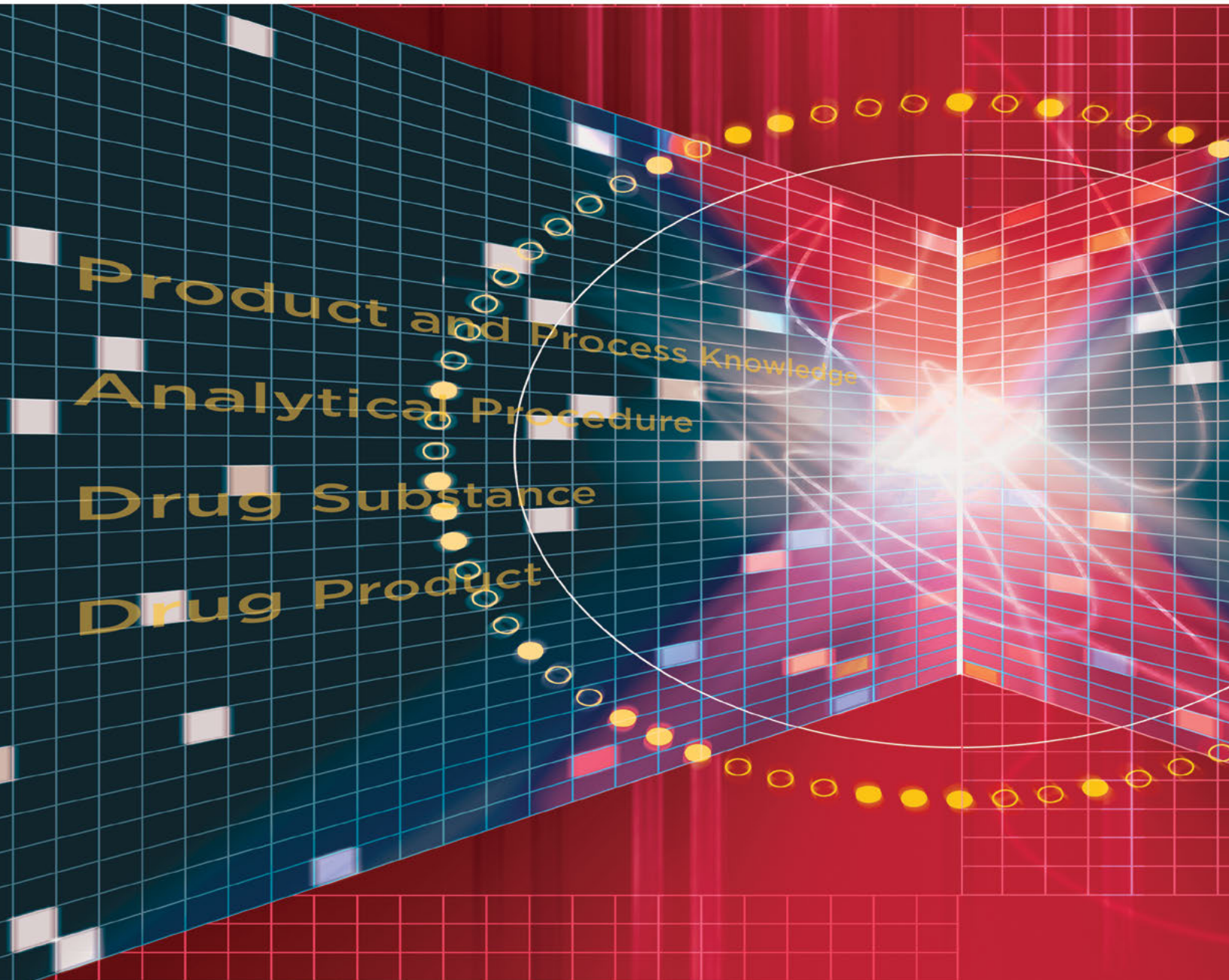
ISPE®

GOOD PRACTICE GUIDE:

Technology Transfer

Third Edition



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Preface

Transfer of manufacturing processes and analytical procedures between facilities or laboratories is a necessary part of pharmaceutical development and commercialization. Technology transfers take the outputs of process or method development activities and transfer the knowledge to a different location where a process or analytical procedure will be operated. This third edition of the ISPE Good Practice Guide: Technology Transfer was developed by an international team of authors from across the industry. This Guide presents a general approach and good practices for effective technology transfer with redacted case studies as examples. The intent is for the reader to utilize Chapters 1, 2, and 3 as a foundation and the subsequent chapters as applicable. The reader is encouraged to utilize the various lists, tables, figures, and templates for illustrative purposes.

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The Guide was produced by a Core Team of contributing authors led by Bruce Davis (Global Consulting, United Kingdom) and John Herberger (Amgen Inc., USA).

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1 Introduction

1.1 Background and Purpose

Transfer of manufacturing processes and analytical procedures between facilities or laboratories is a necessary part of pharmaceutical development and commercialization. Technology transfers may utilize the outputs of process and method development activities and/or documentation of established processes and methods. Knowledge of the product and the manufacturing process is the basis for transfer to a different location (which could be a different site, country, or facility on the same site) where a process or analytical procedure will be operated.

This Guide focuses on how technology transfer can be achieved.

Technology transfer is defined in ICH Q10 [1] paragraph 3.1.2 as follows:

> *"The goal of technology transfer activities is to transfer product and process knowledge between development and manufacturing, and within or between manufacturing sites to achieve product realisation. This knowledge forms the basis for the manufacturing process, control strategy, process validation approach and ongoing continual improvement."*

Technology transfer projects may take place at various points during the product lifecycle. Successful transfers depend on robust project management processes combined with appropriate product and process understanding. They require partnership, cooperation, and coordination between the sending and receiving units to ensure successful and efficient completion, such that the receiving unit can manufacture, test, and release a safe, efficacious, and quality product comparable to that of the sending unit.

Technology transfer projects are dependent on the development and characterization of robust processes that allow consistent and predictable operation of these processes. Similarly, development of robust analytical methods enables timely transfer of methods. These are particularly important aspects; if processes are not well developed and sources of variation are not well known, e.g., due to incomplete or inadequate process/product knowledge, then technology transfer will not be robust.

This Guide has been designed to present industry good practices for successful and efficient execution of technology transfer projects and to achieve a balance between risk management and cost effectiveness while aligning with applicable regulatory expectations, as described in ICH Q7, Q8(R2), Q9, Q10, and Q11 [2, 3, 4, 1, 5] and other regulatory documents. It covers the principles of technology transfer and provides tools for its practical application.

The impetus for technology transfer varies and may be based on several factors, for example:

Progression in a product development lifecycle, from development through scale-up to commercialization
The need for additional manufacturing capacity driven by increased demand or risk mitigation

- The need to streamline capacity when volumes fall, e.g., at patent expiry, when products change commercial status from novel to generic, etc.

- Strategic requirements to relocate business units, e.g., regional economic advantages, regional requirements for local manufacture, global expansion in different regions of the world, etc.

- Identification and qualification of local analytical facilities for testing of intermediates and finished products to meet regional regulatory requirements

- Dual sourcing strategies to mitigate demand variability or to reduce sourcing risks from manufacturing sites