

A Brief Overview of the Federal Regulatory Approval Process for Pharmaceuticals, Medical Devices, and Biological Products

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Introduction

This chapter will provide the technology transfer professional with a basic overview of the U.S. federal regulatory approval process for pharmaceuticals, medical devices, and biological products. Please recognize that the laws and regulations that encompass this topic are vast and complex, especially those related to the conduct of human subject-based research. As such, this chapter is only meant to provide the most basic of overviews, while relying heavily on government-related sources.