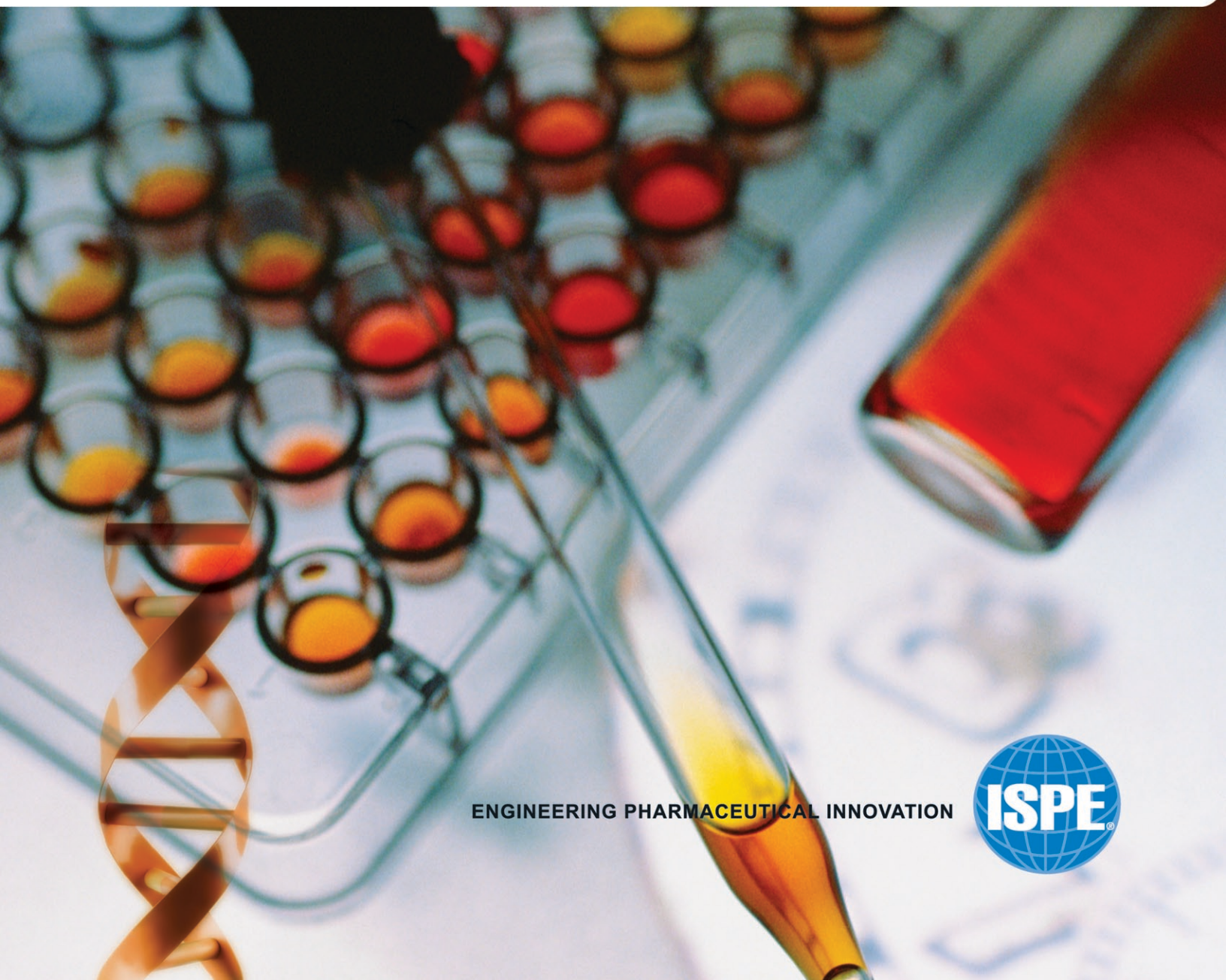
Good Practice Guide

Development of Investigational Therapeutic Biological Products



ENGINEERING PHARMACEUTICAL INNOVATION

Good Practice Guide

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Acknowledgements

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We Dedicate this Good Practice Guide in Loving Memory of Max Seales Yonker (1963 – 2005)

Max joined ISPE in March of 1996 and was honored to be elected to the ISPE International Board of Directors in 2002. Max was a leader in the ISPE Clinical Materials Committee and the ISPE San Francisco/Bay Area Chapter.

She was and will continue to be an inspiration to us all, for her tremendous contribution and passion in the area of investigational therapeutic biological products, from which the idea of this Guide originated from. She spent the last several years of her career participating in the quest for cancer's cure. We celebrate the life of a spectacular woman whose combined brilliance, compassion, wit, and the warrior spirit has touched many of our lives.

Michael Ku
Past Chair (2005)
ISPE Clinical Materials Committee

Table of Contents

1 Introduction

1.1 Overview

With the rapid growth in the biopharmaceutical industry over the past two decades, the number of newly approved biological products has dramatically increased. In 2005, a record 21 biological products received US Food and Drug Administration (FDA) approvals, including therapies for the treatment of rheumatoid arthritis, diabetes, cancer, and rare genetic disorders.

The increasing number of approved biological products on the global market represents the ability of many biopharmaceutical companies to overcome major challenges, especially during the critical process development and manufacturing stages of their product development.

This Guide will consider the major issues that will confront a biopharmaceutical company in moving therapeutic biological products from the laboratory, to the clinic, and beyond.

1.2 Purpose

This ISPE Good Practice Guide (GPG) is intended to provide readers with an understanding of issues surrounding product and process development, manufacturing, investigational product supply chain management, Quality Control/Quality Assurance, and global regulatory requirements for biopharmaceuticals.

The intended audience for this Guide includes the following disciplines:

- Clinical Supply/Clinical Trial Materials
- Clinical Research
- Manufacturing
- Project Management
- Quality Assurance/Quality Control
- Regulatory Affairs
- Research and Development

1.3 Scope

This Guide specifically addresses the methods and challenges surrounding **recombinant therapeutic biological product** development, including considerations during its use in clinical trials. It focuses on:

- Project Planning/Management
- Preclinical/Clinical Phases
- Comparability and Bridging Studies
- Active Pharmaceutical Ingredient (API)/Drug Substance (DS)/Drug Product (DP)/Placebo Process Development

- Manufacturing of DS/DP
- Process Validation
- Supply Chain Management of Biological Investigational Products for Clinical Trials
- Quality Control/Quality Assurance Considerations
- Global Regulatory Strategies

The regulations and guidelines from the US, EU, Canada, Japan, and ICH have been considered in the development of this Guide.

While not within the scope of this Guide, it is recognized that the development of other biologics (e.g., cellular and gene therapy) may require additional considerations for their successful product development from the laboratory to the clinic.

1.4 Benefits

This Guide is intended to provide industry professionals with critical information and planning tools in developing therapeutic biological products through preclinical and clinical development phases. It is intended to enable the effective selection of development priorities, and ultimately, the efficient use of time and resources.

1.5 Objective

This ISPE GPG is intended to provide insights on good practice for successfully developing therapeutic biological products.

1.6 Structure

This ISPE GPG: Development of Investigational Therapeutic Biological Products contains six main sections:

- Definition and types of Biological Products
- Product Development
- Process Development and Manufacturing Considerations
- Supply Chain Management of Biological Investigational Products for Clinical Trials
- Quality Control and Quality Assurance Considerations
- Global Regulatory Strategies

These subjects are considered in the main sections of the Guide. Appendices provide additional material and guidance to assist in the identification of regulations, issues, and topics that also should be considered.