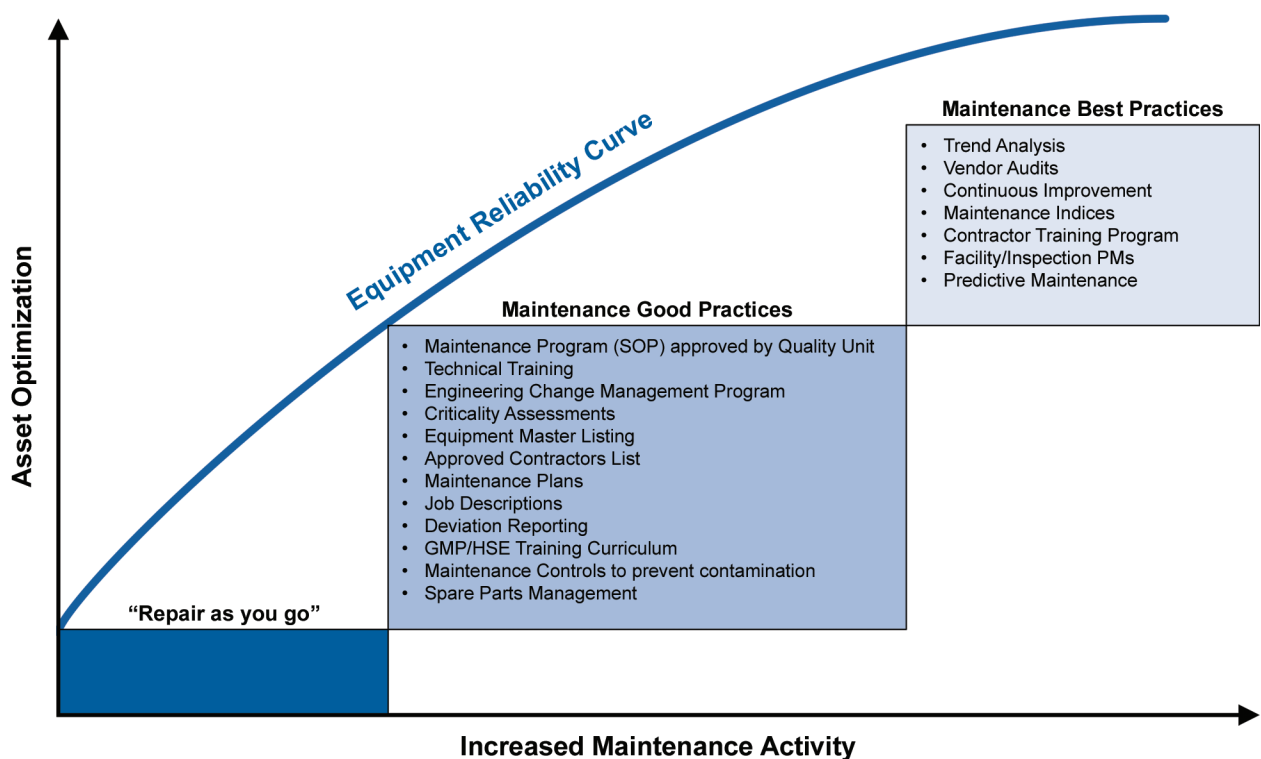
This chapter describes Maintenance Good Practices and Maintenance Best Practices for planning, execution, and management of Maintenance Program activities. Maintenance Good Practices are intended to meet or exceed the minimum requirements of GMP. Maintenance Best Practices extend beyond Maintenance Good Practices and incorporate program refinements, optimization, and advanced maintenance approaches, capabilities, and methodologies.

3.2 Overview

Design, Specification, and C&Q processes for systems and equipment supporting life sciences applications continue to mature and evolve with advances in technology and incorporation of science and risk-based approaches to asset delivery and lifecycle asset management. Maintenance activities must align with these evolving asset development and delivery approaches to support GxP compliant operations. Maintenance Best Practices described herein identify opportunities for improving maintenance performance, efficiency, and compliance beyond good practices for Maintenance Programs.

Figure 3.1 illustrates the relationship between Maintenance Good Practices and Maintenance Best Practices.

Figure 3.1: Relationship between Maintenance Good Practices and Maintenance Best Practices



3.3 Maintenance Good Practices

Maintenance Good Practices are performed to ensure and demonstrate regulatory compliance and/or because they make good business sense for asset reliability and preservation. This includes regular PM plans and schedules for each piece of equipment according to recognized industry practices and equipment vendor recommendations, technical training for personnel performing associated tasks, and maintenance documentation and records. Maintenance Good Practices are understood as those programs, actions, and processes necessary to meet the minimum needs for support of equipment performance and regulatory compliance. For Maintenance Good Practice programs, these documents and records may be paper-based or electronic. Required documentation and records include the following.

- Maintenance Policy and Philosophy
 - Maintenance actions planned and executed to meet minimum requirements of GMPs and other regulatory requirements
 - PM
 - Corrective Maintenance (CM)
- Maintenance Program
 - Basic Maintenance Plans
 - Basic equipment registry and asset management practices
 - Training for GMP and regulatory-related equipment actions
- Maintenance Management Program
 - Work execution with basic records
 - Roles and responsibilities
 - Training
 - > Training record keeping
 - > Training curricula management
 - > Training plan for vendors and contractors
 - Documentation and records
 - > User, Operation, and Maintenance manuals
 - > Engineering drawings, P&IDs, and vendor drawings
 - > Basic records for WO completion
 - > Inspection certificates, calibration certificates, and vendor support records

3.4 Maintenance Best Practices

Maintenance Best Practices build upon Maintenance Good Practices to optimize or refine Maintenance Program planning, execution, and management by the incorporation of approaches, analyses, tools, resources, and alignment with asset lifecycle activities. Examples of these include the following:

- Use of a CMMS
- Use of Maintenance Subject Matter Experts (SMEs)
- Roles and Responsibilities
 - Clearly defined for personnel including craft technicians, supervisors, managers, and approvers such as Quality Assurance (QA)
- Training Program
 - Use of computerized Learning Management System (LMS)
 - Well-defined training curricula
 - Training plans specific to crafts, vendors, and contractors
- Use of a Risk Assessment Process
 - To identify assets or components that support quality critical aspects of manufacturing systems and those supporting other regulated functions (environmental, safety, etc.)
 - To identify non-critical assets or components that may require less frequent maintenance action
- Use of a Reliability Assessment or Failure Modes and Effects Analysis (FMEA) process
 - To refine maintenance task and frequency requirements based on intended/actual use of equipment
 - To provide input for provisioning of spare parts, repair parts, and materials
- Incorporation of PdM and condition monitoring methodologies
- Integration with asset lifecycle activities such as C&Q, change control, process optimization, and decommissioning programs
- Maintenance Data and Documentation Management Program
- Proactive Maintenance Program Development and Delivery

These Maintenance Best Practices are further described in the sections that follow.

3.4.1 Computerized Maintenance Management System

The use of a CMMS provides numerous benefits and capabilities beyond what can be provided by paper-based systems. These capabilities include:

- Comprehensive asset management capabilities including asset registry, action/change history, asset information, hierarchy, location, status, and search capabilities

- Automated schedule management for maintenance actions (current/future WOs, completion status, open items)
- Generation of work plans that incorporate multiple maintenance tasks for the system or area that can be implemented at the same time while the system/area is scheduled for downtime
- Platform for management of maintenance and calibration work instructions, checklists, and completion records
- Work order planning, execution, and management
- Workload planning for maintenance resources and capabilities
- Comprehensive performance reporting and forecasting capabilities
- Activity event log and audit trail capability – suitable for support of compliance requirements
- Linkage to resource, training, and inventory management databases (internal or external platforms)
- Web-based access and management (offered by many CMMS providers)
- Automated management review of WOs

CMMS system use is widespread in the life sciences and general industry. Many organizations continue to rely on paper-based systems for a variety of reasons. Use of a CMMS-based maintenance management program offers the capabilities identified above and more in many cases, depending on the specific commercial product evaluated.

3.4.2 Maintenance Subject Matter Experts

Use of SME resources in key technical roles in the life sciences industry is considered a Best Practice and is also a developing industry practice. For maintenance applications, SMEs should be involved in multiple aspects of Maintenance Program planning, execution, and management including the review of maintenance and calibration:

- Plans
- Work instructions for technology-specific applications
- Schedules
- Task completion documentation
- Plans associated with Change Management actions
- Discrepancies, failures, and action items

3.4.3 Roles and Responsibilities

Roles and responsibilities are defined for all maintenance and calibration personnel including craft technicians, supervisors, managers, and approvers such as QA.

3.4.4 Training Program

Best Practice for training programs is the use of an electronic-based system that handles training requirements, materials, and records. All personnel are proactively trained on Maintenance Program procedures and requirements, GMP requirements, and task-level execution requirements. External training on novel technologies and best practices is provided for program development and technical advancement purposes.

3.4.5 Risk Assessment Process

During the Design, Specification and C&Q processes, quality risk assessments are conducted to identify critical components and critical design aspects (those components or aspects that have potential to impact product quality). Additional risk assessments may be conducted to identify components or design features that support other regulatory requirements (e.g., safety or environmental). The results of these assessments should be utilized as inputs to Maintenance Program development such that:

- Components or design aspects identified as critical from a GxP or other regulatory perspective are identified and assigned appropriate maintenance/calibration tasks and frequencies. QA functions should focus on this subset of components or design aspects to ensure maintenance actions are executed as planned and scheduled.
- Non-critical components or design aspects are identified and assigned appropriate maintenance/calibration tasks that may have longer intervals after initial maintenance actions and/or relaxed tolerances based on functionality and good business practice.

Refer to *ISPE Baseline® Guide: Volume 5 – Commissioning and Qualification (Second Edition)* [2] for more information.

3.4.6 Reliability Assessment Process

Another Best Practice for maintenance operations is the use of a reliability assessment process to refine scheduled maintenance requirements based on the inherent reliability of the equipment and its context of usage, potential failure modes, and expected operating life between failures. The results of reliability assessments provide maintenance task and frequency refinements beyond baseline recommendations provided by equipment manufacturers/vendors. Scheduled maintenance requirements, in turn, drive provisioning requirements for maintenance parts and materials necessary to support maintenance activities as well as workload commitments for skilled resources. Additionally, reliability assessment results can identify recommended spare parts to provision based on potential for failures or unscheduled CM actions.

Refer to *ISPE Good Practice Guide: Equipment Reliability* [7] for more information.

3.4.7 Predictive Maintenance and Condition Monitoring

PdM is a maintenance approach applied to specific types of systems and equipment based on known failure modes, likelihood of failure occurrence, and projected failure timing. The goal of PdM is to identify the optimal timing of maintenance actions; that is, perform maintenance actions just prior to projected equipment failure to avoid both unnecessary periodic maintenance and the result of equipment failures.

Condition monitoring is a type of PdM that utilizes real-time monitoring of equipment operating parameters to trend against known failure modes with the intent to intervene with prescribed maintenance actions prior to equipment failure. Condition monitoring is often used in rotating equipment applications to monitor the status of bearings or bushings based on monitoring of vibration or acoustic measurement data.

3.4.8 Maintenance throughout the System Lifecycle

Maintenance SMEs should participate in the Requirements Definition, Design, and Specification of new systems and equipment to ensure that requirements for equipment reliability, maintainability, and accessibility are addressed. C&Q activities for systems and equipment should include confirmation that appropriate maintenance and calibration programs have been established and are effective. During the Operations phase, incremental system changes or improvements should be assessed for changing Maintenance Program needs. At system retirement or decommissioning, certain activities may need to be performed (e.g., final validation and calibration close out) to confirm that the system was operating as it should at the time of decommissioning.

3.4.9 Maintenance Data and Documentation

System data and documentation are utilized as inputs for Maintenance Program development and maintenance task execution. Examples of documentation include:

- System drawings (e.g., Piping and Instrumentation Diagram (P&ID), General Arrangement (GA), piping isometric drawings, etc.)
- Installation, operation, and maintenance manuals
- Recommended spare parts lists
- BOM
- Recommended lubricants
- Recommended maintenance tasks and frequencies
- Instrument and equipment lists
- Controls information
- Sequence of operations
- Vendor equipment submittals

Documentation utilized to support Maintenance Program development should be retained throughout the life of the system.

System data is utilized by maintenance for the development of equipment registry information and maintenance task development. System data is also utilized by multiple other disciplines for testing and support programs. Typical system data includes:

- Manufacturer
- Model Number
- System Description
- System Number
- Drawing Number
- Specification Number
- Serial Number
- Equipment Range and Unit of Measure
- Process Range and Unit of Measure
- Location
- Component Tag Name(s)

- Component Service Description(s)
- Set point(s)
- Vendor Name
- Vendor Catalog Number
- Purchase Price

A Maintenance Best Practice is gathering, managing, and reviewing system documentation and data proactively as equipment is specified, procured, and received (prior to the creation of an equipment registry and Maintenance Program development). This facilitates accuracy, completeness, and timeliness of data and documentation to support program development needs. Availability and delivery of data and documentation can be scheduled to align with specific project milestones (e.g., drawings issued for construction, purchase order issued, equipment delivery, etc.) and in this manner, data and documentation can be anticipated, scheduled, accounted for, and managed in a proactive manner.

3.4.10 Proactive Maintenance Program Delivery

Maintenance Program development can be initiated as soon as system designs are confirmed and equipment design information is available. A Maintenance Best Practice is to develop the equipment registry, Maintenance Program, and spare/repair parts provisioning concurrent with system C&Q so that the systems are fully ready for operation upon turnover to operations. This helps avoid delays in initial system operation and ensures continuity of maintenance and calibration support throughout the C&Q and system turnover/delivery processes.

4 Maintenance Program

4.1 Overview

This chapter describes the Maintenance Program, its elements, and the regulatory requirements.

The hierarchy and associated terminology for an organization's Maintenance Program are as follows:

- Maintenance Program outlines the policies that describe the approach that an organization intends to use with respect to aspects of performing maintenance
- System Maintenance Strategy is the rationale (the “why”) for a particular approach being used at a system or process level
- Maintenance Plans are the specific details (the “what” and “how”) at a component or individual piece of equipment level

Note: Maintenance classifications apply to equipment, systems, and facilities. For the purpose of this Guide, the term asset is used interchangeably with equipment, systems, and facilities.

4.2 Examples of Maintenance Program (Outline), Maintenance Strategy, and Maintenance Plan

The FDA 21 CFR Part 211.68 [17] states:

“[Equipment] shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance.”

Additionally, the EU EC Directive 2003/94 [18] states in Article 8(1):

“Premises and manufacturing equipment shall be . . . adapted and maintained to suit the intended operations.”

A Maintenance Program should document an organization's approach to performing maintenance regarding aspects and requirements. The Maintenance Program should outline the policies for:

- Maintenance Plans and WOs
- Maintenance classifications (preventive, predictive, condition monitoring, corrective)
- Maintenance systems and execution (e.g., equipment identification, documentation, work order management, resource planning, scheduling, maintenance materials management)
- Risk assessment
- Spare parts management
- Deviations
- Roles and responsibilities
- Training programs, plans, and records

- Performance management (e.g., continual improvement, maintenance metrics)
- Deferred maintenance
- Maintenance interfaces
- Change control
- Contract management and outsourcing
- Self-audits or assessments

The Maintenance Program should also include management processes and controls, e.g., for incorporating new systems and the associated equipment, supervision and overview of the processes and activities, and authority to approve and make changes.

Figure 4.1 depicts key aspects of a Maintenance Program.

Figure 4.1: Key Aspects of a Maintenance Program



The Maintenance Program should define how Maintenance Good Practices and Maintenance Best Practices are to be implemented.

Examples of Maintenance Good Practices of a Maintenance Program include:

- Describing long-term vision, drivers, and goals
- Establishing maintenance technical training
- Establishing the minimal requirements for performing maintenance in the organization
- Developing an asset management plan for assets from commissioning through decommissioning
- Identification of Maintenance Plans for GMP systems or equipment
- Identification of Maintenance Plans for GMP components associated with GMP systems or equipment
- Documented rationale (System Maintenance Strategy) for maintenance performed on GMP systems or equipment
- Maintenance Program (approved by Quality unit)
- Defined approval authority and change management program for GMP systems or equipment
- Equipment master listing
- Active, up-to-date Maintenance Plans
- Job descriptions with a skills matrix to define and track required skill sets
- Active, up-to-date GMP training curriculum (employees and contractors)
- Controls to prevent GMP impacts from maintenance activities
- Vendor audits
- Contractor training program
- Approved contractor list
- 5S/6S

Examples of Maintenance Best Practices of a Maintenance Program include:

- Asset criticality assessment (based on GMP, safety, and operational risks)
- Developing and monitoring Key Performance Indicators (KPIs)
- Maintenance analytics
- Emphasis on proactive maintenance
- Spare parts management

- Facility surveillances and inspections
- Establishing a continual improvement program
- Developing and implementing Maintenance Strategies for all critical assets (including non-GMP assets)
- Risk-based maintenance strategies

The Maintenance Program provides the framework for the risk assessment. It may be beneficial to involve maintenance/reliability engineering personnel in the stages of the risk assessments (i.e., during design).

The process for handling unplanned maintenance activities should be described in the Maintenance Program, including a procedure on how unplanned work is evaluated for patient safety and product quality in addition to how approval and documentation will be managed. The Maintenance Program should also include a procedure for returning equipment and/or classified areas back to service after maintenance activities are completed, which will verify a system is returned to the qualified state.

The Maintenance Program should be developed by a cross-functional team, led by the maintenance unit, including SMEs from:

- Engineering
- Quality
- HSE

4.3 System Maintenance Strategy

A System Maintenance Strategy is a rationale or set of criteria used to develop Maintenance Plans. Inputs to a System Maintenance Strategy may include:

- System or component classification
- Quality and maintenance risk assessment
- Original Equipment Manufacturer (OEM) recommendations
- Data analysis of key process and maintenance data
- Experience with similar equipment
- Process requirements
- Intervals and tolerances
- Spare parts strategies and requirements

An example of a Maintenance Good Practice is a documented rationale for maintenance performed on GMP systems or equipment, which includes a process for handling corrective or on-demand maintenance.

The inputs to the Maintenance Strategy may have been identified during the design, construction, installation, testing, and C&Q phases of system construction. If readily available and done so using GEP, this information should be first utilized. Otherwise the following sections describe the key aspects to developing a Maintenance Strategy.

4.3.1 System Description

The system description is a brief overview of the system or components to define operating context, functions, and system boundaries. Manufacturer and model numbers of major components should be identified. Items that may be contained in the system description include:

- Process Flow Diagram (PFD)
- Block Diagram
- P&ID
- Valve and Line Schedule
- Equipment Schedule
- Operating context from RCM analysis
- C&Q documentation
- Materials of Construction (MOC)

4.3.2 System and Component Classification

The system and component classification defines:

- Location priority/criticality ranking
- GMP impact
- Process safety management (e.g., mechanical integrity)
- Environmental classification of system and components (with rationale)

4.3.3 Science-Based Quality Risk Management

Risk management is a systematic application of management policies, procedures, and practices to the task of identifying, assessing, controlling, and monitoring risks. It normally is an iterative process.

Risk management should be based on good science and product and process understanding, e.g., an understanding of CQAs, which is based upon and ultimately traceable back to the relevant regulatory submission.

Qualitative or quantitative techniques may be used. The focus should be on the risk posed to patient safety and product quality.

Risk management should reduce risks to an acceptable level. Complete elimination of risk is neither practical nor necessary.

For a given organization, a framework for making risk management decisions should be defined to ensure consistency of application across functions. Such a framework is implemented most effectively when it is incorporated into the overall QMS.

4.3.3.1 *Quality Risk Management for Maintenance*

This Guide supports a risk-based approach to the determination of which category of maintenance practices (see Chapter 3) should be applied to a system or its components. Risk management should be part of the analysis performed prior to an asset being placed in service and in many cases will involve the maintenance unit. The maintenance unit has the responsibility to apply its Maintenance Program and develop Maintenance Plans according to the risk assessment.

A QRM approach should be used to identify and manage to an acceptable level the risks associated with maintenance activities and to identify those elements of maintenance that may impact product quality and patient safety.

Risks to patient safety and product quality are not the only risks to consider. In addition to the GMP requirements, a comprehensive Maintenance Program should address other drivers for performing maintenance. The organization also may apply the same approach to other applicable risk areas such as:

- Healthy and safety
- Environmental protection
- Business continuity

However, it is expected that many of the recommended practices of this Guide will contribute toward meeting or exceeding other requirements of a Maintenance Program. It should be noted that requirements based upon other drivers may result in additional controls or activities that extend beyond the Maintenance Good Practices recommended in this Guide.

Risk management provides an opportunity to scale activities appropriately. The benefit is achieved only if organizations are prepared to use risk assessments to justify a reduction or increase in the scale of activities or an omission or inclusion of an activity.

Risk assessments may help with determining which level of maintenance practices to apply by identifying:

- Systems and components which may affect patient safety and product quality
- Systems and components for which extra maintenance practices could be applied to minimize risk to HSE or business continuity

Risk assessments also describe functional failures, failure modes, consequences, and the mitigation approach, including:

- RCM Analysis
- FMEA
- Root Cause Failure Analysis (RCFA)
- OEM recommendations
- Data analytics of key process and maintenance data
- Input from SMEs
- Operational experience

The risk-based approach should be focused and resourced for maximum effectiveness. Organizations should not invest more effort and time into the risk management process than is commensurate with the potential impact on the supported business processes. Risk assessments should be periodically reviewed and continually reviewed as additional information, data and expertise, and new methods become available.

For more information on risk management from a reliability perspective, refer to *ISPE Good Practice Guide: Equipment Reliability* [7], Chapter 4.

4.3.4 Maintenance Tasks

Maintenance Tasks may describe CM, PM, and PdM tasks with supporting rationale, if not already included in the risk assessment and required by the site. This may include:

- CMMS records
- GMP library
- Equipment manuals
- Corrective Action and Preventive Action (CAPA) or discrepancy information
- Periodic asset reviews or evaluations
- Change controls

4.3.5 Intervals and Tolerances

Intervals and tolerances may describe the rationale for the selection of intervals, on-condition maintenance or calibrations, and the selection of failure and adjustment limits. This may include:

- Critical operational data and measurement uncertainty analyses
- CMMS records
- Periodic equipment reviews or evaluations
- Change controls
- CAPA or discrepancy information
- Data analytics of key process and maintenance data

4.3.6 Spare Parts

The spare parts section of the Maintenance Strategy may describe spare parts requirements, including sourcing information. This may include:

- FMECA (to identify critical spare parts)
- CMMS records
- GMP library
- Equipment manuals

- Periodic asset reviews or evaluations
- Change controls
- CAPA or discrepancy information
- BOM
- Vendor parts information (part number, description, lead time)
- Obsolescence strategy

An example of a Maintenance Strategy template is provided in Chapter 12 (Appendix 4).

4.4 Maintenance Plan

Maintenance Plans are the specific maintenance instructions or tasks, resulting from the System Maintenance Strategy, that are performed on components, equipment, or systems. Maintenance Plans should be prepared in accordance with requirements established in the Maintenance Program and System Maintenance Strategy. The plans should be executed to maintain systems (and their components) in proper working order and to monitor performance in order to detect discrepancies or conditions that might lead to failure.

Maintenance Plans may include:

- CM and On-condition/on-performance based maintenance
- PM
- PdM
- Job plans
- Spare parts management
- Operational inspections, surveillances, and checks

Maintenance Plans resulting from the System Maintenance Strategy are usually time based or use/condition performance based, depending upon the asset and process requirements. Maintenance Plans may be commonly known as PM WOs although they can take other forms as well (e.g., corrective WOs, predictive WOs). For further information, see Section 4.5 of this Guide.

Maintenance Plans can be established and performed on a system level and/or component level. Instructions for maintenance can be common and applicable to several systems or specific to a given system or component. Tasks outlined in the Maintenance Plan should be described in sufficient detail to ensure proper and consistent work execution by the range of persons qualified to execute the work. Maintenance Plans should provide clear and concise instructions to the technician performing the tasks and should take account of the technician's knowledge, experience, and skill sets. Maintenance Plans also could include acceptance criteria for any tests and inspections to be performed to ensure proper performance.

Maintenance Plans are documents that are used when developing the tasks needed to properly maintain systems (or their components, i.e., facility, site, or manufacturing equipment). Maintenance Plans provide a consistent approach to preparing and developing the list of maintenance tasks that should be followed to ensure the continued operation and maintenance of an equipment component, process, or system in a systematic way.

An example of a Maintenance Good Practice is traceability (e.g., documentation) of maintenance performed on components in a GMP system or equipment. This could include specific details on PM, PdM, CM, spare parts, etc.

Two examples of Maintenance Plans are provided in Chapter 12 (Appendix 4).

An estimated time to complete each step should be identified as well as any parts, tools, or special equipment that is required. Additionally, any required special permits to safely complete the work should be included (e.g., confined space, hot work, working at heights, etc.).

An example of a Maintenance Best Practice is to have visual aides to go along with the maintenance task list items in the Maintenance Plan. The aides could be overlays on a P&ID showing component locations and specific tolerance or a series of pictures showing what “good” and “bad” would look like on the specific component being maintained.

If the maintenance is performed on a large system (e.g., Water for Injection (WFI) distribution system) or piece of equipment with complex PM (e.g., bioreactor), a checklist can be created to help maintenance staff in performing the tasks. An example of a Maintenance Plan Checklist is given in Chapter 12 (Appendix 4).

Typically, the first section of a Maintenance Plan should contain the PM title and the equipment or system information, such as:

- Title
 - Must include information to help searching for and locating a job plan for future use (rebuild pump, replace seal, change oil, calibrate, etc.)
- Equipment/System Identification Number or Asset Number
 - Usually as identified in the CMMS system or Equipment Master List
- Equipment/System Brief Description
 - Identifies the specific equipment that is covered, e.g., Compressor 1, Tablet Press 40 stations
- Lockout/Tagout (LOTO), Job Hazard Analysis (JHA), Personal Protective Equipment (PPE) required to perform the task and permits required (e.g., fire or confined space permits)
- Customer contact information
- Equipment/System Location
 - Identifies the physical location of the equipment within the site or facility, i.e., building number or room number, etc.
 - > Equipment/System manufacturer
 - > Equipment/System model number
 - > Equipment/System serial number
 - > Equipment/System classification (i.e., GMP or non-GMP)

- Maintenance Plan Task Type
 - Identifies the overall type of work and usually related with the craft or workgroup that executes the task, i.e., mechanical, electrical, etc.
- Maintenance Plan Task Frequency
 - Establishes the periodicity or frequency at which the specific tasks listed in the plan will be performed, i.e., weekly, monthly, quarterly, meter based on running hours, differential pressure, etc.
 - In some instances, this overall Maintenance Plan frequency is not mentioned in the header; instead the specific tasks are organized in terms of the specific frequency of execution
- Maintenance Plan Version Control
 - Allows traceability of changes over specific tasks or equipment information.

The second section of the Maintenance Plan should contain the specific maintenance task instructions that have the following attributes:

- Task or Item Number
 - Identifies Maintenance Tasks listed in the plan and lists line item numbers.
- Maintenance Task Description
 - Includes the very brief description of the work to be performed, e.g., change the oil in the gearbox, inspect and lubricate pump. Include references to applicable SOPs here if stored in a different system of record.
- Frequency
 - Identifies the frequency at which the maintenance task is to be performed, e.g., 7 days, 30 days, 90 days, 180 days, or 365 days – usually days are used rather than weekly, monthly, quarterly, etc.
 - Meter based frequencies also can be used, i.e., 100 hours, 500 hours, etc.
 - Situational frequencies based on inspection results also can be included.
- Craft
 - Identifies the type of craft or workgroup skill required to perform the maintenance task, e.g., machinist, mechanic, or electrician
- Crafts Persons Required
 - Indicates the number of crafts persons required to perform the maintenance task
- Equipment Condition
 - If the equipment should be running or shutdown when certain maintenance tasks are performed, this condition should be indicated here.
 - In some cases where a specific task is not called out for pre or post-cleaning activities, the safety condition of the equipment may be indicated here, e.g., in biological or explosive operations, a chemical clean and flush may be required before executing work to protect the maintenance technician