Technical Report No. 65 (Revised 2022)

Technology Transfer

Technology Transfer Team

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1.0 Introduction

Technology transfers play an increasingly important role in the regulated pharmaceutical and biopharmaceutical industries. The expanded use of contract development and manufacturing organizations, advances in manufacturing flexibility, increase in corporate mergers and acquisitions, and enhanced regulatory complexity all contribute to the need for technology transfers to maintain the continuity of drug supply. In order to replicate systems safely, maintain high-quality standards, and meet regulatory requirements, manufacturers have established approaches to successfully transfer manufacturing and analytical technology and knowledge from one site to another.

Pharmaceutical technology transfer (TT) uses a systematic approach to ensure the knowledge required to execute the manufacturing process and product testing performed at one site can be incorporated at a new site, while maintaining understanding and product characteristics. This results in the same safe, effective, and consistent pharmaceutical product being manufactured at both locations. TTs can occur at all stages of the product lifecycle, from drug development through clinical trials to commercial release.

The information in this technical report can be used to guide TT of both small- and large-molecule drug substances (biologics) as well as sterile and nonsterile drug and biological products. This document describes the steps for a single TT event. For large, complex TTs, these tools can be implemented in separate parallel processes, with a TT team established and a procedure executed for each discrete aspect being transferred. For instance, separate TT teams could be established for the transfer of drug substance manufacturing, drug product manufacturing, and packaging, with a management oversight committee ensuring the interconnectivity of the overall TT program across the supply chain.

The product realization requirements outlined in this technical report follow the guidelines of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and should be documented in the chemistry, manufacturing, and controls (CMC) section of the regulatory filing.

1.1 Purpose

This technical report aims to provide a standardized approach to the TT process by supplying a matrixed "Reference Guide to Technology Transfer Activities and Deliverables," which can be used to coordinate cross-functional TT activities that help achieve operational readiness and culminate in regulatory approval. As specific details around each TT differ greatly, based on the type and complexity of the manufacturing process or analytical method being transferred, only a certain level of detail could be covered in a single technical report. This technical report is intended to provide a level of detail and approaches that can be applied across TT types.

1.2 Scope

This technical report covers the full range of requirements needed for TTs, such as new product introductions and the transfer of products that are being manufactured for phase III clinical trials or commercial release, which are the most comprehensive in nature. In transfers of products at an earlier stage of development, when process and product knowledge is less understood and therefore CMC requirements are less detailed, certain steps described in this technical report will not be necessary. This report does not detail those differences.

While this information was not developed specifically for medical devices, combination products, and advanced therapy medicinal products due to their unique requirements, many of the fundamentals expressed here can be applied to those products.

For this technical report, it is assumed that all involved parties have established systems for commercial production. Thus, standard requirements such as equipment and facility maintenance, annual product