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GOOD PRACTICE GUIDE:

Decommissioning of Pharmaceutical Equipment and Facilities



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GOOD PRACTICE GUIDE:

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ISBN 978-1-936379-99-6

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Preface

The *ISPE Good Practice Guide: Decommissioning of Pharmaceutical Equipment and Facilities* aims to provide both definition and explanation of the process of decommissioning. This Guide is intended to be a "one-stop-shop" for the basic information required for the decommissioning of equipment and facilities. This Guide contains templates, flowcharts, and example documents currently in use in the USA and Europe.

This Guide has made use of individuals who have a great deal of experience of decommissioning, from small plant items through to complete operational sites. These individuals have been through site closures, decommissioning and product/equipment transfer. This has brought together a wealth of information and example documents that can significantly aid in optimizing the decommissioning process.

The main questions faced in these situations are:

- What do I need to do?
- What processes do I need to follow to maintain compliance?
- What documentation do I need to produce?

Decommissioning determination, detailed in this Guide, has brought a risk-based approach to the process and enabled significant reductions in the man hours that are used by focusing resource and effort where it is most needed. The risk-based approach focuses on the identification of systems and the level of testing and associated documentation required to meet regulatory requirements.

This Guide includes attachments which provide industry examples, currently in use in decommissioning of pharmaceutical equipment and facilities, together with checklists that may be useful to the reader.

The Guide is an assembly of the advice and experience from a wide range of personnel in the life sciences industry. We hope that it will help the reader avoid learning lessons the same way the authors did!

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Acknowledgements

The following members of the ISPE Decommissioning Task Team worked on one or more of the Sections of this Guide and volunteered countless hours to attend meetings and review the many drafts, which were produced over a 6-year period.

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Special Thanks

The Task Team would like to give particular thanks to Gail Evans (Technical Writer/Editor) and Lynda Goldbach (ISPE Guidance Documents Manager) for general support and professional insights, and to Michelle Gonzalez (Amgen – retired) for her work on the Glossary.

Many other individuals reviewed and provided comments during the preparation of this Guide; although they are too numerous to list here, their input and patience in supporting this guide is greatly appreciated.

Company affiliations are as of the final draft of the Guide.

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1 Introduction

1.1 Background

Decommissioning is a general term used to describe the process of removing something from active status. It may be a precursor to putting facilities/equipment into storage – maintaining a Good "x" Practice (GxP) compliant status or a non-GxP compliant status, repurposing or demolition/disposal of the item.

There are many factors to consider in this process including documentation required, process management, Environment, Health, and Safety (EHS) requirements, compliance, financial, operational, and maintenance requirements and supporting contracts, as well as interfaces with other facilities and site utilities.

1.2 Overview

The closedown of a pharmaceutical or medical device facility needs to be managed to ensure business continuity and GxP compliance up to, during, and post closure. This should be managed in a planned, controlled and cost-effective way that ensures a consistent supply of product for patients and a positive future for employees.

It is recommended that a decommissioning project plan is created at an early stage with all stakeholders.

The plan can start as a strategy document to encourage discussion and agreement on the process concepts with the stakeholders, with development into a detailed plan once the concepts, roles, and responsibilities are agreed. This should help to ensure that all factors have been given due consideration and both the scope of work and related roles and responsibilities are clearly defined. It is also recommended that a formal decommissioning checklist be used to track progress and ensure that all necessary activities are completed.

The process followed will be most effective if it is scalable. Depending on the scope and scale of the project, associated documentation may range from a simple checklist (in the case of a single system) or a detailed overall decommissioning plan that includes many systems or areas (such as decommissioning of an entire facility).

When decommissioning GxP areas or equipment, decommissioning checklists should employ the site Change Control Management Systems (CCMSs) to manage the maintenance and calibration requirements. This should include managing final revalidation, Planned Maintenance (PM) activities, and calibration close out, prior to closing the records, as well as the impact on existing qualification documentation and the related procedures for the area.

1.3 Scope

This Guide is intended to provide information on industry good practices to be used for the decommissioning and disposal of assets ranging from a single item of equipment to an entire facility.

1.4 Benefit

This Guide provides benefits including:

- Incorporation of a risk-based approach
- Consideration of both regulatory and business needs

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- Definition of a structured process
- Provision of examples and templates

1.5 Purpose and Objectives

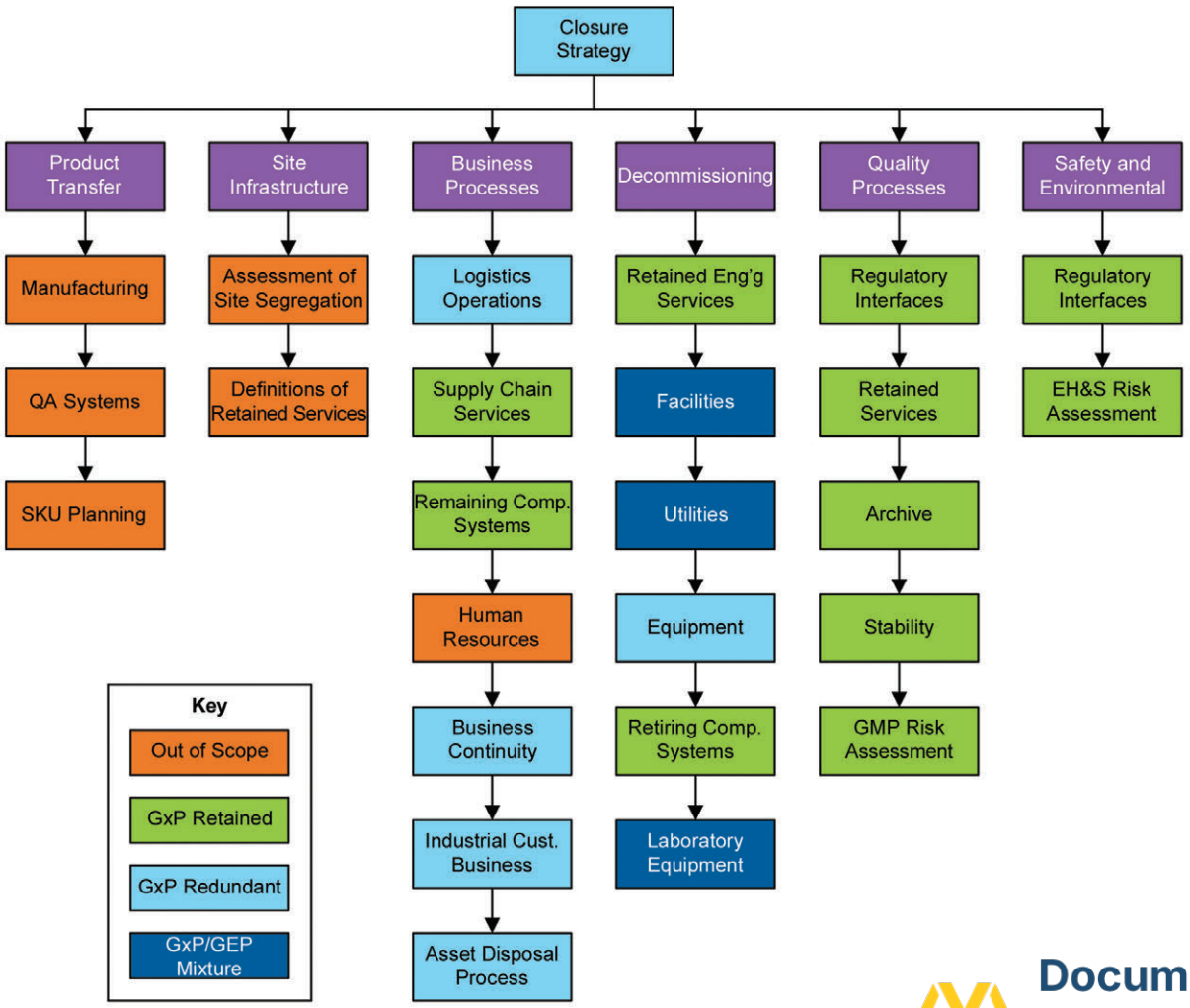
This Guide is intended as a “one-stop-shop” for basic information required for the decommissioning of equipment and facilities. It is the intent of this Guide is to highlight methods and systems that would satisfy the requirements of Regulatory Authorities based on practices that have been developed in the US and Europe.

The Guide contains templates, flowcharts, and example documents currently in use in the US and Europe. Principles described are applicable globally, though there may be specific regional requirements that are not within the scope of this Guide.

Activities need to be collated in a manageable way that can be delegated and monitored in order to achieve decommissioning. This process should enable timelines that have been conveyed to staff, corporate management, and the transfer partners to be achieved.

Figure 1.1 illustrates how a closedown process can be divided into manageable segments.

Figure 1.1: Aspects and Classification of the Closure Strategy



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Each of the above segments should have a clear objective, strategic action plan, and defined roles and responsibilities. They should be documented and agreed. Progress should be monitored.

Change management can be a weakness in corporate information systems and databases, e.g., not being updated in a timely manner. A database should show historical data for products made in a closed facility and the effective date of closure, so that data analysis across a supply chain can be performed accurately.

The process to define the decommissioning activities should be based on risk. This is defined by the decommissioning determination statements which are key to the process of this guidance. All of the items, systems, and processes to be decommissioned should be assessed and categorized as either Good Engineering Practice (GEP) or Good "x" Practice (GxP). Several activities may be common to both GEP and GxP. For further information, together with more detail on the process, see Chapter 5.

This Guide is intended to take readers through the processes needed to effectively decommission equipment and facilities using the approach described within this Guide. This Guide also provides a number of templates and worked examples of how this approach can be carried out in practice.

1.6 How to Use This Document

The checklists supplied with this Guide provide a list of items to consider when planning decommissioning activities. It is recognized that Standard Operating Procedures (SOPs), as well as local codes and regulations, may vary by site. Consequently, the persons responsible for planning the decommissioning should understand local requirements and incorporate the required level of detail necessary to ensure the desired results are achieved.

The goal of the checklists (see Appendix 1) is to promote discussion between key stakeholders, within or external to the organization, that will lead to the development of a comprehensive plan.

The Project Manager, EHS representative, or Engineer should apply professional judgment and knowledge to the planning of decommissioning activities.

There is no single template for decommissioning planning due to variations in the types, scale, and scope of decommissioning activities across the industry. Sample documents have been provided to provide a starting point for the reader. The reader may choose to use the sample documents in whole, or in part, in order to facilitate the planning and documentation of the decommissioning activity. Regardless of format, persons responsible for planning the decommissioning are responsible for generating a plan that is appropriate for the intended use.

When the full plans for the decommission activities are pulled together it is important to be able to track progress through the plans. The use of simple checklists can aid this process. These checklists can be reviewed periodically, and the items that are completed checked off. For more complex projects the plan can be used to develop a detailed schedule to assist with progress monitoring. For those items that apply, include the path forward in the plan, or include a challenge in the appropriate decommissioning checklist for the work or verify that the activity is included in some other document (change management system checklist, etc.)

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2 Key Concepts and Responsibilities

2.1 Key Concepts

The key concepts contained within this Guide include:

1. Guidance on decommissioning planning
2. The use of a decommissioning determination process
3. Planning for GEP and GxP systems

Note: The term GxP is used within this guide to show that all areas of Good Practice, required by the relevant pharmaceutical regulations, need to be considered.

This Section provides the framework and approach for the decommissioning of areas and systems used both in operations and in support of operations. The framework for this approach will be the complete set of GEP activities for areas and systems and will follow on from the GxP activities for those that have been assessed as GxP. It will also include the utilities and related systems that are associated with the areas and systems. The need for understanding direct and indirect impact will also be defined as part of Chapter 5.

When a production facility is commissioned, each system will normally have a plan defining which systems require qualification and the scope of the activity. (This document is referred to in some ISPE guidance as a Validation Determination Statement (VDS)). This plan should define whether GxP will apply to a system; this is usually done only at the start of the life cycle. As time progresses, new equipment and processes are often introduced. The assumptions made at the start of a life cycle may not continue to be valid. An evaluation, as part of the decommissioning planning, should confirm that there is an accurate list of the systems in scope, and that their category, i.e., GEP or GxP, is correctly assigned. The level of risk and potential impact to product quality should be identified as part of the documented activities to define the scope of decommissioning in the same way that this was done during start-up.

This *ISPE Good Practice Guide: Decommissioning of Pharmaceutical Equipment and Facilities*[1] shows how there are common practices that apply to the preparation and to the decommissioning determination, which lead on to taking either the GxP route or GEP route for decommissioning. These common practices are defined in Chapter 5 with more specific information in Chapters 6 and 7.

The overall structure of this Guide is based on:

- Common practices
- GxP decommissioning
- GEP decommissioning
- Asset disposal
- Demolition/remediation

The basis of this Guide is to use a risk-based approach to review what needs to be put in place to manage and document the decommissioning process. Central to this is the decommissioning determination process, which results in producing decommissioning determination statements.

[1] This Guide is structured in the same way as the *ISPE Good Practice Guide: Good Engineering Practice* [1].

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The category of the equipment, i.e., GEP or GxP, and the activities required to retire the equipment, both as GEP activities and as GxP activities, should be confirmed and defined in the Decommissioning Plan.

Environmental, Health, and Safety (EHS) issues, using Hazard and Operability Study/Review (HAZOP) and a risk assessment, should be considered, as well as pharmaceutical regulations.

It is the responsibility of the System Owner to ensure that all systems within their department/area of responsibility have a Decommissioning Determination Statement (DDS). This should be created to determine whether the systems have any direct impact on, or risk to, product quality (i.e., GxP impact).

For all systems, whether there is an impact on product quality or not, the process should be documented. This may be a single document for a group of simple items or process, or part of the Decommissioning Plan which will be specific to a more complex item, system, or process. If the item or system has a GxP impact, the GxP protocol activities should be executed prior to the GEP decommissioning activities.

2.2 Responsibilities

Responsibilities for the various activities and approvals associated with the decommissioning process should be assessed and defined for the specific decommissioning activity to be performed. The roles and responsibilities for these activities should be defined and formally captured as part of the decommissioning document set.

The specific responsibilities may vary depending on the nature of the facility or system being decommissioned, their complexity, and the result of the assessment of GxP/GEP activities.

Definitions used in this process include:

Head of Quality Assurance (QA)

It is the responsibility of the Head of QA to check that the procedures being followed comply with current GxP requirements, and ensure that all discrepancies are correctly recorded and investigated according to a defined protocol.

Head of Engineering

It is the responsibility of the Head of Engineering to check that the procedures being followed comply with current GEP requirements.

Area Manager

It is responsibility of the Area Manager or their deputy to ensure that the decommissioning plans, protocols, and decommissioning summaries are implemented and documented.

System Owner

It is the responsibility of the System Owner to ensure that the procedure described and documented is adhered to, that all systems are included within the scope of testing, and to ensure that any discrepancies, deviations and/or limitations arising from the work are highlighted and are resolved as necessary.

The System Owner is responsible for the documents and should ensure that they are completed.

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Tests

It is the responsibility of the person executing the test to ensure that the decommissioning activities are performed as stated in the protocol/dossier and are correctly documented and reported.

This process will consist of a series of tests to demonstrate the status of the system or area. The type of tests required for final decommissioning are based on those performed during routine qualification, or where applicable revalidation. The tests, the sequence to carry out the tests, and the acceptance criteria should be established in a pre-approved protocol or plan.

The documented evidence within the dossiers can be gathered retrospectively or concurrently. Where appropriate, systems can be grouped together to reduce repetition. These have been called streams (or families). A stream is defined as a number of systems, or group of equipment, that are interfaced together to perform its intended complete function or a number of identical systems.

This should produce the documented evidence that a system was operating to meet the specifications when it was removed from service, e.g., removal of an autoclave from service six months after it has completed annual revalidation:

- A revalidation should be performed with the instrument calibration closed out
- A risk-based approach may be used, e.g., a single point verification of the temperature control probe at the operating temperature rather than a full three-point calibration

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3 Key Regulatory Requirements

3.1 Background

The decommissioning of a pharmaceutical or medical device facility is rigorous and typically involves some level of regulatory agency review, regulatory inspection/survey, and permit or license closure or transfer.

There are a range of different regulations that apply, including local authority, EHS, US Food and Drug Administration (US FDA) [2], Medicines and Healthcare products Regulatory Agency (MHRA) [3], or other regulatory agencies. The process of decommissioning usually involves a similar range of requirements as Commissioning and Qualification. However, it may be more difficult to obtain environmental and functional information at the end of a product production life cycle than at the beginning.

3.2 Pharmaceutical Regulatory Authorities

The regulatory requirements for validation and qualification for decommissioning are usually less clear than those for setting up operations; however, the same basic rules apply.

Routine activities require regular checks, periodic reviews, and revalidation activities to document that the status passed at start-up is maintained throughout the operational life cycle of a system. When a system is retire or decommissioned, these checks should be performed again to verify that the appropriate state has been maintained at the end of the operational life of the system.

Example: Calibration of a Critical Instrument

If a critical instrument is calibrated every six months to ensure that it continues to meet process requirements, this calibration should be repeated at the end of operations to show that the instrument is still within specification. If the instrument is found to be out of specification, this failure should require formal investigation by a Corrective Action and Preventive Action (CAPA) or similar process, in order to investigate all production that used the measurement from this instrument. The investigation would need to identify when the instrument could last be proved to be in specification. Unless other measurements or data are available to show the parameter being measured was within specification, this could lead to product recall, with the worst case involving the recall of product since the last time the instrument could be demonstrated to be within specification.

A decommissioning determination statement should be included for each system, piece of equipment, or section of a facility. This document should provide a single point of focus to criticality and impact assessment. This process should feed into the overall decommissioning plans.

It is possible that the decommissioning determination may derive different conclusions on decommissioning determination than were obtained in the original validation determination as these would be against current requirements, risk and current knowledge of the process or system.

When computer systems are decommissioned, consideration should be given to the effect of system retirement on aspects such as:

- Strategy: the impact on the overall technology strategy should be documented. Updates to documentation or other necessary actions should be initiated.

- Process: the impact on the support of the business processes should be described.

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- Technology: the scope and boundaries of the system to be retired should be determined and documented, as well as the rationale and justification for the retirement. Other systems, instruments, or equipment that interface with the retiring system should be identified. Care should be taken to consider the locations that data and other information are stored both within and independently from the systems being decommissioned (*ISPE GAMP® 5* [4] and the *ISPE GAMP® Guide: Records and Data Integrity* [5].

- Infrastructure components (networking, etc.): those that will need to be decoupled from the system should be identified.

Data and documentation should not be disposed of until they have reached the end of the record retention period, as specified in the Record Retention policy.

Retirement can be a major task, especially for Information Technology (IT) systems, due to the volumes of data and records involved.

Consideration should be given to:

- Establishing procedures covering system retirement, including withdrawal, decommissioning, and disposal, as appropriate

- Documentary evidence to be retained for actions taken during retirement of a system

- GxP records to be maintained, their required retention periods, and which records can be destroyed

- The need to migrate records to a new system or archive, and method of verifying and documenting this process

- Maintaining the ability to retrieve these migrated records on the new system

For further information see *ISPE GAMP® 5* [4] and the *ISPE GAMP® Guide: Records and Data Integrity* [5].

3.3 Other Regulatory Authorities

In the United States, several state environmental agencies require a final environmental closure assessment. All state radiation safety agencies require some level of final survey and agency inspection for facilities that have handled Radioactive Materials (RAMs). Hazardous and non-hazardous waste generation may require final disposal with appropriate documentation (manifests) that provide a complete tracking from the transporter to the disposal site. Controlled substances will also require similar tracking with documentation for appropriate destruction of the materials. Similar requirements exist in Europe. There is a comparison of the differing regulations in the US and EU given in Section 3.4 below.

3.4 Regulatory Approvals

Regulatory agencies and bodies responsible for facility permits and licenses regulating hazardous, biological, radiological, and controlled substances in pharmaceutical facilities will vary from region to region. It is not the intent of this Guide to provide a complete list of these agencies. Provided below is a list of typical agencies that may be involved in the United States and Europe. Part of the due diligence outlined in Section 5.1.4 should include a thorough review and compilation of site permits and licenses.

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The research required to determine the requirements for decommissioning of a pharmaceutical or medical device facility can be time-consuming and should be considered when developing the project schedule. It is important to include the definition of and schedule requirements for permit and licensing in the early planning stage to account for these activities, to review and approve decommissioning plans, final status survey reports, permit/license amendment/termination requests, etc. In addition, if specific equipment is being moved or relocated to another facility, the equipment may need the appropriate licensing and permitting. This should also be captured in the project schedule and the project plans. Table 3.1 is provided as an example, for illustrative purposes only.

Table 3.1: Additional Information on Comparable Regulations Used in the EU and US

Permit/License Category	Permit	US	EU/UK
Environmental	Air Emissions	Environmental Protection Agency (EPA) State Environmental Agency	Clean Air Act 1993
	Waste Water	Publicly Owned Treatment Works (POTW)	Water Industry Act 1991
	Storm Water	State Environmental Agency	Water Industry Act 1991
	Waste	EPA, State Environmental Agency	The Environmental Permitting (England and Wales) Regulations 2007 (SI 2007 No. 3538) (as amended 2009 and 2010)
	Oil Storage Tanks	State Environmental Agency	Dangerous Substances and Explosive Atmospheres ACOP L138 (Second Edition)
	Underground Storage Tanks	State Environmental Agency	Dangerous Substances and Explosive Atmospheres ACOP L138 (Second Edition)
	Closure Environmental Assessment/Property Transfer	New Jersey Department of Environmental Resources (PADER) – Industrial Site Reauthorization Act (ISRA) Ohio – EPA Connecticut Department of Energy and Environmental Protection (DEEP) – Property Transfer Program	Not Applicable
Finished Product	Drug Master File	US Food and Drug Administration (US FDA)	US Food and Drug Administration (US FDA) Notified body (e.g., Lloyd's Register Quality Assurance (LRQA))
Biological Materials	Biological Materials	Center for Disease Control/ National Institutes of Health (CDC/NIH (US)) – National Select Agent Registry	Advisory Committee on Dangerous Pathogens Infection at work: Controlling the risks

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Table 3.1: Additional Information on Comparable Regulations Used in the EU and US (continued)

Permit/License Category	Permit	US	EU/UK
Controlled Substances	Controlled Substances	US Drug Enforcement Administration (US DEA)	Controlled Drugs (Drug Precursors) (Intra-Community Trade) Regulations 2008 (SI 2008 No. 295) Controlled Drugs (Drug Precursors) (Community External Trade) Regulations 2008 (SI 2008 No. 296)
Hazardous Chemicals	Hazardous Chemicals	Municipal or County Fire Department	Control of Substances Hazardous to Health Regulations 2002 as amended
Alcohol	Ethanol Use	State Alcohol Beverage Control Board Dept. of the Treasury Alcohol and Tobacco Tax and Trade Bureau	Excise Notice 473: production, distribution and use of denatured alcohol
Radiation	Radiological Material (RAM)	State Radiation Safety Agency	Control of Artificial Optical Radiation at Work Regulations 2010 (SI 2010 No.1140) Ionising Radiations Regulations 1999 (SI 1999 No.3232)
	Radiation Producing Equipment	State Radiation Safety Agency	
Pressure Vessels	Pressure Vessel Permits	State Department of Labor	Pressure Systems Safety Regulations 2000 (S.I. 2000/128)
Elevators	Elevator Certificates and Inspections	State Department of Labor	Lifting Operations and Lifting Equipment Regulations 1998 (S.I. 1998/2307)
Fire Safety	Fire Hose, Alarm, Hydrant, and Sprinkler Inspections	State, County or Township Approval or Permit	The Regulatory Reform (Fire Safety) Order 2005
Transportation	Hazmat Registration	US Department of Transportation (US DOT)	European Agreement concerning the International Carriage of Dangerous Goods by Road ADR applicable as from 1 January 2013
Note: Other regional and local codes may apply			

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4 Closure Planning

Planning for the closure of a manufacturing facility should be comprehensive and will involve a broad range of activities supported by multiple business and technical disciplines.

Closure of existing manufacturing facilities and removal of production assets from operational use follow a life cycle process. The life cycle starts with defining and approving the business case for closure and concludes with attaining the desired future state.

A Closure Plan should be developed and should provide sufficient detail to allow the implementation, management, and completion of the closure process; the plan may begin as a strategy document used to obtain agreement between all parties of the concepts. The following topics should be included and developed in the Closure Plan:

- Strategy development
- Business case summary
- Scope
- Business impact
- Requirements
- Activities
- Deliverables
- Transformation steps

4.1 Strategy Development

This should define the scope and allow initial definition of the strategy for team and management agreement before the plan is developed.

4.2 Business Case Summary

The business case should include the rationale and justification for the manufacturing facility closure, the desired future state and an overview of the transition process. A business case is typically a comprehensive study, so a summary should be provided for the Closure Plan.

4.2.1 Rationale

The rationale and justification should be specific in terms of the benefits to be accomplished and inherent business risks associated with the manufacturing facility closure and should be backed up by supporting analyses. Rationales may include:

- Product discontinuation
- Facility obsolescence
- Operating costs

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- Temporary, extended shutdown (product demand)
- Redundant capabilities
- Outsourcing
- Compliance risks (Environmental, Health, Safety, GxP, etc.) versus cost of renovation or remediation
- Facility sale or transfer

4.2.2 Desired Future State and Transition Process

The desired future state should be communicated explicitly and documented in terms of ultimate goals and objectives. Goals and requirements relating to the transition process, including any phased capabilities, incremental shutdowns, or a future restart for operation should be defined and documented. Maintenance, calibration, and monitoring requirements during the transition period should also be considered and planned as required.

4.3 Scope Definition

The complete scope of the capital assets included in the planned closure should be defined and documented to establish the basis for all activities needed to complete the closure, decommissioning, and disposition process.

4.3.1 Site

The facility or portions of the facility to be closed, decommissioned, or divested should be described.

4.3.2 Facility

Facilities on the site that are included in the scope should be identified and described.

4.3.3 Facility Area

Decommissioning may involve only a specific area within a manufacturing facility, with the remainder of the facility continuing in operation.

Decommissioning may also be a phased activity, where a partial declassification of a manufacturing facility is required while production activities continue in another area. A partial declassification of a site should define expectations clearly and assess the impact on continuing operations, e.g., where production has ceased, but stock remains in the warehouse. In this case, the production area can be formally declassified and decommissioning initiated; however, supporting activities such as site security, pest control, and warehouse environmental control and monitoring should continue in a revised form.

A risk control plan may be used to define Good Manufacturing Practice (GMP) risks to the operating part of the facility and the associated controls for approval by Quality.

The specific areas of a facility to be decommissioned should be clearly identified and documented and boundaries established. Services such as piped utilities, Heating, Ventilation, and Air Conditioning (HVAC), electrical, etc., that pass through the area but are to remain in service for other operating areas, should be clearly identified. Unplanned service interruptions to operating areas should be avoided during the decommissioning process.

Where a facility is to be mothballed, the need for ongoing site management activities, e.g., security and fire protection, should be considered.

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4.3.4 System/Equipment

Decommissioning may involve specific systems, major equipment items, or portions of a system within a facility that will otherwise remain in operation. These systems and equipment items should be clearly identified and documented and boundaries established.

Where only portions of a system are to be decommissioned (e.g., Purified Water distribution to facility second floor), boundaries should be defined. The boundary definitions should be accompanied by descriptions of the specific interfaces between what is to remain in service and what is to be decommissioned.

If it is envisioned the decommissioning activities are likely to be phased, the plan should take account of the control measures required, e.g., status labeling for equipment not in use/clean/ decommissioned (no longer requiring calibration/maintenance).

Critical maintenance should continue until equipment is out of use, e.g.:

- Cleaning of out of use areas that impact on areas that are still in use, e.g.:
  - Sanitation actions for sinks and drains should be continued
  - Flushing regime for high purity water points in areas not in use may be necessary based on the design of some systems to prevent localized increase of bioburden
  - Calibration of critical instruments and controls should be continued

Environmental monitoring actions should continue in critical areas (and potentially adjacent areas, if considered necessary) throughout the decommissioning process.

Individual components are not typically decommissioned on a stand-alone basis, but are considered part of a system or equipment item being decommissioned. Removal/replacement of an individual component is considered a normal maintenance activity.

Closure Plans should include a documented assessment of the data held on equipment and systems which are to be decommissioned.

4.3.5 Supporting Systems/Services

Systems or utility services that support assets to be decommissioned should be identified, particularly if these services/systems are to remain operational to support other areas of a facility or other processes. Decommissioning of service Points of Use (POUs) may be required. The decrease in demand for these services may provide additional capacity for other needs. Boundary definition at these POUs should include documentation of the specific interfaces between the supporting system and an asset to be decommissioned.

4.3.6 Other Supporting Assets

The scope should identify any portable or remote assets or services that are used exclusively in support of an asset to be decommissioned, e.g.:

- Spare parts
- Portable equipment
- Special tools

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- Handling and test equipment
- Documentation
- Electronic records

4.3.7 Product and Process

Specific products, processes, and supporting operations (e.g., laboratory support, shipping and receiving samples management (retention and stability)) should be identified and described. Product divestment/transfer activities may require the establishment of cross functional transfer teams and responsibilities defined for change control actions and regulatory variations.

4.4 Planning and Scheduling

Planning and scheduling activities associated with facility closure can be initiated once the Business Case is approved. Planning and scheduling activities are iterative and should start with the initial high-level information that was established in the Business Case should be developed to the level of detail necessary to guide execution of closure activities unambiguously. The plan and associated schedule should be sufficiently comprehensive to address all topics discussed in this Chapter.

The plan and schedule may be revised at selected Facility Closure project milestones, as additional or revised information is available.

Depending on the scale of the project and the need for different specialist teams, the plan may consist of subplans and involve subteams. Aspects covered by the subplans and subteams can include, e.g.:

- Facilities
- Equipment
- Laboratory equipment
- Computerized systems and documentation
- Archiving and handover of data custodianship to external groups

Interface points between the specialist teams should be understood and schedules communicated. Potential conflicts in schedules should be discussed and resolved.

4.5 Impact Assessment

A detailed impact assessment should be performed, based on the Business Case and defined scope of assets, product, and processes being decommissioned. The impact assessment should identify the impact on other aspects of the business and on those facilities and systems required to remain in a qualified state during the decommissioning process. While this assessment has likely been addressed at a high-level as part of the Business Case, additional details will need to be determined which in turn will enable further risk assessment to facilitate planning.

Closure Planning should include:

- Definition of the assessment processes to be utilized

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- Scope of areas and activities to be assessed
- Roles and responsibilities
- Review and approval requirements
- Communication of results

4.5.1 Financial

The financial costs and/or benefits of closure planning, including those related to the decommissioning and divestiture processes, as well as any fees and penalties involved should be understood and defined in detail. These may include costs, benefits, fees, penalties, or expenses attributed to:

- Taxes
- Insurance
- Sale of assets
- Depreciation
- Demolition/salvage/disposal
- Contractor support fees and expenses
- Remediation
- Personnel
- Regulatory fees or penalties
- Legal expenses, fees or penalties
- Cancellation of support contracts
- Cancellation of supply chain agreements

Financial information and planning should be kept strictly confidential and may need to be defined in a separate document, rather than in the overall Closure Plan.

4.5.2 Administrative and Human Resources

Closure Plans should include administrative and Human Resource (HR) considerations associated with closure planning. These may be considerable and could potentially involve reallocation of employees. The effect of staff consultation and outplacement activities should be factored into resource requirements for closure planning to allow sufficient contingency.

Administrative and HR considerations and planning should be kept strictly confidential. These considerations could be defined in a separate document rather than the overall Closure Plan.

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4.5.3 Product and Process

The impact assessment should address impact to or disposition of product(s) and process(es) affected by facility closure or decommissioning. The impact on product and process should be assessed thoroughly, as significant business and regulatory considerations will usually need to be addressed. Product discontinuation or transfer of processes to other facilities may be the primary driver for facility closure.

Typically, this is the longest phase of the closure program. It may involve selection of, and transfer to, a third party for production or analysis, or both. Consideration should be given to the time involved in method transfer activities, manufacture of and testing of stability batches, as well as the initial technical transfer activities. Management and ownership of change control activities by giving and receiving parties, as well as regulatory specialists, is considered essential to maintaining these timelines.

4.5.4 Capital Assets

The closure planning impact assessment should identify and assess the impact to all facility, systems, and equipment and the associated documentation and data archiving/migration requirements directly affected by the closure. To the extent known, the future disposition of these assets should be identified so that associated planning can be developed. Asset disposition may include the following:

- Sale or transfer of ownership
- Repurposing *in situ*
- Repurposing and transfer to other area for storage or operational use
- Disposal/salvage
- Remain in-place with caretaker status
- Remain in-place, abandonment

4.6 Regulatory

Impacts to GxP Regulatory status may include product registrations/submittals, process definition, facility registrations, and associated documentation and records. Environmental, Health and Safety Regulatory status may also be affected by facility closure. The impact assessment should identify all potential regulatory actions which need to be addressed.

4.6.1 Post-Operating Validation Requirements

Following the final process use of a GxP equipment/system to be decommissioned, Post-Operation Verification/Validation activities should be conducted. These should confirm that Critical Process Parameters (CPPs) remained within previously verified ranges and the equipment/system remained fit for its intended use through completion of final processing. Calibration checks or recalibration should be conducted to demonstrate that critical instruments remained in calibration through completion of final processing. The decommissioning review may include a summary of associated change controls, maintenance records, deviations, and validation reports and, where applicable, final media fill, filter integrity testing, Purified Water (PW) system monitoring, and particulate monitoring of process air. This should be compiled into the Post-Operation Verification/Validation.

The Closure Plan should include an inventory of equipment and systems and assess all Post-Operating Validation Requirements, methods, and deliverables for GxP systems similar to the content of a Verification Plan for new or renovated Facilities, Systems, and Equipment.

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4.6.2 Environmental, Health, and Safety

Closure Planning needs to address Environmental, Health, and Safety considerations.

4.6.2.1 Life Safety Systems

Life safety systems (fire alarm, fire suppression, emergency announcement systems, help/notification systems, breathing air systems, etc.) may be deactivated as part of the closure/demolition processes. The Closure Plan should identify systems that will no longer be active, timing of deactivation, and work-around/contingency procedures that will be established to ensure the safety of onsite personnel involved in facility closure/demolition.

4.6.2.2 Emergency Egress

The Closure Plan should identify how changes in emergency egress routes will be addressed as facility closure/demolition progresses. Additionally, changes in emergency egress routes impacting adjacent areas outside the scope of the Closure process should also be addressed.

4.6.2.3 Personal Protective Equipment

Requirements for Personal Protective Equipment (PPE) must be established and communicated in the Closure Plan, including general requirements consistent with site operations and additional specific requirements reflecting demolition activities. The Closure Plan should also address demolition/decommissioning contractor responsibilities for managing PPE requirements.

4.6.2.4 Remediation

The Closure Plan should include identification of known remediation requirements and provide instructions/action plans for addressing potential remediation actions discovered during the closure/demolition process.

4.6.2.5 Permits

Requirements for cancellation of special permits associated with operations to be discontinued should be identified and addressed by the Closure Plan. These may include:

- Air emissions permits
- Waste emissions permits
- Hazardous material permits
- Baseline emissions report as per the EU Directive 2010/75/EU on Industrial Emissions [6]
- Others

4.7 Legal

Legal considerations include liabilities or benefits that may be associated with facility closure, including compliance with local codes and ordinances that may no longer be applicable following facility closure as well as applicable requirements for disposal of certain assets. Legal fees may include representation, consulting, litigation, penalties associated with cancellation of contracts, or other considerations that must be understood and applicable planning developed and resources allocated. Insurance requirements for liability coverage and capital asset protection must be addressed for the transition process as well as for future state needs. The legal department should be involved in closure planning as an integral part of the team.

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As part of the product transfer process, existing supplier agreements and associated Quality agreements should be transferred or retired.

The impact assessment should include a complete evaluation of potential legal liabilities or benefits that may be associated with facility closure including termination of services contracts and other contractual agreements. This can include compliance with local codes and ordinances that may no longer be applicable following facility closure as well as applicable requirements for disposal of certain assets. Termination of contractual obligations, insurance requirements for liability, and capital asset protection must also be assessed.

4.8 Divestiture Method

Closure planning should include identification of the divestiture methods that will be employed. Multiple divestiture methods may be employed within the scope of a single closure project.

4.9 Requirements Definition

The requirements definition process must be included in Closure Planning and should consider areas and activities that are directly or indirectly impacted by closure. The Closure Plan should identify the process for defining requirements, scope, roles and responsibilities, review and approval, and communication of results.

4.10 Engineering

Engineering typically plays a significant role in the decommissioning of facility, systems, and equipment. Engineering activities include:

Conducting engineering studies and developing deliverables to identify the overall effect of the decommissioning process on adjacent or supporting facilities and systems, including:

- Facility civil and structural
- Facility airflows
- Facility personnel, process, and material flows
- HVAC zoning drawings
- Security and egress drawings
- Utility system capacity and diversity study updates
- Definition of boundaries for the demolition/decommissioning process and development of demolition drawings and specifications
- Development of specifications defining acceptable demolition and disposal methods
- Development of drawings and design reports reflecting the desired future state
- Coordination with Operations and EHS to identify hazardous materials that have been used to support the process and may still be present in piping systems or other equipment, even in trace quantities

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- Coordination with Operations and EHS to define requirements and appropriate decontamination, removal and disposal processes for systems and equipment that have been exposed to hazardous materials

The Closure Plan should identify the scope of the Engineering effort that will be required for the project, including Engineering Design Phases (e.g., concept, detail demolition design, etc.), contract engineering support requirements, and required deliverables.

Post completion of site decommissioning if the site is later to be reinstated from its GEP mothballed state, a detailed recommissioning plan will be required.

If part of the plant is to be kept operational, a risk control plan is typically developed to demonstrate that risks to the ongoing operations from the decommissioning activities are being adequately managed.

4.11 Demolition

Demolition planning should be described in general terms only since detailed demolition requirements, plans, schedule, and activities will need to be developed by Engineering and/or demolition contractors. The Closure Plan should identify at a high-level the scope of the demolition activity, special considerations, applicable procedural requirements for EHS, applicable procedures and methods required to protect adjacent areas or systems outside the scope of demolition, contractor qualification requirements, and other requirements that must be supported by the demolition activity.

4.12 Decommissioning Verification Program

The Closure Plan should identify at a high-level the Decommissioning Verification Program that will be utilized, including the decommissioning approach, responsibilities (by organization), expected scope of activities, and associated deliverables. Decommissioning Verification is a Good Engineering Practice that verifies and documents the desired end state has been achieved.

A separate, detailed Decommissioning Verification Plan should be developed in sufficient detail to define the requirements, methods, activities, and specific deliverables necessary to complete decommissioning for each facility, system, and equipment item in scope. For smaller projects this may be a report summarizing the verification of the activities described in the Decommissioning Plan.

Note: GxP considerations for facilities, systems and equipment should be addressed by the Post-Operation Validation Program for products and processes previously supported.

4.13 Disposition of Facility, Systems, and Equipment

Facilities, systems and equipment will be dispositioned according to the divestiture methods defined for the closure process. Numerous requirements and activities may be necessary to safely prepare and disposition the assets for reuse, storage, or disposal. These activities may include:

- Cleaning
- Decontaminating
- Reviewing/assembling equipment history to identify exposure to hazardous materials or restricted substances
- Phased demolition/decommissioning requirements

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These general requirements should be identified in the Closure Plan along with acceptable methods and procedural requirements. System-specific requirements should be developed further by Engineering and/or the demolition contractor and be conveyed in specific planning documents.

Requirements and activities necessary to disposition facilities, systems and equipment will vary based on the divestiture method and planned future state for each (e.g., disposal, storage, transfer, remain in-place with caretaker status, etc.).

It is important for the company to determine the minimum requirements for equipment to be saleable. Definitions of cleaning standards required for cleaning verification should be established early on in the process, these could be based on local requirements or corporate guidelines. Minimum cleaning verification limits should be set for the cleaning of production equipment as fit for sale. **Note:** this is a health and safety limit and not related to GxP as the limit may extend to the disassembled unit not just product contact parts but could include motors, etc., where visually clean is not achievable. In addition, some equipment may be old and not comply to current safety labeling, e.g., not being CE marked.

Equipment or systems to be sold or disposed of should have guidelines as to the need for deletion of company sensitive data and personal information; if this cannot be deleted the equipment may not be transferable. The need for safety certification dependent on local legislation should also be established before sale or transfer of equipment begins.

In cases where portions of a site or facility are to be sold or transferred to other owners, the impact of divestiture to ongoing operations must be studied and resolved. This should include utilities distribution, site/facility access, etc.

4.14 Disposition of Product and Process

Planned disposition of products and processes affected by facility closure should be addressed in the Business Case and further described by the Impact Assessment. Detailed planning for product and process disposition should be addressed by separate planning.

Closure planning and product and process disposition should be supported by coordination and execution of all other activities in the closure process. The Closure Plan should identify the intended product and process disposition so that coordination activities can be conducted in conjunction with the closure process. These activities may differ based on the intended disposition of product and processes, including:

- Transfer of operations refer to the *ISPE Good Practice Guide: Technology Transfer (Second Edition)* [7]
- Temporary shutdown of operations
- Termination of operations
- Location of retention samples and documentation

4.15 Acceptance and Release (End State)

Requirements and expectations for an acceptance and release process should be defined within the Closure Plan. Acceptance and release provides confirmation by stakeholders that all requirements and activities defined within the Closure Plan have been met with satisfactory results and there is adequate documented verification that the Closure Process is complete.

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4.16 Communication

A communications plan should be included in the Closure Planning process. Planning should address:

- Requirements and methods for communicating status of the closure/demolition process (internally and externally to the company, where applicable)
- Incremental changes in operational status, de-energization of systems and equipment
- Changes in requirements for PPE
- Emergency situations and communication

4.17 Security

Security requirements must be addressed in the Closure Plan, to include:

- Maintaining site/facility security and prevention of unauthorized access
- Maintaining security of facilities with respect to preventing ingress of water, weather, insects, vermin, etc.
- Maintaining security of confidential information relative to facility closure project activities

4.18 Protecting Adjacent Operations

Requirements and approved methods for protecting operations adjacent to facilities/systems undergoing demolition must be addressed in the closure plan. This may include:

- Construction of physical barriers to prevent ingress of contamination
- Airflow and pressurization control
- Environmental monitoring. Risk assess the need for increased environmental monitoring activities.

  Factors to consider include reduction in demand for purified water as areas are decommissioned continued flushing of all ring main points. Out of use area sinks and drains may require disinfection and area cleaning. Should a part of the system be taken out of use, a change control will be required that details system shutdown/start-up, storage during commissioning.
- Rerouting of personnel, product or material flows. Effective signage will be required for areas decommissioned/not in use.
- Local personal protection equipment

4.19 Change Management

Engineering change management/GxP change management processes should be utilized to document and manage incremental changes to the closure/demolition process. The Closure Plan should identify the process to be used and applicable procedures to be followed.

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4.20 Adverse Event Response

During the closure and demolition processes, site and local capabilities for responding to adverse events may be impacted or may transition to other capabilities as the closure and demolition processes progress. The Closure Plan should identify procedures for responding to adverse events including during all transition periods.

4.21 Community Outreach

Communication of planned closure/demolition activities having the potential to affect the surrounding community should be addressed in closure planning, to include:

- Temporary closure or detour of public roads
- Increased truck traffic, changes in site access points
- Discontinuation of previously known hazardous operations
- Removal of hazardous substances from the site
- Hazardous operations associated with the closure/demolition processes
- Other activities that may affect the community.

Community outreach communications and information releases must be aligned with the overall Communication Plan and Information Security requirements.

4.22 Documentation

Documentation requirements associated with facility closure include information to be retained (e.g., facility, system, and equipment information) and transitional or temporary documents (e.g., demolition drawings). Specific information requirements for each discipline/activity should be defined and addressed in the Closure Plan. Detailed information requirements may be addressed by discipline-specific plans and requirement documents and should define which documents are to be retained and which are temporary or transitional. Documentation requirements pertain to printed documents and records as well as electronic records. Unique requirements for electronic records should be researched and determined during the Decommissioning Planning process.

It is recommended that an archived document and sample index be created to enable future retrieval.

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5 Common Practices for GEP and GxP

The closure of a pharmaceutical or medical devices manufacturing facility needs to be managed to ensure business continuity and GxP compliance up to, during, and after closure. The closure should also be managed in a planned and controlled way that ensures a consistent supply of existing products to patients, as well as ensuring that regulatory requirements are met in the most cost-effective way.

5.1 Health and Safety

Specific health and safety procedures should be developed for each stage of the decommissioning process, and consider a range of aspects from the effect of closure on the staff to the processes of demolition and remediation.

5.1.1 Health and Safety Plan

A site-specific Decommissioning Health and Safety Plan (HASP) that covers planned activities and associated engineering controls, work practices, and PPE requirements should be developed prior to commencing any site decommissioning work. Where no additional precautions are necessary, the plan may refer to existing Health and Safety Plans such as the:

- Chemical Hygiene Plan
- Emergency Response Plan
- Exposure Control Plan
- Spill Prevention
- Control and Countermeasure Plan
- Waste Guide

This HASP should address the appropriate resources and procedures for handling different types of waste generated during decommissioning. Procedures for mitigating potential site safety concerns should also be addressed.

This HASP should be prepared in accordance with Occupational Safety and Health Administration's (OSHA) requirements as listed in 29 CFR 1910.120(b)(4) [8] or other applicable regional standards. Recommended elements of the HASP include:

- Site hazard assessments
- Personnel protective equipment
- Decontamination procedures
- Site controls
- Site communications
- Emergency Contingency Plan

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5.1.2 Training

Personnel should be trained on the requirements of the Decommissioning HASP prior to and during (as necessary) decontamination/decommissioning activities.

5.1.3 Working Planning and Exposure Control

Where feasible, exposure control during cleaning and decontamination activities should be accomplished through engineering, PPE, and procedural controls.

Engineering Controls

- The existing air-handling system should be utilized during cleaning and decommissioning. It should provide conditioned air and maintain the work areas negative to transition and clean areas.
- Hot Zone: the hot zone is defined as the area where cleaning is being performed. Personnel should wear appropriate PPE in the hot zone, as specified in the HASP.
- Decontamination Zone: the decontamination zone is defined as the area where personnel should gown and de-gown. For contract personnel actively engaged in cleaning, the decontamination zone should be identified as part of the site characterization plan for the work areas.

Personal Protective Equipment

- Work should be performed using the Personal Protective Equipment (PPE) identified according to the task in the HASP.
- Company personnel, contract personnel, and site visitors should put on appropriate PPE prior to entering work areas.

Risk assessments should consider the nature of Active Pharmaceutical Ingredient (API) residues which are likely to be present at the facility, as well as any hazards posed by the cleaning agents used.

Procedural Controls

- Work should be performed following the safe work procedures identified according to the task in the HASP.
- Site inspections should be conducted to verify that the cleaning methods described in the HASP are utilized and a Site Visit Checklist should be completed.
- Personnel should wear the relevant PPE listed in the HASP.
- There should be no lone working in any closed room. Workers should be in contact with a supervisor via radio.
- Room air pressurizations should be monitored at the beginning of each work shift. A log should be maintained to document air pressurization.
- Solvent containers should be approved for flammable liquids. Open containers should not be permitted.
- Solvent dispensing should be performed in a designated area. Dispensing should be performed using approved bonding, grounding, and dispensing equipment.

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5.1.4 Due Diligence

The following list covers a series of questions that may be asked by prospective buyers of a facility as part of the due diligence process which is a requirement for some regions.

Note: Information provided must be compliant with local regulations.

Due Diligence Enquiries

Proposed buyers may request full and complete replies to the pre-contract enquiries from the seller. A complete copy of a referenced document should be provided.

EHS Organization and EHS Management System

a. List any facility employees with responsibility for managing (or advising on) EHS issues, including occupational health and hygiene issues. State how much of their time is allocated to EHS.

b. Provide details of any EHS reports or audits carried out in the last five years, whether external or internal, and any actions taken as a consequence.

c. Provide details of any environmental impact assessments (for planning or other purposes) performed in relation to the facility.

d. Provide details of all EHS training provided at the facility during the last 12 months, including topics, durations, numbers of people trained, etc.

e. Provide key EHS performance data for the facility for the past five years. Include data on Lost Time Injury and Illness (LTII), environmental releases, and any other site performance indicators for EHS.

f. Provide details of any external recognition or certification received in respect of EHS, such as ISO 14001 [9], OHSAS 18001 [10], and local award schemes.

Compliance with EHS Legislation

a. List all EHS laws and regulations currently applicable to the facility and the current status of compliance with them.

b. Has the owner been advised of the breach of any EHS legislation with respect to the facility?

c. List any EHS laws or regulations that have been proposed by regulators which would apply to the facility. Describe any potential effects or consequences on operation of the facility.

Compliance with Facility Consents

a. List all EHS consents (including permits and authorizations) that have been issued to the facility by any statutory body, including a timetable for renewal of such consents. Include any consents relating to water discharges, noise emissions, emissions to air, storage or handling of materials, treatment and disposal of wastes, etc. Provide copies of any EHS consents.

b. Provide details of any appeals or other proceedings, discussions or negotiations with any relevant body with respect to the granting, revocation, renewal, or variation of any EHS related consent.

c. Would any EHS consents need to be reissued following a change in ownership of the facility? If so, could the conditions become more stringent when reissued?

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d. Confirm that all conditions attached to facility EHS consents have been and are being complied with.

General EHS Liabilities and EHS Adverse Events

a. List any EHS issues, at the facility or any neighboring property, which may give rise to a potential or real liability for the facility (e.g., land contamination, employee injury or illness). Provide details of any steps taken to mitigate the liability (e.g., remedial work or compensation) and any actual or estimated costs.

b. List any EHS prosecutions, enforcement notices, notices of violation, or any other legal actions, involving the facility in the last five years. Describe the outcomes of these actions.

c. Is the seller aware of any actual, intended or possible legal proceedings in relation to EHS matters affecting the facility or any neighboring property?

d. Describe any polluting incidents that have taken place (or are taking place) at the facility, including the entry of hazardous substances into any surface or ground water or public or private sewer. In each instance, provide the following:

- Copies of any reports, correspondence, court orders, notices or recommendations relating to the incident
- Details of any remedial work carried out, including certificates of satisfactory completion

e. Provide a list of all work related occupational illnesses diagnosed in the last five years that have been linked to work at the facility.

f. Provide a list of all injury or illness compensation payments made to employees (or their families) in the last five years.

g. Provide details of any health surveillance (including audiometric testing) undertaken for facility employees and the results obtained.

h. Provide a list of all complaints received from neighbors and the local community in the last five years, together with information on how these were resolved. (Include complaints relating to noise, air emissions, odors, vehicle movements, etc.)

Facility Location and Access

a. Provide details on the local geology and ground characteristics. Include information on the facility's proximity to:

- Earthquake zones or fault lines
- Existing, abandoned, or planned mine workings
- Existing, capped, or planned landfill sites
- Overhead or underground power cables transmitting high voltage electricity
- Recognized or suspected ecologically sensitive areas

b. Has the facility (or its immediate surroundings) ever suffered from flooding, either from local rivers or storm surges?

c. Is it likely that there are unexploded munitions or chemical ordnance in the site or nearby?

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d. How many onsite parking spaces are there?

e. Is there adequate access for emergency vehicles to all parts of the facility?

f. Describe the security measures in place to prevent unauthorized access to the property, buildings, external stores, etc.

Environmental Considerations

Soil and Groundwater

a. Provide a summary of the history of the property and all neighboring properties.

b. Is the site on an area of water extraction or over an aquifer?

c. Has the site been entered upon any statutory register to indicate the presence or possible presence of hazardous substances in the soil or groundwater?

d. Has the ground water or any aquifer beneath the property, or any neighboring property, been contaminated by hazardous substances, sewage, or any other substance that presents a potential hazard to health?

e. Has any remediation of soil or groundwater ever been requested or carried out? If so, please provide details.

f. Have there been any site investigations to assess the condition of the property's soil and groundwater? If so, provide copies of relevant reports and tests.

g. Has the property ever been used for any potentially contaminative use?

h. Are there any past or current potential sources of soil or groundwater contamination at the facility, i.e.:

- Has waste (including construction waste) from the site, or elsewhere, ever been dumped above ground, buried or burned on the property?
- Has the property ever been derelict land?
- Are there currently (or have there ever been) any pits, ponds, or lagoons on the property in connection with waste treatment or waste disposal?
- Has hardcore, rubble, soil, sand, or any other material been brought onto the property which originated from a contaminated site or is of an unknown origin?

i. Please confirm that the land upon which any buildings and structures on the property have been constructed is not reclaimed, "made", or filled land.

j. Is there currently, or has there ever been, any evidence to suggest potential contamination of soil or groundwater at the facility, e.g.:

- Stained soil or significant evidence of damage to vegetation?
- Flooring, drains, or walls that are stained by substances other than water or are emanating noxious odors?
- "Aggressive" ground conditions where special protective measures are required to protect concrete or other underground structures?

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- Chemical damage to underground telephone cables, electrical cables, fiber optic cables or other utility media?

k. Is the seller aware of any proposal to use any neighboring property for any potentially contaminative use?

General Storage, Storage Tanks, and Pipework

a. Provide a list of materials and chemicals that are stored or located at the facility (in quantities over ten liters for liquids and over 10 kg for solids).

b. Are incompatible materials in storage adequately segregated at the facility?

c. Is all racking at the facility of adequate strength, in good condition, and protected from accidental collision?

d. List all above ground tanks located at the facility used to store hazardous chemicals (including waste and petroleum products). Provide details of their design, construction, age, contents, and capacity.

e. List all above ground pipework located at the facility used for hazardous chemicals (including waste and petroleum products). Provide details of its construction, age, and use.

f. Are there currently, or have there ever been, any underground tanks located at the facility used to store hazardous chemicals (including waste and petroleum products)? If so, provide details including design, construction, age, contents, capacity, and current condition.

g. Is there currently, or has there ever been, any underground pipework located at the facility used for hazardous chemicals (including waste and petroleum products)? If so, provide details of its construction, age, use, and current condition.

h. Are there now, or have there ever been, any above ground or underground tanks or pipework located adjacent to the property used to store or transfer hazardous chemicals? If so, provide any details available.

i. Provide details of any secondary containment at the facility provided for tanks, pipework, fill points, tanker delivery areas, etc.

j. Provide details of any leak detection testing at the facility for storage tanks, pipework, and secondary containment on the property, together with the results.

k. How are bunds drained of storm water?

l. Have there ever been any incidents of leakage from storage tanks or pipework, either at the facility or adjacent to it? If so, provide details.

Hazardous Materials in Building Fabric and Work Equipment

a. Provide details of any hazardous materials (e.g., asbestos, lead paint, urea formaldehyde foam) that have been used in the structure or fabric of any building at the facility, including copies of any surveys conducted to identify such materials. Provide details of any action taken to remove these materials from the property.

b. Is there any electrical equipment (e.g., substation transformers, switchgear) at the facility containing Polychlorinated Biphenyls (PCBs) at concentrations greater than 50 ppm? Provide copies of relevant tests, certificates, etc.

c. If PCB containing equipment is present at the facility, is it located in areas where any leakages would be contained?

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