Your ANDA or Ours?

A Smarter Approach to Pharma Product Transfers

Exploring strategic options for pharmaceutical product transfers and ANDA management to optimize your portfolio and accelerate market access.

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PLD Pharma Services

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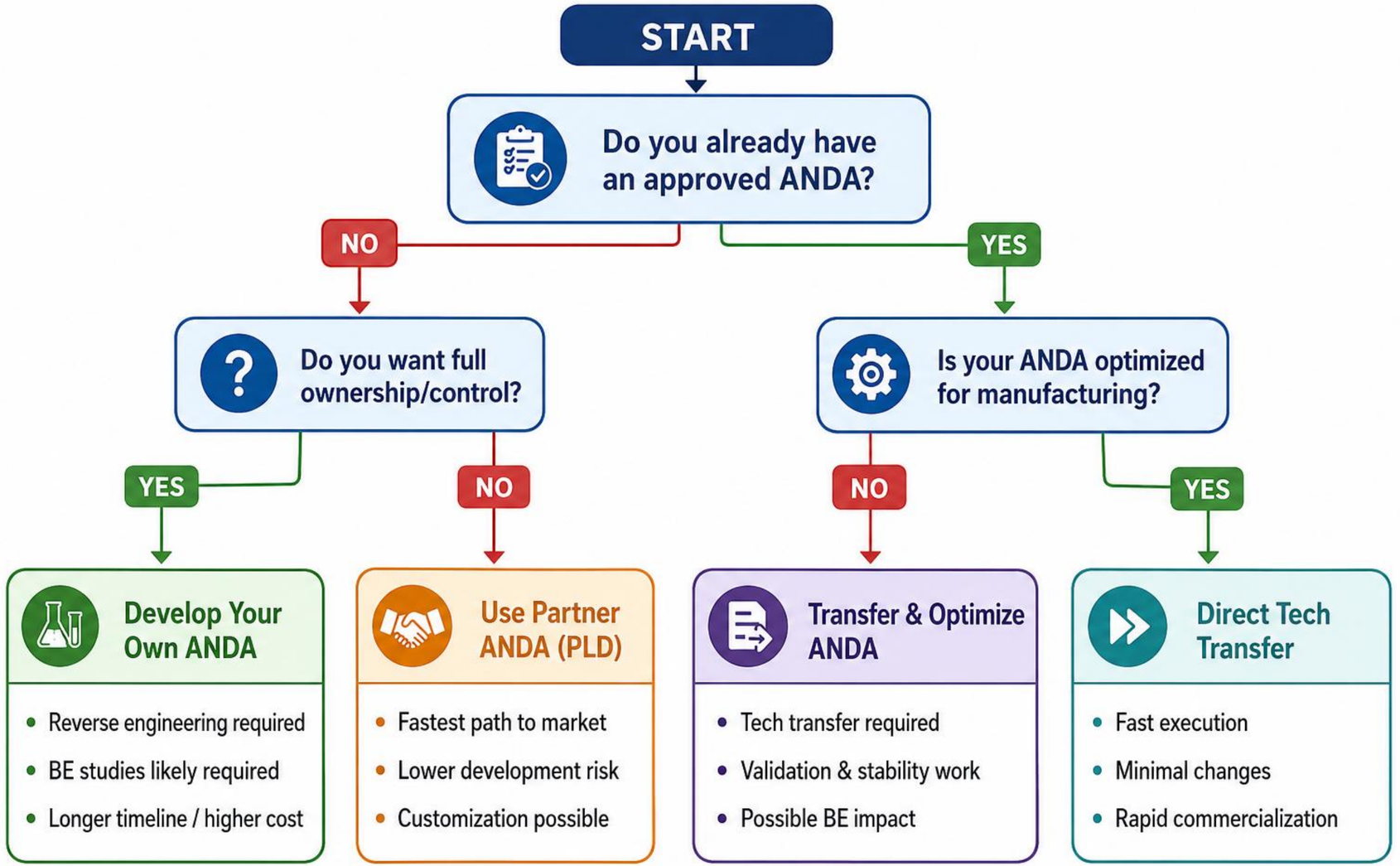
Decision Tree



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US Regulatory Context

OTC Monograph	A nonprescription medicine that complies with FDA-established, product-specific guidelines regarding ingredients, labeling, and manufacturing.
ANDA	**Abbreviated New Drug Application** that is submitted to the FDA to get approval to manufacture and market a generic version of a brand-name drug that is already approved
NDA	**A New Drug Application** (NDA) is the formal, comprehensive proposal submitted by pharmaceutical sponsors to the FDArequesting approval to market a new medication in the U.S.. It provides the "whole story" of a drug—including preclinical data, human clinical trial results, and manufacturing processes—to prove it is safe and effective.

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Why it Matters

When transferring pharmaceutical products between manufacturers, one of the most critical decisions is ANDA ownership. Should you transfer under your existing ANDA, or leverage your partner’s?

Each path carries distinct regulatory, operational, and financial implications.

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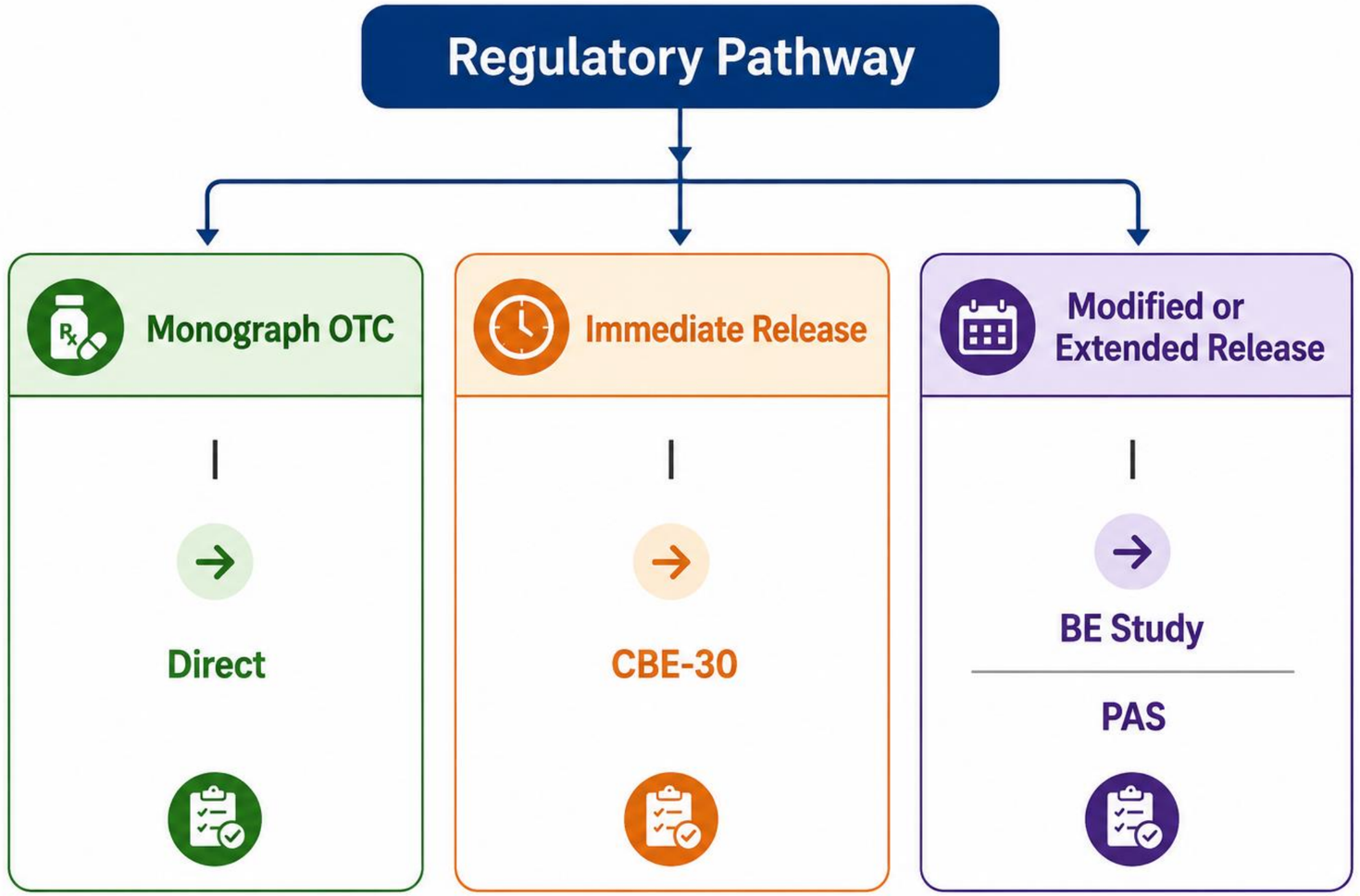

Three Strategic Approaches to Product Transfers

Using Your ANDA
Maintain ownership of your approved application while we handle manufacturing. You retain full regulatory control and market authorization with seamless technology transfer.

Using Our ANDA
Leverage our existing approved applications for faster market entry. Reduce regulatory burden and accelerate time-to-market with our established product portfolio.

Hybrid Solutions
Customized arrangements combining elements of both approaches. Flexible partnerships tailored to your specific product portfolio and business objectives.

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What Makes ANDAs Complex

- Matching reference product
- Process sensitivity
- Regulatory expectations
- Scale-up challenges

Impacts:

- Speed to Market
- Investment
- Risk

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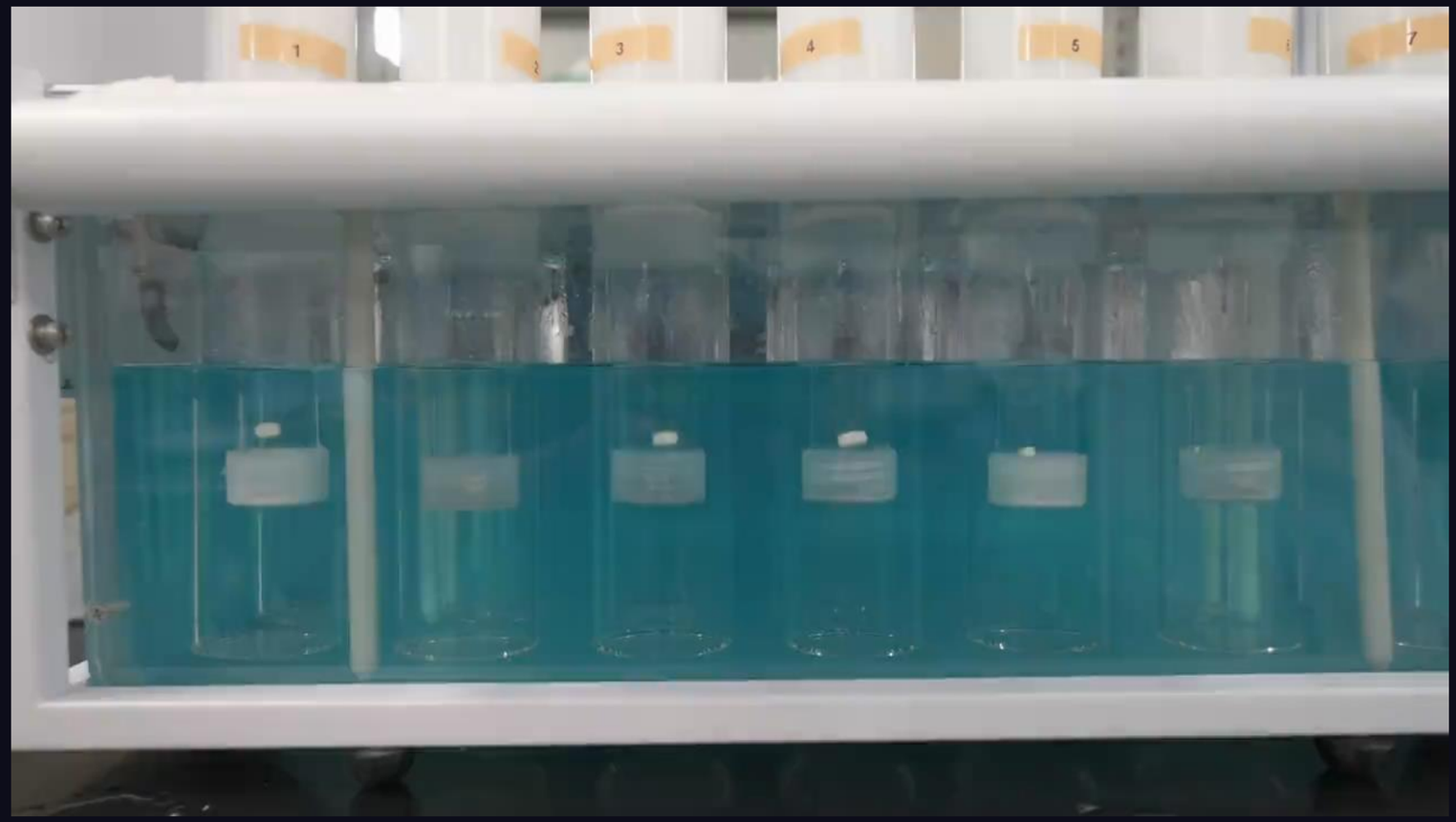

Modified Release

Not all tablets dissolve at the same rate. This dissolution bath shows the controlled release profile of a modified release tablet, an important part of ensuring consistent performance and product quality.

Bio Equivalency Studies

BE Basics

- What is BE?
- Why required?
- Fasted vs fed

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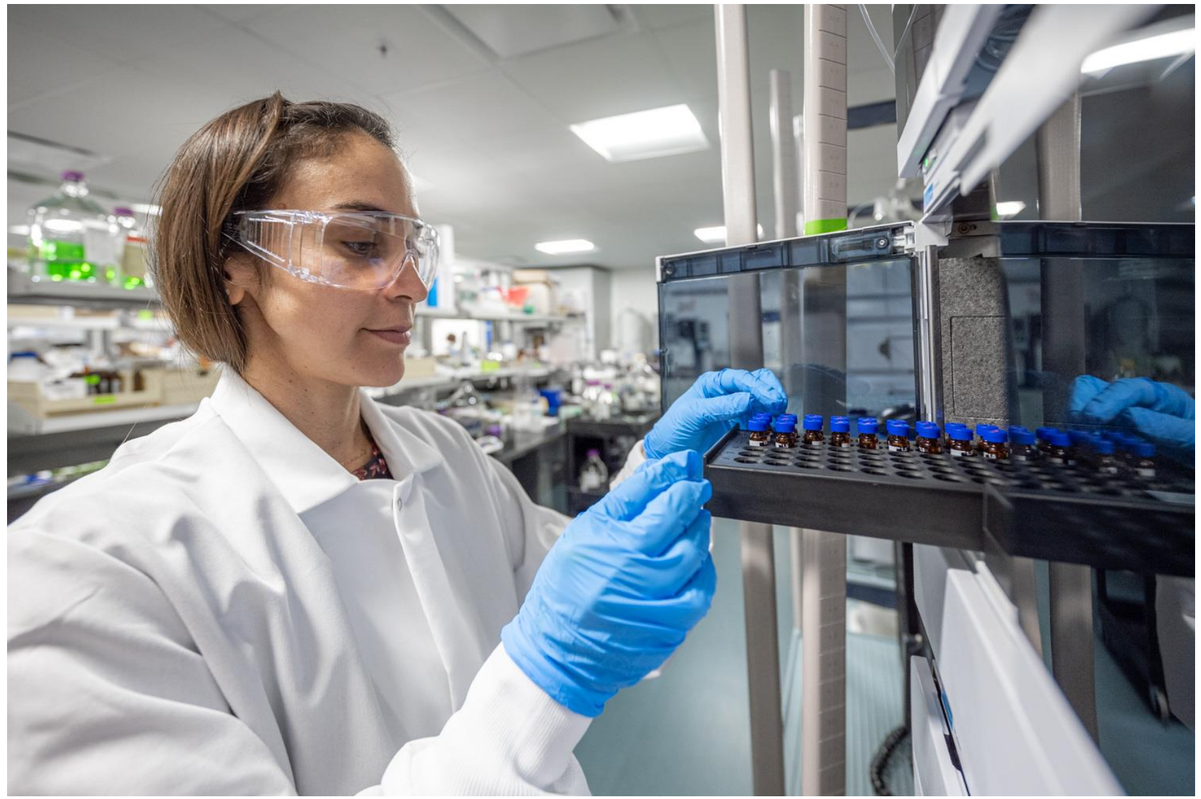
Bio Equivalency



BE Metrics

- Cmax
- AUC

What Happens when BE Fails?

- Reformulation
- Study redesign
- Increased population

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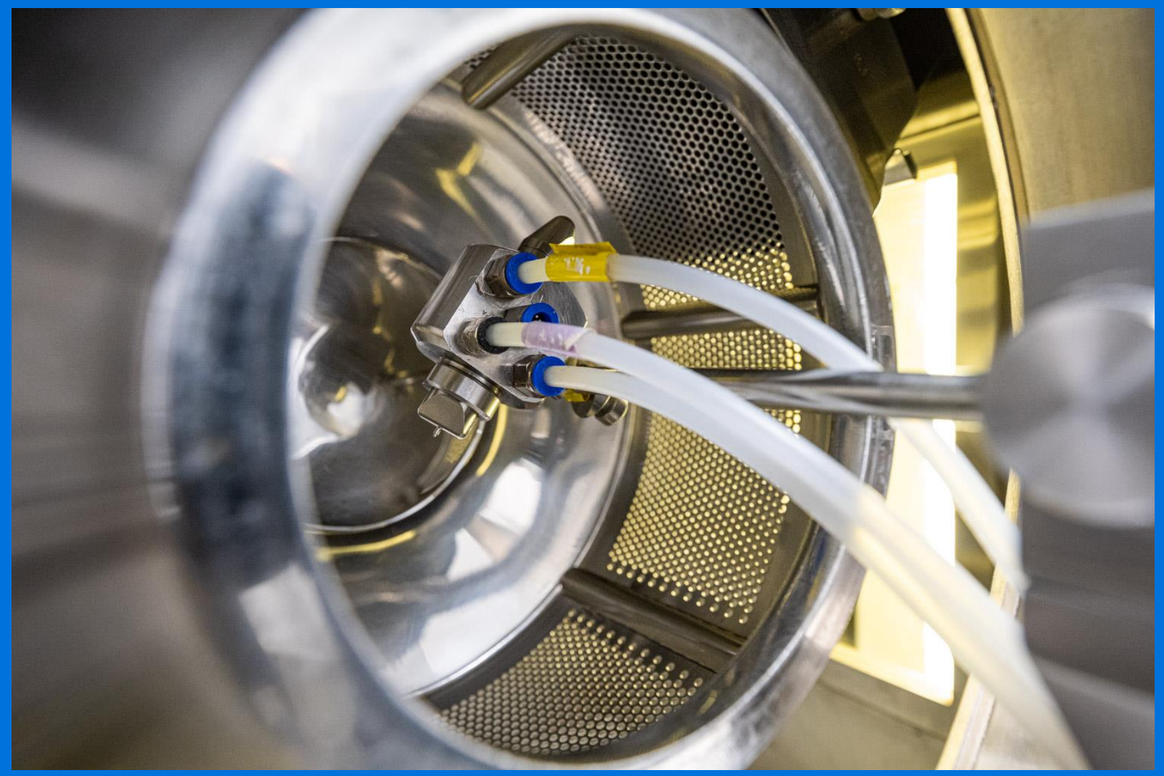
Tech Transfer: Where It Gets Real

- **Moving from development → manufacturing**
- Requires:
  - Regulatory alignment
  - Engineering Batches
  - Stability
  - Validation



Product Transfer

- Immediate vs modified release
- Pre-2013 vs post-2013 ANDA
- Level of change required

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Immediate Release Challenges

Successful technical transfer of older ANDA where cost-effectiveness was achieved by:

- Modernizing the mixing process using a baffled bin instead of a high-shear granulator
- Modernizing the processes.

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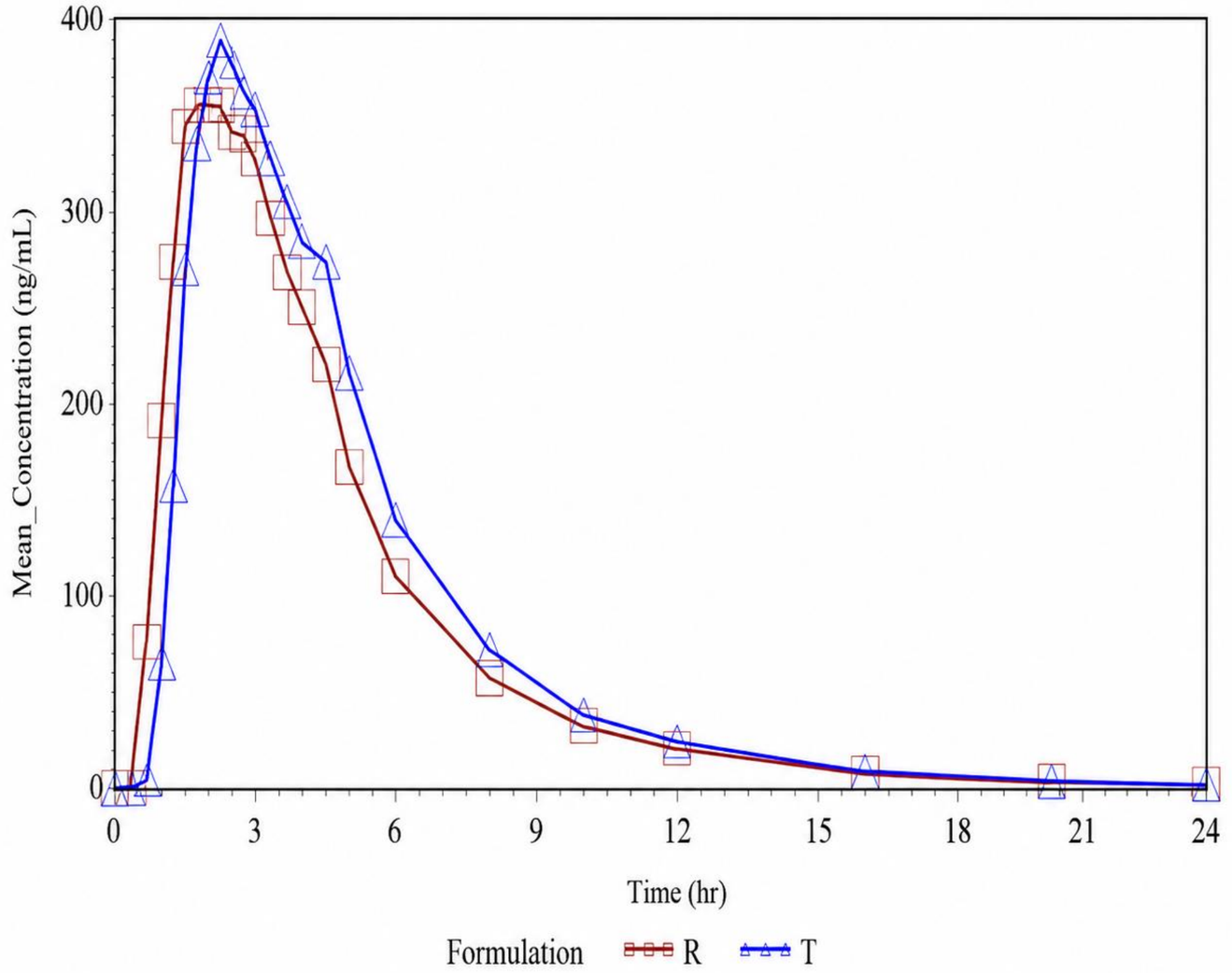
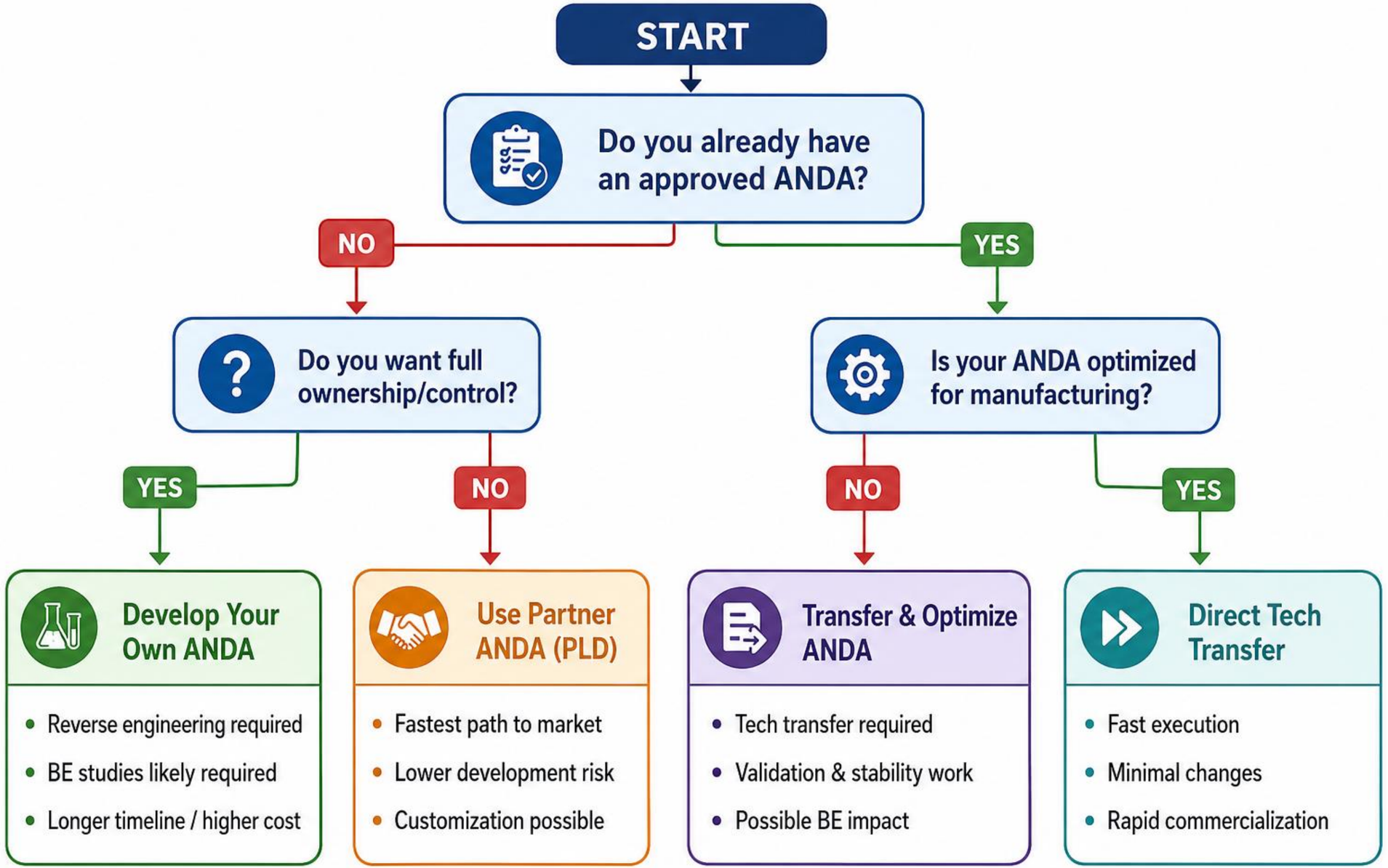
Modified Release Challenges

This plasma concentration-time profile illustrates the goal of formulation development for modified-release products: achieving a release and absorption pattern that closely mirrors the reference listed drug.

Figure 1 - Linear plot of plasma concentration vs time



Decision Tree



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Let's Discuss Your Transfer Strategy

www.pldpharma.com

Contact our team to evaluate the best approach for your products

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