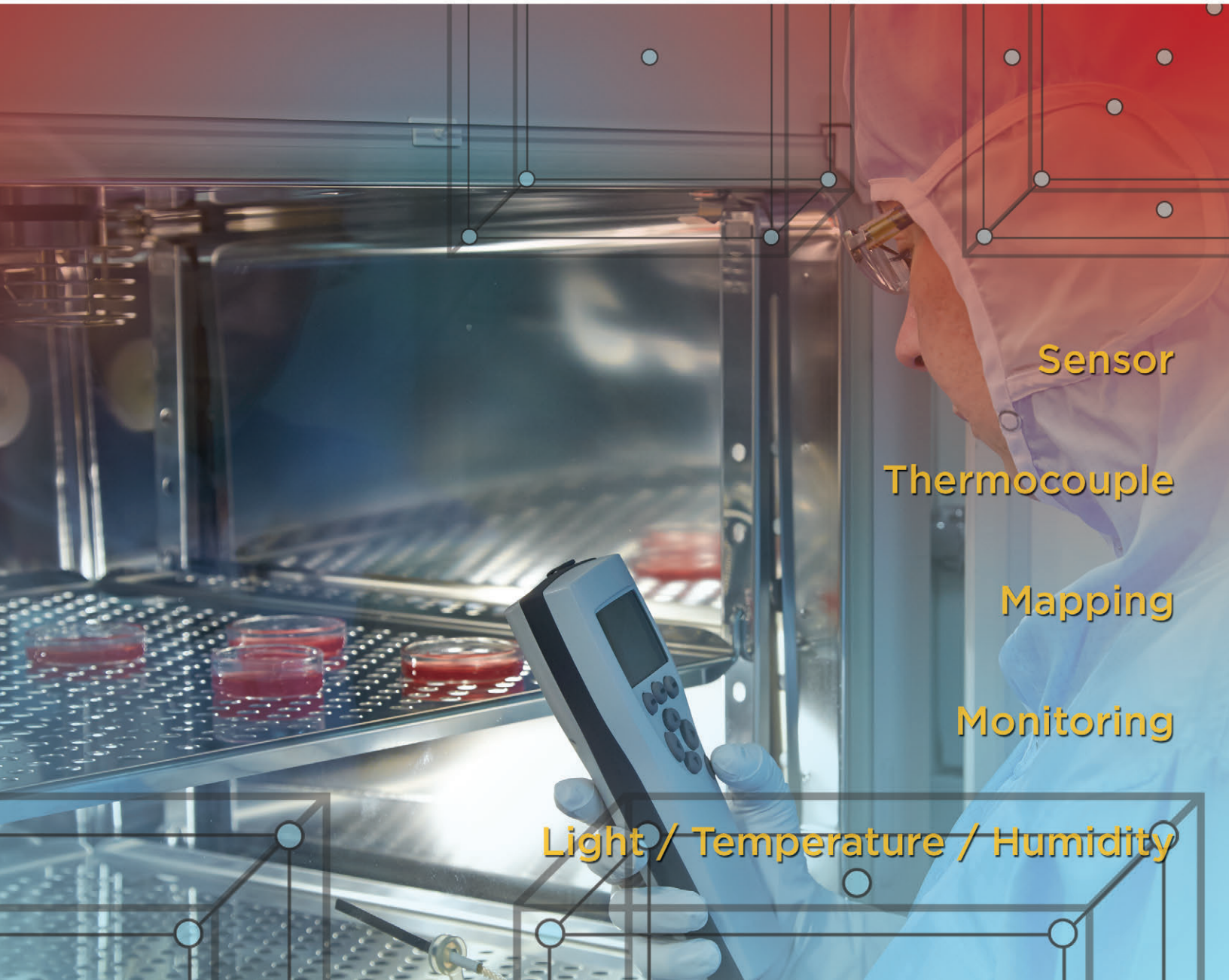
ISPE®

GOOD PRACTICE GUIDE:

# Controlled Temperature Chamber Mapping and Monitoring



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# Preface

The ISPE Good Practice Guide on Controlled Temperature Chamber Mapping and Monitoring provides guidance on the definition of the requirements (producing a user requirements document), design, purchasing, commissioning (including temperature mapping), qualification and maintenance of controlled temperature chambers operating under current Good Manufacturing Practices.

Types of Controlled Temperature Chambers considered by this guide range from purchased Commercial Off the Shelf items, such as freezers and incubators, walk-in cold rooms and walk-in freezers, to custom built units, such as warehouses.

This ISPE Good Practice Guide provides industry good practice for the temperature mapping of controlled temperature chambers, development of test acceptance criteria and a risk based approach to practices for periodic review of system performance.

# Acknowledgements

The Guide was produced by a Task Team led by Nick Haycocks (Amgen Inc.).

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# 1 Introduction

A Controlled Temperature Chamber is defined as a system, unit, equipment, or room in which the environmental conditions (usually temperature) of a chamber are controlled/maintained/regulated to meet specific user requirements.

The *ISPE Good Practice Guide: Controlled Temperature Chamber Mapping and Monitoring* expands on the ISPE Concept Paper on Controlled Temperature Chamber Mapping [1] to include topics such as:

- Commissioning
- Testing strategies
- Acceptance criteria
- Qualification approaches
- System monitoring
- Operational issues
- Periodic review

## 1.1 Purpose and Objectives

With the increasing complexity of global distribution for medicines requiring controlled temperatures and the recently introduced regulations, the *ISPE Good Practice Guide: Controlled Temperature Chamber Mapping and Monitoring* was developed by an industry team in order to provide guidance on good practices for the definition of the requirements (producing a user requirements document), design, purchasing, commissioning (including temperature mapping), qualification and maintenance of controlled temperature chambers, warehouses, and refrigerated storage areas used to store raw material, work in progress, or finished product, and which operate under current Good Manufacturing Practice. The approach described is consistent with that described in the ISPE Good Practice Guide: Cold Chain Management [2].

## 1.2 Scope

This Guide provides guidance on Controlled Temperature Chambers operating under Current Good Manufacturing Practices (CGMPs). Types of Controlled Temperature Chambers considered by this guide include purchased "commercial off the shelf" items (such as freezers, refrigerators, and incubators), warm rooms designed to maintain consistent temperatures, ovens, and custom built units, such as controlled room temperature environments, e.g., warehouses, walk-in cold rooms and freezers. This Guide does not include systems designed for heating/cooling of material such as blast freezers, although some of the concepts described may be useful when commissioning/qualifying these systems.