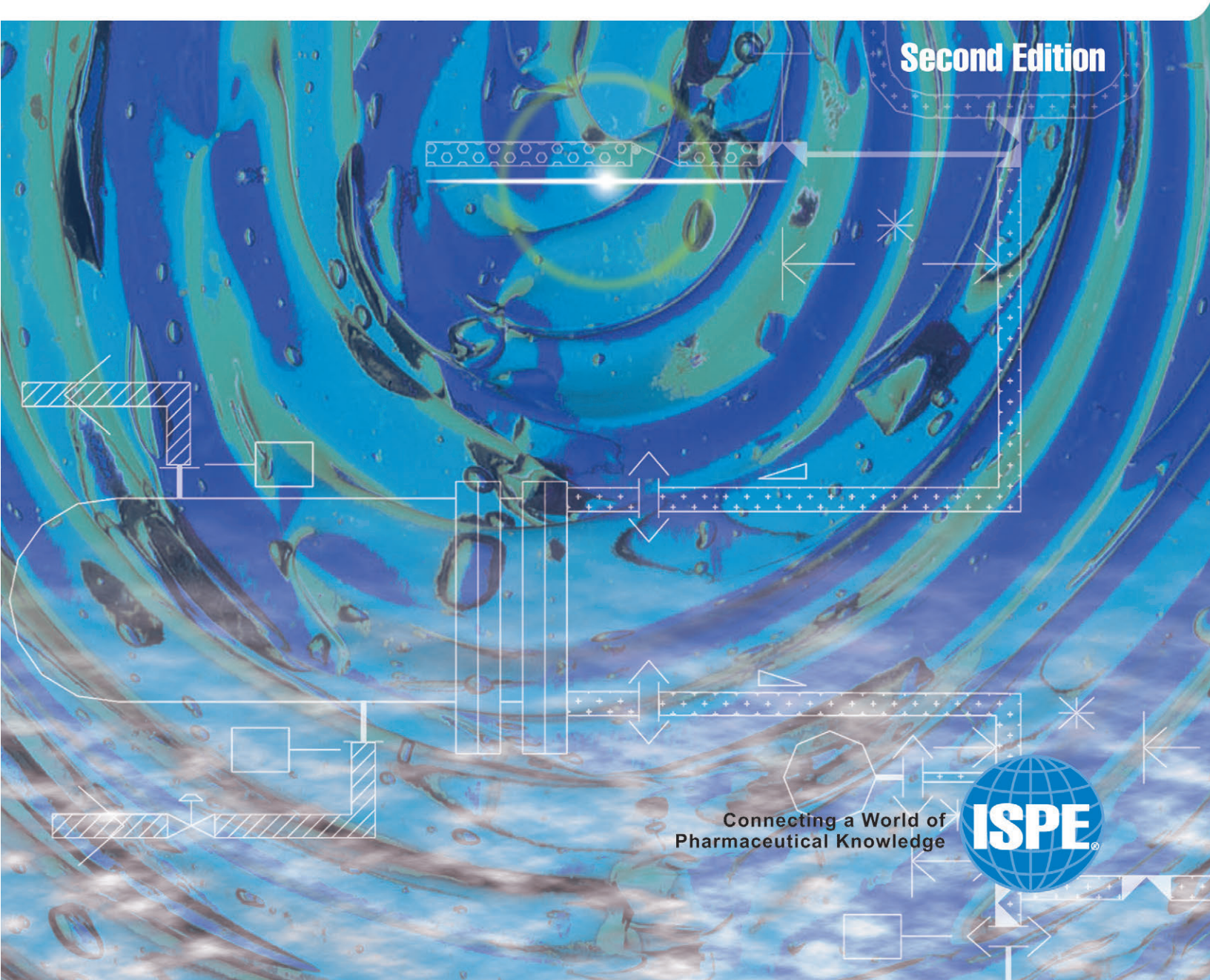
Good Practice Guide

# Approaches to Commissioning and Qualification of Pharmaceutical Water and Steam Systems

Second Edition



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# Approaches to Commissioning and Qualification of Pharmaceutical Water and Steam Systems

## Second Edition

**Disclaimer:**
This Guide is meant to assist pharmaceutical companies in managing the commissioning and qualification of pharmaceutical GMP water and steam systems. ISPE cannot ensure and does not warrant that a system managed in accordance with this Guide will be acceptable to regulatory authorities. Further, this Guide does not replace the need for hiring professional engineers or technicians.

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ISBN 978-1-936379-73-6

# Preface

The ISPE Good Practice Guide: Approaches to Commissioning and Qualification of Pharmaceutical Water and Steam Systems focuses on the engineering approaches and practices involved in providing cost effective water and steam systems in a timely manner that are specified, designed, installed and operated to meet their intended purpose. Specifically, this Guide addresses the lifecycle process of designing, constructing, commissioning, and qualifying water and steam systems regulated by international healthcare authorities.

This Guide describes how a capital project delivers process, commissioning and qualification (verification) activities, and on-going monitoring work together through the validation lifecycle for GMP water and steam systems.

The main benefit of this Guide is that it describes a project execution, commissioning and qualification (verification) approach for GMP water and steam systems based on process understanding. The required quality of water or steam is achieved without unnecessary project expense due to duplication of effort and non-value adding activities.

This Guide describes current, established, good practice, and references other guidance documents published by ISPE, where applicable. The focus is on achieving cost-effective compliance with existing regulations and associated guidance.

# Acknowledgements

The Guide was produced by a Task Team led by Nissan Cohen (Rohrback Cosasco Systems) and Diana Fischer (Bausch and Lomb).

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# 1 Introduction

## 1.1 Overview

Water and steam may be used in cleaning operations, laboratory activities, and the manufacture of pharmaceutical or biopharmaceutical products. Water and steam may come into contact with product or process contact surfaces, or may be used in the testing of products.

Good Manufacturing Practice (GMP) processes may produce drug substances or drug products. Water also may be used as a final product, e.g., as US Pharmacopeia (USP) packaged waters or other pharmacopeial equivalent, or as a combination drug product, including:

- Sterile Water for Injection
- Sterile Water for Irrigation
- Sterile Water for Inhalation
- Sterile Purified Water
- Bacteriostatic Water for Injection
- Water for Hemodialysis

Systems that generate and distribute pharmaceutical water and steam are subject to commissioning and qualification or verification practices.

Commissioning and qualification or verification is intended to bring a pharmaceutical water or steam system into operation, as part of design and construction. The water or steam systems (i.e., equipment and controls) are subject to GMPs. Commissioning and qualification or verification should verify that these systems create water and steam (i.e., product) of a consistent and repeatable quality. Qualification also should verify that supporting quality systems have been integrated into the validation lifecycle in order to maintain the validated state of the system.

Historically, the qualification model has consisted of an independent confirmation of the entire system installation and operation after the engineering commissioning has been completed.

The ISPE Good Practice Guide: Approaches to Commissioning and Qualification of Pharmaceutical Water and Steam Systems, along with the ISPE Good Practice Guide: Applied Risk Management for Commissioning and Qualification [1], changes this focus based on the use of a risk assessment to determine the process steps and controls that ensure the system output meets the quality requirements.

## 1.2 Purpose

This Guide addresses both a traditional commissioning and qualification and a science and risk-based approach to the commissioning and qualification of pharmaceutical water and steam systems.[1] This Guide aims to assist in the integration of the capital project management process, the commissioning and qualification process, and the on-going operation into the Quality Risk Management (QRM) validation lifecycle.

[1] Note: other approaches also may be used for commissioning and qualification.