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CONSULTING, LLC

Think Lean. Launch Strong.

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A Modern Framework for
Smarter Commercialization in
Emerging Pharma and Biotech

WHERE INTEGRITY MEETS STRATEGY

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Executive Summary

Emerging pharma and biotech companies are being asked to commercialize faster, with *leaner teams, tighter capital, and rising market complexity*. Nearly **60% of drug launches fail** to meet commercial expectations (Sedulo Group, 2023), and six-month post-launch sales remain **19% below pre-COVID benchmarks** (IQVIA, 2023). Meanwhile, up to **90% of clinical development programs fail**, with timelines often spanning **10–15 years**, and costing more than \$1–2 billion (Sun, 2022).

Research also shows that operational pressure—not scientific potential—often drives early partnering or exit decisions for emerging biotechs, reinforcing the importance of building the internal structure needed to retain strategic options (McKinsey & Company, 2022; Ernst & Young Global Limited, 2024).

Emerging biopharma companies (EBPs) now drive **nearly half of all U.S. new active substance (NAS) launches** and more than half of 505(b)(2) approvals (IQVIA, 2025). Yet many are expected to deliver enterprise-level execution with far fewer resources—leading to *fragmented vendor networks, unclear ownership, overextended teams, and delayed decision making* at the exact moment when precision matters most.

CatalysRx was built to close this readiness gap.

Transformation happens when the right people, systems, and processes connect with purpose.

To support emerging teams preparing for their next commercial launch, CatalysRx delivers an integrated, tailored readiness ecosystem designed specifically for resource-constrained pharma/biotech companies, built around three integrated components:

PSPS Gap Map™

A proprietary framework assessing—**People, Systems, Processes, and Scale**—to determine whether an organization can execute with clarity, discipline, and speed. The PSPS Gap Map™ highlights strengths, developing areas, and gaps—giving leaders the visibility needed to prioritize effectively.

Commercial Readiness Diagnostic™ (CRD)

A focused, rapid assessment that uncovers gaps, risks, bottlenecks, and internal or external misalignment—and converts these insights into:

- a PSPS Gap Map™,
- a vendor & workflow alignment review,
- the risks and handoffs that matter most for launch, and
- a practical Quick Wins Action Plan

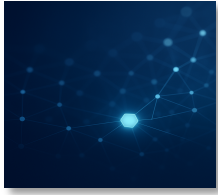
The CRD provides early clarity and cross-functional alignment before committing resources, selecting partners, or building infrastructure.

Precision Launch System™ (PLS)

A lean, structured operating model that turns diagnostic insights into a step-by-step commercialization plan. PLS™ helps emerging teams build only what they need — when they need it — avoiding the unnecessary hiring, overspending, and over-building common in large consultancy models.

Together, these tools give leaders the structure, visibility, and operating rhythm they need to **Think Lean. Launch Strong**. They align teams, accelerate decisions, and create the discipline required to compete in an increasingly complex market.

Because every breakthrough therapy deserves a clear, confident path to the patients who need it most.



The Reality:

Why Great Science Isn't Enough

Across the industry, data tells a consistent and yet sobering story:

Emerging pharma and biotech organizations now sit at the center of today's innovation landscape. They drive **nearly half of U.S. new active substance (NAS) launches** and **more than half of 505(b)(2) approvals** (IQVIA, 2025). Yet the commercialization environment they face is more demanding and less forgiving than ever before.

Despite strong scientific momentum, launch performance across the industry is declining, with nearly **60% of drug launches failing** to meet commercial expectations (Sedulo Group, 2023), and average six-month post-launch sales remain **19% below pre-COVID benchmarks**, with some brands underperforming by more than **40%** (IQVIA, 2022).

At the same time, **up to 90% of clinical programs fail**, and the journey from discovery to approval often spans **10–15 years**, requiring more than **\$1–2 billion** in investment (Sun, 2022).

Industry research shows that emerging biotechs often face pressure to make critical decisions earlier than planned—not because the science isn't ready, but because internal support and structure haven't kept pace. Teams that strengthen internal readiness are better positioned to retain strategic options when it matters most (McKinsey & Company, 2022; Ernst & Young Global Limited, 2024). In many organizations, clinical development and commercial planning evolve in parallel, creating late-stage disconnects that surface as evidence or access gaps at launch.

For emerging teams operating with lean budgets and lean structures, this creates a perfect storm:

- **Pricing pressure and rising payer scrutiny**

Access drives launch momentum. High out-of-pocket costs push abandonment above 50% (IQVIA, 2023), and affordability challenges often limit early uptake of specialized therapies — even when the clinical value is strong.

- **Fragmented internal and external ecosystems**

Emerging teams must align internal functions while coordinating CROs, CMOs, 3PLs, Quality, artwork/labeling vendors, and regulatory partners. When these groups operate independently, gaps emerge in timelines, data flow, and ownership. For lean organizations, even small disconnects across these functions can slow readiness and elevate launch risk.

- **Systems and data that outpace internal capacity**

In lean, emerging organizations, commercial, medical, and operational systems may not evolve in a fully coordinated way — simply because teams are focused on meeting immediate needs with limited resources.

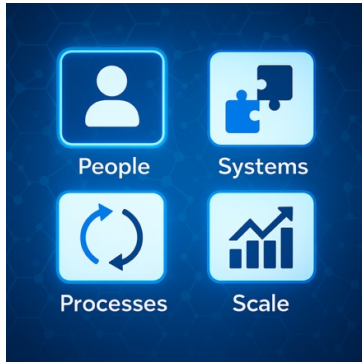
- **Limited team capacity during critical growth phases**

As companies approach major milestones, small teams must balance daily responsibilities with growing operational, and launch-preparation needs — often without the support structures that larger organizations rely on.

- **The cost of misalignment compounds quickly**

Delays in decisions and unclear ownership shift teams into reactive execution, slowing momentum when speed and precision matter most.

The reality is: *great science alone doesn't guarantee commercial success* — effective execution does. Emerging pharma and biotech companies need a **tailored commercialization framework** that clarifies *what* to develop, *when* to develop it, and *how* to prevent unnecessary overbuilding. CatalysRx assists lean teams in navigating complexity, enhancing alignment, and scaling with confidence.



PSPS Framework (PSPS): The Four Dimensions of Commercial Readiness

Emerging pharma and biotech companies rarely fail due to science alone. More often, execution breaks down because internal teams, systems, processes, and partners evolve faster than they can be aligned. To bring clarity to this complexity, CatalysRx uses the **PSPS Framework**—a structured, fit-for-purpose model that evaluates readiness across four critical dimensions:

People, Systems, Processes, and Scale.

PSPS provides leaders with a unified lens to understand *where execution is strong, where friction is emerging, and where early risks may stall momentum*. It becomes the anchor for prioritization, sequencing, and confident decision-making.

People — Alignment, ownership, and day-to-day execution

People determine whether work moves with clarity. Roles, decision pathways, and ownership must be defined early and aligned to the complexity of the work so teams can execute with accountability and speed.

Systems — Integrated tools and data that support cross-functional work

Systems should enable—rather than hinder—execution across commercial, medical, regulatory, and operations. But without intentional sequencing and cross-functional planning, systems may develop independently, creating complexity rather than connection.

Processes — Clear routines that reduce friction and improve speed

Processes translate strategy into action by defining how work flows across internal teams and external partners. They ensure consistency, transparency, and repeatability during periods of rapid growth.

Scale — The ability to expand infrastructure, spend, and partnerships intentionally

Scale is not about adding more—it's about adding what matters. Emerging organizations must grow in step with data, milestones, and operational readiness to avoid over-building too early.

The Next Catalyst: Artificial Intelligence (AI) + Human Insight

AI is rapidly becoming an extension of the Systems dimension within PSPS. When applied responsibly, AI enhances pattern recognition, strengthens signal detection across early commercial data, and reduces operational friction. But *its power is unlocked only when paired with human insight*—reinforcing the People and Processes pillars rather than replacing them. CatalysRx helps emerging teams integrate AI intentionally, ensuring tools enhance clarity and decision-making without adding complexity.



Real-World Proof: Provell Pharmaceuticals, LLC



As COO/CEO, Steve Hodge applied PSPS principles within a lean commercial organization—reaching 1.2M+ patients and 100,000+ HCPs in one of the most competitive and highly dispensed therapeutic categories in the U.S. Success came from clear ownership, integrated 3PL, CMO, and vendor workflows, sequenced systems and processes, a lean operating footprint, and coordinated internal-external decision-making—demonstrating how clarity and alignment can outperform size.

Commercial Readiness Diagnostic (CRD)

Rapid Clarity for Lean Emerging Teams

Introduction

Emerging pharma and biotech companies operate with lean structures, accelerated timelines, and mounting complexity – often without early visibility into where readiness gaps exist. The CRD provides fast, objective clarity on where the organization stands today – and what must be prioritized next – before teams commit time, budget, or partners. It's the first step in helping leaders **Think Lean. Launch Strong.**

The CRD delivers the early visibility emerging teams need to make confident decisions before committing time, budget, or commercial partners.

Why Early Clarity Matters

Lean teams operate under tight timelines and increasing external pressure. Without early clarity on what is strong, what is missing, and what needs immediate attention, organizations risk building in the wrong order or stretching limited resources. Early clarity accelerates alignment, prevents unnecessary spend, and ensures decisions and infrastructure evolve intentionally — not prematurely.

The CRD exists to bring this clarity forward, quickly and objectively.

Common Patterns Identified in the Diagnostic

- Clarifying ownership across priority workstreams
- Reducing friction across internal and external teams (e.g., CRO, CMO, 3PL)
- Establishing simple cross-functional operating routines
- Sequencing systems and data appropriately
- Eliminating redundancy that slows execution

The 30-day Pathway





Weeks 1-2 – Intake, interviews, cross-functional workflows, partner mapping, risk identification

Week 3 – PSPS Gap Map™, readiness scoring, vendor alignment insights, early risks

Week 4 – Quick Wins Action Plan including a 30/90-day priority roadmap

The outcome is a clear, objective assessment of where the organization stands – and what must happen next.

What the CRD Includes

-  PSPS Gap Map
-  Vendor & Workflow alignment review
-  Launch-critical risks & dependencies
-  Quick Wins Action Plan

What the CRD 'IS' and 'IS NOT'

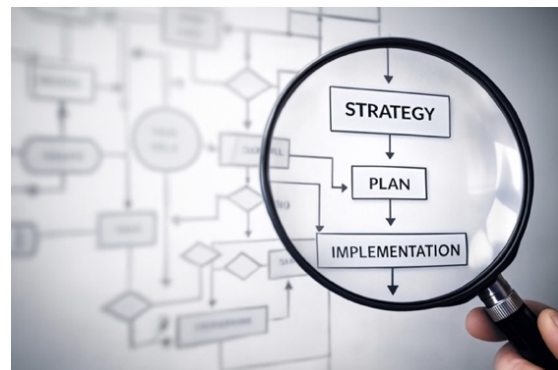
IS...

- An objective clarity tool for where things stand today
- A readiness assessment
- Independent, cross-functional & integrated
- Built to identify strengths, gaps, risks



IS NOT...

- A 90-day quick-fix
- A template or cookie-cutter playbook
- A transformation program
- A replacement for internal teams



Precision Launch System (PLS)

A Fit-for-Purpose Operating Model for Emerging Launches

The Commercial Readiness Diagnostic™ provides clarity on where an organization stands. The Precision Launch System™ (PLS) provides the operating structure that converts that clarity into coordinated, disciplined execution.

PLS is a fit-for-purpose commercialization model built specifically for emerging pharma and biotech companies—organizations expected to deliver enterprise-level performance *without* enterprise-level infrastructure. It defines the minimum effective set of people, systems, processes, and routines to launch with confidence—ensuring the right people are matched to the right work, with the skills, experience, and judgment required for success—while avoiding the overbuilding, over-hiring, or unnecessary complexity common in traditional consulting models. PLS emphasizes execution readiness over role alignment alone, recognizing that experienced leadership and the right level of capability are essential in lean, high-pressure launch environments.

PLS ensures that execution scales with intention, not by default.

The PLS Promise: Build Only What You Need—Nothing You Don't

PLS aligns work around what matters most for launch, sequencing infrastructure in the right order, at the right time. It clarifies how decisions are made, how work moves across teams, and how internal and external partners operate as a single ecosystem.

The result is a disciplined launch foundation that accelerates progress, reduces friction, and strengthens organizational readiness—without burdening lean teams with unnecessary overhead.



PLS at a Glance:

- Aligns people, systems, processes and scale
- Reduces rework and prevents overbuilding
- Clarifies ownership and strengthens coordination
- Creates an operating rhythm that accelerate execution
- Designed specifically for lean, emerging teams

PLS in Action: Turning PSPS into Execution

<p>Precision People Alignment:</p> <p>Right people. Right work. Clear ownership.</p> <p>Clear leaders, decision paths, and aligned contributions—matching capability to what matters most.</p> <p>Outcome:</p> <p>Clarity and accountability.</p>	<p>Precision Systems Integration:</p> <p>Systems and partners aligned to launch needs.</p> <p>Stage-appropriate tools and vendors, set up to support execution—not complicate it.</p> <p>Outcome:</p> <p>Integrated, execution-ready systems.</p>	<p>Precision Process Control:</p> <p>Essential Workflows. Predictable execution.</p> <p>Critical routines that clarify decisions, reduce rework, and provide regular, honest visibility into progress, risks, and emerging issues.</p> <p>Outcome:</p> <p>Transparency and speed.</p>	<p>Precision Scaling Strategy:</p> <p>Build only what's needed—when it's needed.</p> <p>Outcome:</p> <p>A lean, scalable foundation.</p>
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Real World Evidence (RWE)

A Practical Case Study for Lean, Emerging Launch Teams

Lean, Integrated Execution in Practice

Provell Pharmaceuticals provides a clear example of how a lean, well-aligned team can deliver strong commercial performance—even in a competitive, high-volume category. As COO/CEO, Steve Hodge applied the same principles that now shape the **PSPS Framework™**, **Commercial Readiness Diagnostic™**, and **Precision Launch System™** to guide Euthyrox® through launch and sustained market execution.

Within one of the largest and most heavily genericized therapeutic categories in the U.S. – hypothyroidism – our team operated in an environment shaped by intense pricing pressure, automatic substitution, and consolidation of formulary control among national buyers (e.g. the Big 3). These dynamics created a commercial landscape where *differentiation was limited, variability was common, and disciplined execution across internal teams and external partners was essential*. Through this experience, we observed firsthand how clinical variability, operational complexity, and real-world practice patterns intersect to influence market behavior.

What the RWE Revealed

Real-world utilization patterns reflected the broader variability observed in clinical practice. Patients frequently cycled through dose adjustments before achieving stability, and refill behavior often shifted in response to fluctuations in TSH values and patient symptoms. An independent in-use stability study comparing different levothyroxine packaging configurations under controlled high-humidity conditions identified measurable differences in potency stability over time (Alliance Technologies, 2021). Blister-packaged tablets demonstrated consistent assay results across the study period, while bottle-packaged products showed greater variability when exposed to humidity. These findings offered a practical reminder that environmental and handling factors—alongside clinical and behavioral variables—can contribute to real-world variability within the category.

Collectively, these signals underscore how even modest sources of inconsistency can introduce noise across patient experience, prescribing patterns, dispensing behavior, and payer dynamics.



Unmet clinical need:

Despite widespread levothyroxine treatment, a meaningful subset of patients remains symptomatic or fails to normalize TSH, even with dose-adjusted therapy. Several published studies have estimated that **15-20%** of treated patients continue to exhibit persistent abnormal TSH levels or incomplete symptom resolution—often described as “refractory hypothyroidism” (Benvenga et al., 2017).



Why This Matters for Emerging Launch Teams

Real-world variability creates friction across patients, prescribers, pharmacies, and payers. For emerging teams, this reinforces the need for early clarity, tight coordination, and disciplined sequencing. Understanding how products behave in practice helps leaders anticipate risks, reduce organizational noise, and build only what’s needed for consistent execution.

Bringing It All Together

A Clear Path Forward for Emerging Launch Teams

Emerging pharma and biotech companies face a familiar challenge: the need to move fast with lean teams, limited resources, and mounting external pressure — all while navigating an environment defined by variability and cross-functional interdependence. The realities outlined earlier in this white paper are reshaping how small companies must operate: rising execution risk, fragmented systems, vendor misalignment, and increasing pressure to do more with less.

Great science may open the door, but without clarity and a structured way to sequence and prioritize, even strong programs can struggle to maintain momentum.

Across the PSPS Framework™, the Commercial Readiness Diagnostic™, and the Precision Launch System™, one theme stands out: **teams win when the right people focus on the right work at the right time.** Lean organizations cannot afford to overbuild or run unfocused parallel workstreams. They need a disciplined approach that helps them determine what must happen now, what can wait, and what should never be built at all.

Real-world evidence reinforces this reality. Variability — clinical, operational, or behavioral — introduces noise that slows teams down. These are the same forces contributing to launch underperformance across the industry. When leaders understand how these realities impact execution, they can anticipate issues earlier, strengthen internal alignment, and build only the infrastructure required for consistent, confident progress.

Industry research shows that when internal structure doesn't keep pace with scientific progress, emerging biotechs may feel pressure to partner or exit earlier than intended. Stronger internal structure and alignment help leaders retain strategic options, negotiate from a position of strength, and capture more long-term value ([McKinsey & Company, 2022](#); [Ernst & Young Global Limited, 2024](#)).

CatalysRx helps emerging teams convert complexity into a clear roadmap. By connecting people, systems, processes, and scale, we provide a practical way to sequence, prioritize, and execute — so leaders can advance programs, prepare for launch, and move with intention despite the external pressures shaping today's market.

Think lean. Launch strong.

It's not just a message. It's a way of operating — built to meet the realities facing emerging teams today.



About CatalysRx

Where Integrity Meets Strategy

Who We Are

CatalysRx is a boutique commercialization advisory firm built to support emerging biotech and pharmaceutical teams navigating the complexity of early development, pivotal milestones, and launch preparation. Our role is simple: help leaders cut through noise, sequence and prioritize the right work, and build only the infrastructure they truly need.

Founded by Steve Hodge — a former COO/CEO with deep operational and commercial experience — CatalysRx combines strategic clarity with a hands-on, player-coach partnership. We understand the realities facing small teams because we've lived them: limited resources, growing execution risk, fragmented vendors, and increasing pressure to deliver more with less. CatalysRx provides the structure, rhythm, and alignment needed to keep programs moving with intention.

How We Help

CatalysRx delivers a unified model designed specifically for lean, fast-moving teams preparing for their first or next commercial launch:

PSPS Framework™

A clear, structured lens that evaluates readiness across **People, Systems, Processes, and Scale**. This helps leadership understand strengths, gaps, and where to focus next.

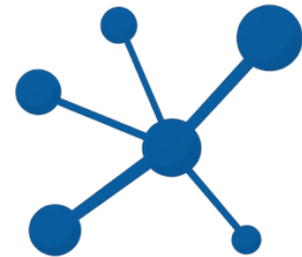
Commercial Readiness Diagnostic™ (30 Days)

A rapid, practical assessment that provides a PSPS Gap Map™, vendor and workflow review, and a prioritized Quick Wins Action Plan to create early clarity and align cross-functional teams.

Precision Launch System™ (PLS™)

A lean operating model that drives consistent execution through precise sequencing, cross-functional alignment, and player-coach support — all without overbuilding infrastructure.

Together, these components form a scalable pathway that helps small teams reduce variability, anticipate risks, and build toward a confident launch.



Our Philosophy

- We believe clarity outperforms complexity.
- We believe sequencing outperforms speed.
- We believe lean teams can deliver exceptional commercial results when aligned on what matters most.

CatalysRx was built around those principles — helping emerging companies move faster, stay focused, and execute with integrity.

Let's Build Your Precision Path to Launch

To learn more, visit www.catalysrx.com or contact: steve.hodge@catalysrx.com

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