PROPHARMA GROUP®

Improving Product Quality
During Technical Transfers

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DEFINITION

DEFINING TECHNOLOGY TRANSFER

The transfer of skill, knowledge, technologies, and methods of analysis and manufacture. Also called Transfer of Technology (ToT).

THE TRANSFER CHALLENGE

Transferring a manufacturing process for an API, drug substance, drug product, medical device, or combination product to a facility in a cost effective and controlled manner within the boundaries of Quality, Compliance, Budget, and Schedule, while maintaining or improving the robustness of the process being transferred.

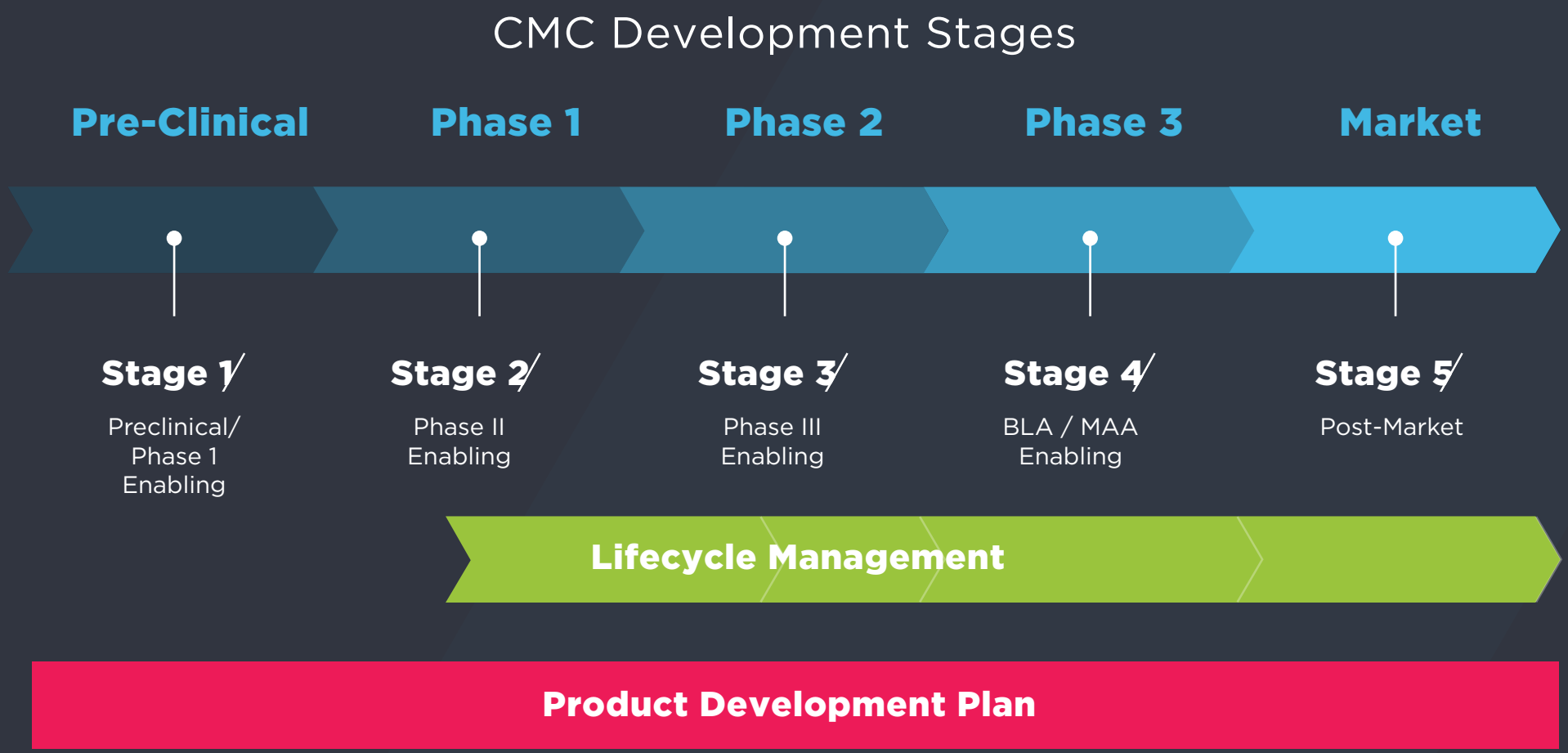
There are a lot of moving parts to a Technical Transfer. They impact, or are impacted by, just about every functional unit of a company. The sheer number of activities can be overwhelming, unless time is spent developing a comprehensive and integrated plan.

DEFINITION (cont.)

WHEN TO IMPLEMENT TECHNICAL TRANSFER

- As part of a proactive strategy to meet phase-appropriate capacity, compliance, and business imperatives
- Company needs to move production to another site, or another location within the same facility
- Current production site has compliance issues
- Product goes off patent

DEFINITION (cont.)



OPPORTUNITIES

Where do opportunities exist to improve upon the robustness of the process being transferred?

QUALITY

Typically the quality department has a list of improvement opportunities. By building off of existing procedures that you likely already have in place, you can actually further streamline and build efficiencies towards your technology transfer. Such areas of importance include:

- **Review of Customer Complaints and Internal Quality Metrics**
  Identification of any trending
- **Review of Annual Product Reports**
  Identification of common themes in historical problems
- **Review of Batch Records, Deviations, and CAPAs**
  Categorize by root cause, look for commonalities
- **Review of the receiving site**
  The review of the receiving site is not just about problems. It's also about the QMS as a whole of the new site and any gaps in their system.

OPPORTUNITIES (cont.)

PRODUCTION

The second focus area to find opportunities for improvement lies in the manufacturing, primarily in the equipment and technology being utilized.

- **Manufacturing technology**
  Do you have the ability to update to modern processing without changing the science behind the product?

- **Equipment technology**
  Will an incremental change in technology result in a better product?

ENGINEERING MANAGEMENT

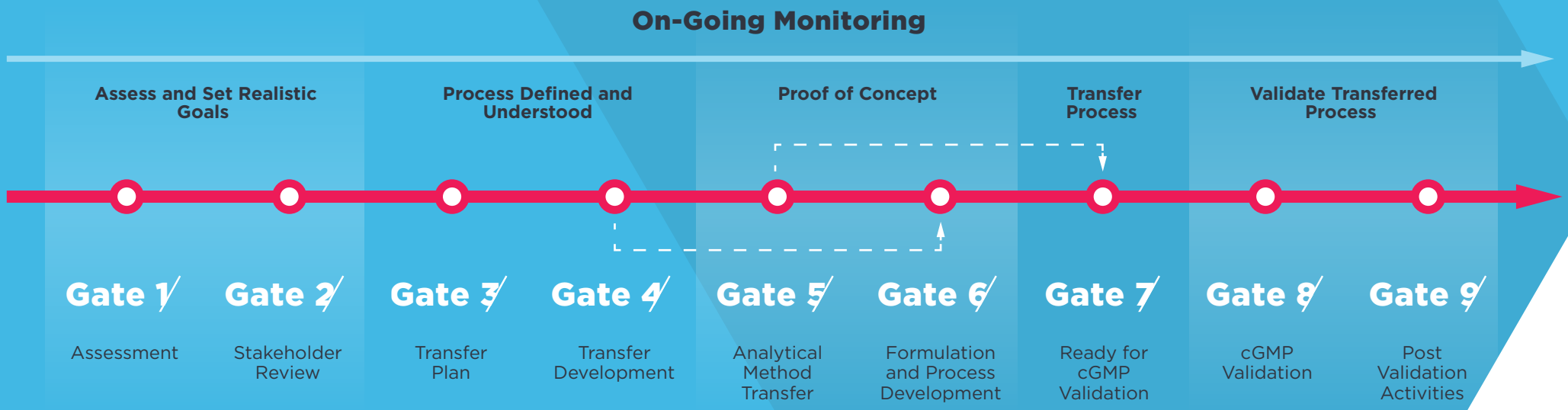
The third focus area to find opportunities for improvement is in the basic principles of engineering management.

- **Engineering management**
  Review engineering files to find opportunities in change controls, maintenance records, or future project plans.

NINE-GATE TECH TRANSFER

Now, more than ever, companies are transferring products and processes from one site to another, often facing pressures on time, resources, and regulatory limitations.

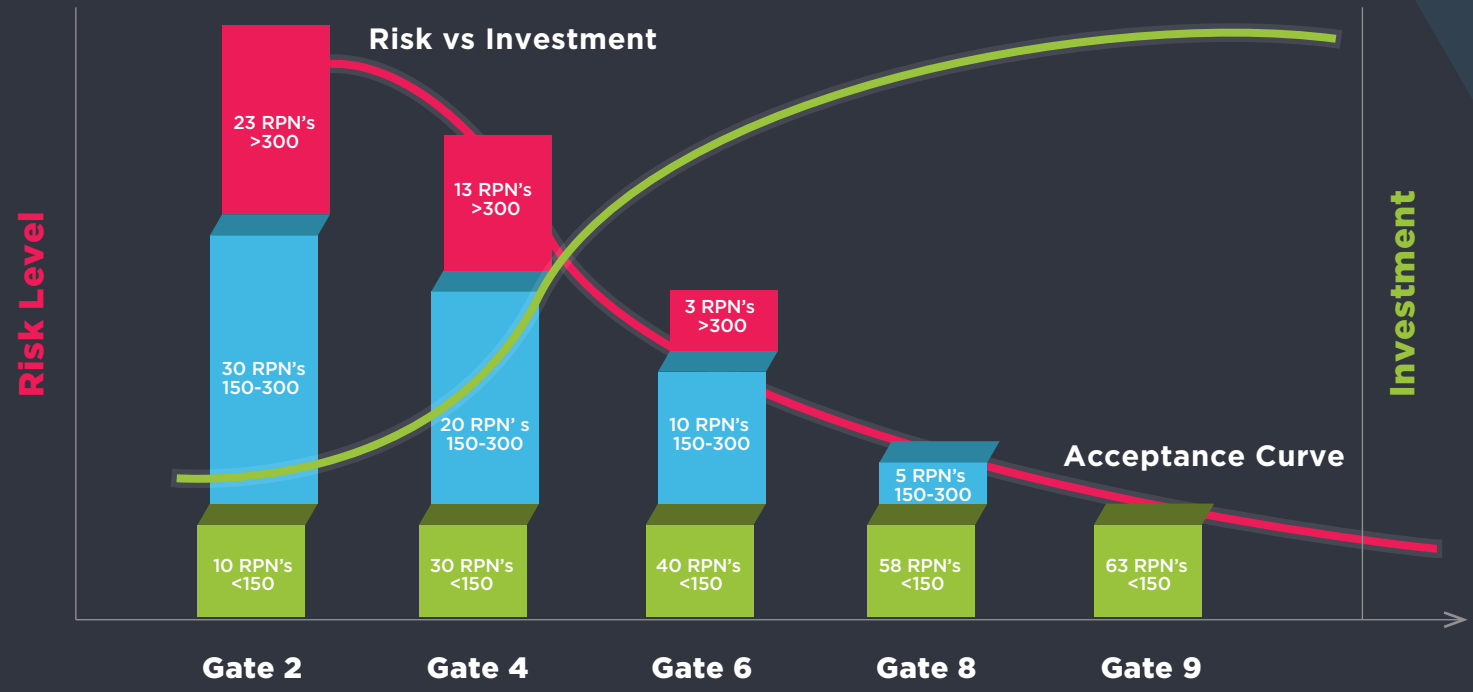
ProPharma Group's Nine-Gate Technology Transfer is a process proven to increase the speed to market, while maintaining the highest levels of regulatory compliance and efficiency. The process creates a manageable approach to the 75 work packages associated with a typical product or technology transfer. Milestone gates are developed with applicable durations, risk reduction activities, and identification of key decisions required to meet all safety, compliance, schedule, and cost restraints, resulting in a significantly improved commercialization process.



NINE-GATE TECH TRANSFER (cont.)

CALCULATED RISK

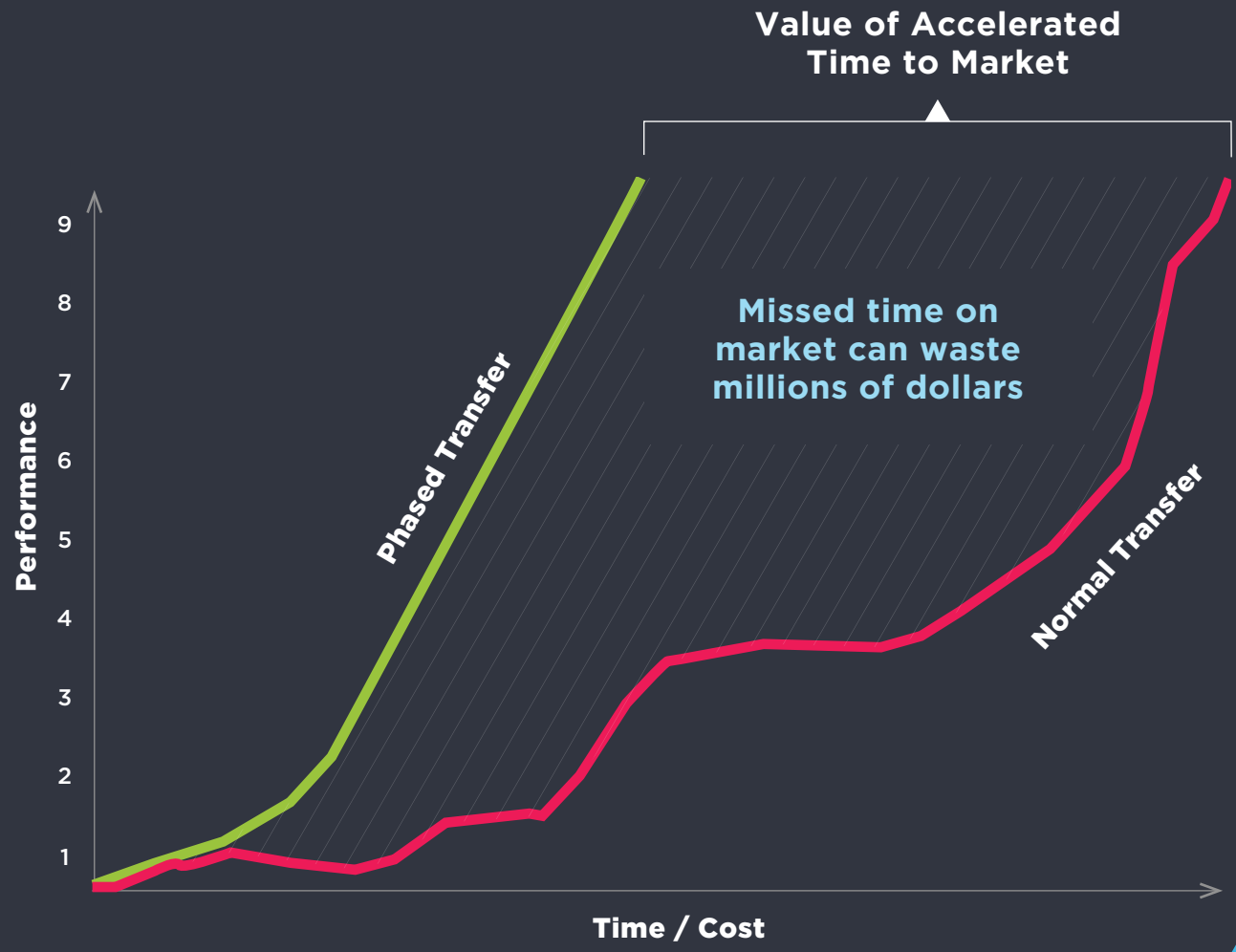
Each gate is designed to reduce company risk as the process progresses, by ensuring the process meets predefined criteria before proceeding to the next stage. This allows teams to have clear expectations of deliverables and create a repeatable process that fosters improvement based on transfer metrics.



REAL WORLD EXAMPLE

CRITICAL IMPACTS

The waste that can, and likely will occur when not utilizing a proven system is multi-faceted. Spend time understanding the opportunity of shortening the time and cost of your tech transfer process and increasing the performance of a well-planned, phased transfer of your product. It's not easy, but doable, and definitely worth it.



REAL WORLD EXAMPLE (cont.)

CRITICAL IMPACTS (cont.)

The most critical factors (and those most visible to stakeholders) are of course the impact on time and money, however individual subsets of factors play a leading role in those two key metrics. A few examples of how a struggling technology transfer can encounter delays and unplanned costs include:

- Unplanned downtime
- Costly rework
- Confusion, caused by unclear roles and responsibilities
- Low yields
- Material waste

We have witnessed these, among many other issues as a result of utilizing a process that has not been thoroughly vetted and tested. The ultimate cost of a delayed and largely unsuccessful technical transfer is a reduction in your product's speed to market, and critical market share.

TECHNOLOGY TRANSFER SERVICES

A Robust, Documented, and Repeatable Process for Success

Technology transfers are complex projects that require a coordinated effort from almost every workstream in your organization. A pharmaceutical, biotechnology, or medical device firm looking to execute a technology transfer can certainly expect the need to balance the integration of quality, schedule, and cost, no matter the complexity of the project. Move forward with the wrong combination, and your high-speed, low-cost transfer will encounter quality problems, reducing that product's speed to market and ultimately critical market share.

ProPharma Group's Nine-Gate Technology Transfer approach provides a regimented process to consistently transfer production technologies from development to production, or from site-to-site, efficiently and in compliance with applicable regulatory agencies. Our Nine-Gate approach can be customized to your organization's unique needs and applied during any phase of a technical transfer or program lifecycle. Because we understand that schedule is a critical measuring tool, by employing this documented process you are less likely to miss key milestones during the transfer. In conjunction with our project managers, who are experienced in project management, process engineering, quality assurance, and more, this robust process increases the probability of a successful transfer.

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