



GOOD PRACTICE GUIDE:

# Decommissioning of Pharmaceutical Equipment and Facilities



GEP / GxP Activities

Closure Planning

Documentation

Asset Disposal

Remediation and Demolition





GOOD PRACTICE GUIDE:

# Decommissioning of Pharmaceutical Equipment and Facilities

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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!

# 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.

The Guide was produced by a Task Team led by Mark Foss (CooperVision, United Kingdom) and Nick Haycocks (Amgen, Inc., USA).

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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