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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 Guide, the second edition of the ISPE Good Practice Guide: Technology Transfer, focuses on how the goal of technology transfer can be achieved.

The intent has been to produce a user-friendly document that presents clear processes for transferring technology between two parties.
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The Guide was produced by a Task Team led by Bruce Davis (Global Consulting) and John Herberger (Amgen).

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The Team Leads would like to express their grateful thanks to the many individuals and companies from around the world who reviewed and provided comments during the preparation of this Guide; although they are too numerous to list here, their input is greatly appreciated.

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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’ 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 Guide, the second edition of the ISPE Good Practice Guide: Technology Transfer, focuses on how the goal of technology transfer can be achieved.1

This goal is defined in ICH Q10 [1] paragraph 3.1.2 as:

“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 realization. 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 times during the product life cycle. They require partnership and coordination between sending units and receiving units to ensure successful and efficient completion of a project, such that the receiving unit can successfully manufacture, test, and release a safe, efficacious, and quality product.

Technology transfer projects are dependent on the development and characterization of robust processes that allow consistent and predictable operation of these processes, as required. A robust process can facilitate technology transfer from development to commercial manufacturing.

The intent has been to produce a user-friendly document that presents clear processes for transferring technology between two parties.

The 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. It covers the principles of technology transfer and also provides some tools for its practical application.

The transfer of technologies, analytical procedures, processes, and products, occurs for a variety of reasons and may be based on a number of factors,2 e.g.:

- The natural progression in a product development life cycle, from development through scale-up to commercialization
- The need for additional manufacturing capacity driven by increased demand or risk mitigation
- The strategic requirement to relocate business units (e.g., due to rationalization or economic advantages in different regions of the world)
- The by-product of corporate mergers and consolidations

1 For the purpose of this Guide, the term “site” is interchangeable with “unit.”.
2 Drivers will differ from organization to organization and it is outside the scope of this Guide to expand upon them.