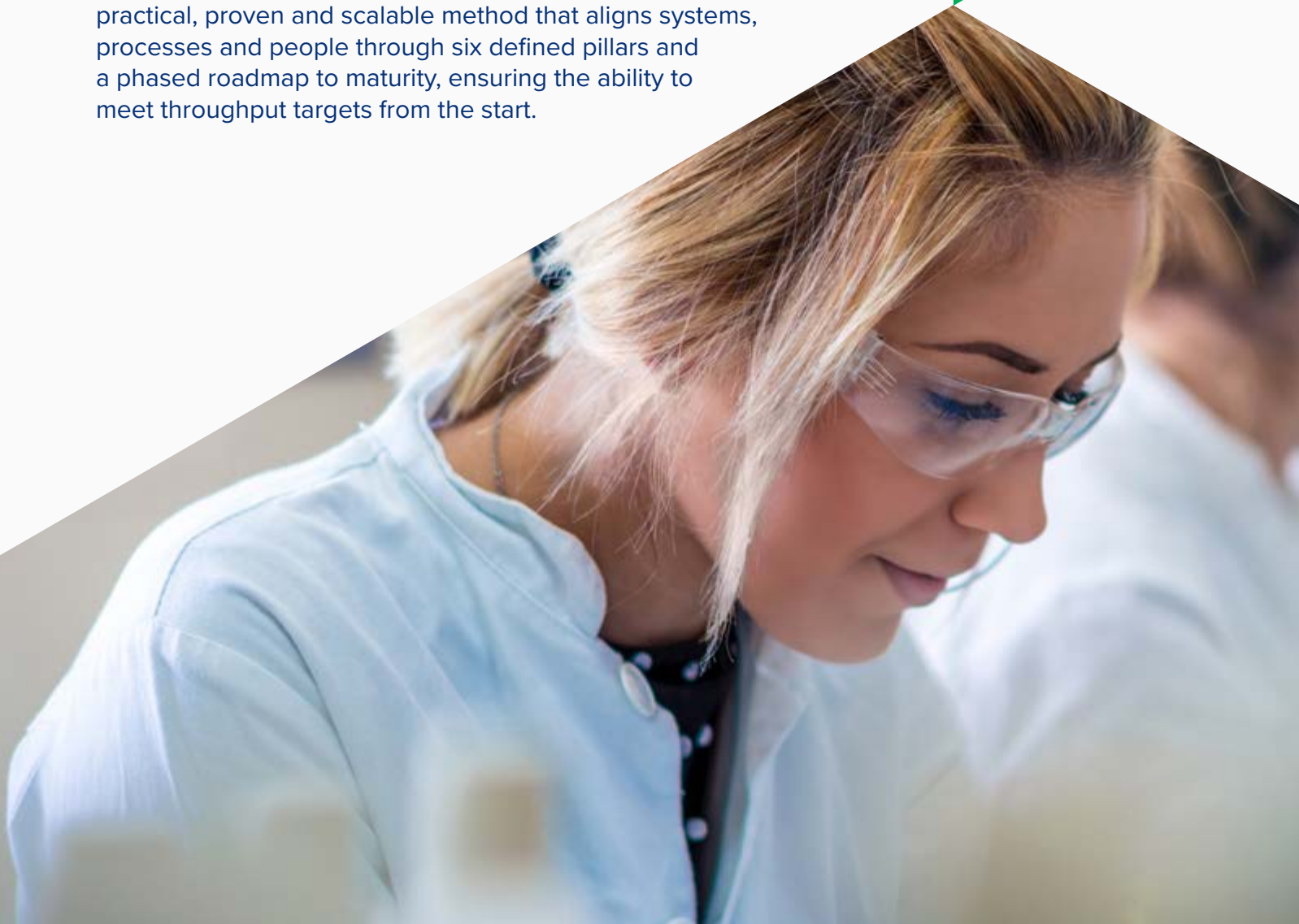


OPERATIONAL READINESS FOR LIFE SCIENCES:

SAFE, EFFICIENT AND COMPLIANT OPERATIONS FROM DAY ONE

Operational Readiness Framework from CAI is a practical, proven and scalable method that aligns systems, processes and people through six defined pillars and a phased roadmap to maturity, ensuring the ability to meet throughput targets from the start.





DELAYS, DEVIATIONS AND SETBACKS: COMMON PITFALLS IN FACILITY STARTUPS

When building a pharmaceutical manufacturing plant or other life sciences facility, the ideal scenario goes like this:

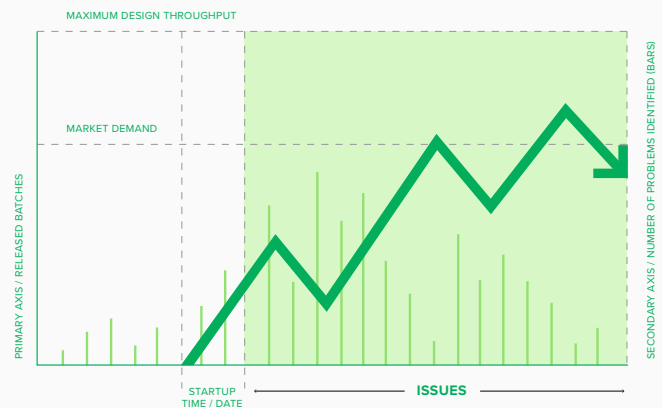
- Construction is completed with minimal setbacks and launch occurs on time
- Handoff is seamless from facility development to the operations team
- Production occurs at the desired throughput levels from Day One

Yet, as many have experienced, it never seems to happen this way. Instead, startup tends to look like the example shown on the top right, where unresolved risks and issues remain after startup, creating setbacks and errors and limiting production. The desired outcome is reflected in the graph on the bottom right, where risks are identified and addressed prior to launch. With risks and post-startup setbacks minimized or eliminated, production is accelerated right away.

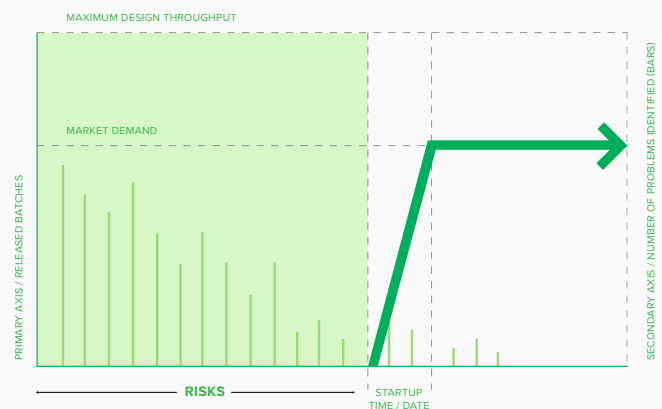
In the example where risks are not addressed prior to launch, launch is delayed and/or there is a period afterward (sometimes years long) where there are mistakes, inefficiencies and compliance issues. It's costly and requires extensive rework, all while not producing the amount of product (and revenue) the facility was designed to manufacture.

By taking a proactive risk-focused approach ahead of the startup period instead of reacting to issues as they come, we are able to launch in a state of Operational Readiness – prepared to operate at the levels and throughput that match the facility design.

A TALE OF TWO STARTUPS



OPTION A: Unresolved risks and issues remain after startup, leading to delays and a disruptive launch



OPTION B (OPERATIONAL READINESS): Risks are identified and addressed prior to startup, leading to an accelerated and successful launch



Operational Readiness: The Foundation for Seamless Startup

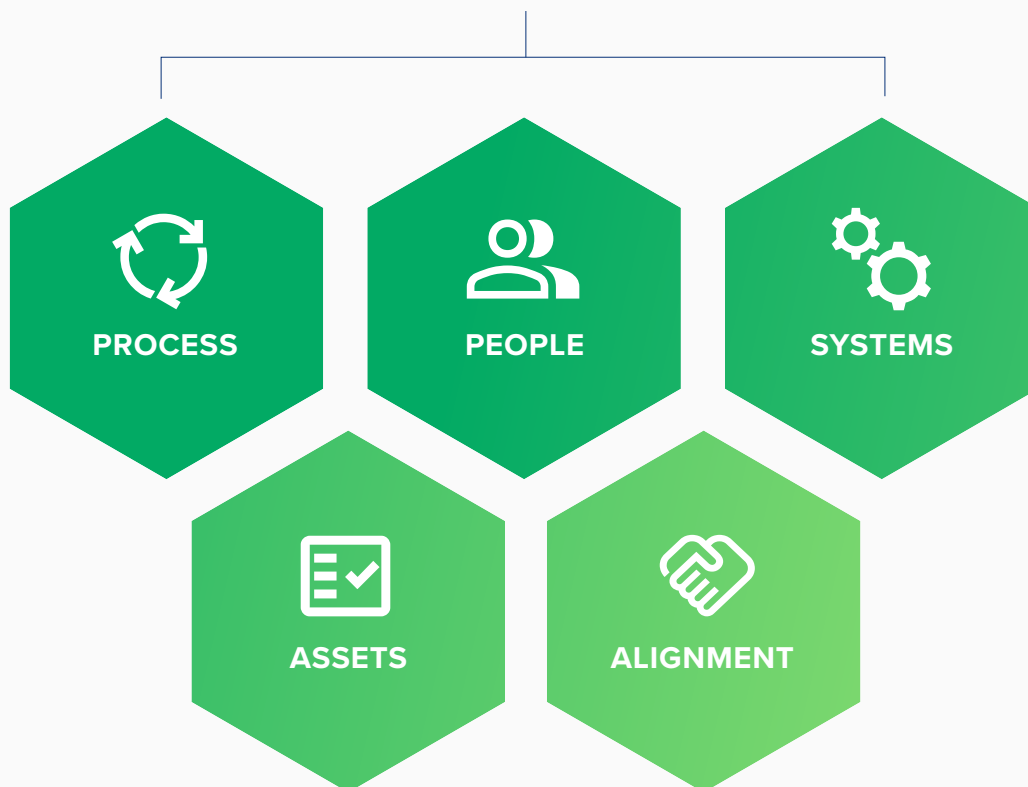
Operational Readiness goes beyond simply checking boxes—it's about ensuring that every element of a facility is fully prepared, coordinated and aligned to achieve production goals from Day One. Too often, organizations focus on individual fundamentals in isolation: teams work diligently within their silos, systems are installed, assets are delivered and staff are onboarded. Yet, when these elements don't come together in harmony, the result is misalignment, costly delays and missed targets.

Consider these common scenarios: Two teams independently reach their startup milestones, only to find their outputs don't integrate, leading to rework and wasted effort. Or assets are installed without operational input, resulting in equipment that

doesn't support production needs. Sometimes, employees begin work without clear training or defined roles, causing errors and inefficiencies. These situations do not occur due to lack of effort, rather from lack of alignment.

True operational readiness is achieved when process, people, systems and assets all work together as an integrated whole. Processes must be clearly defined and optimized, providing a roadmap for every activity. People need to be trained, qualified and empowered, fully understanding their roles and responsibilities. Systems must be robust, reliable and seamlessly integrated to support operations. Assets should be fit for purpose and ready to deliver value from the start. Most importantly, alignment is the thread that weaves these elements together—ensuring that every decision, action and resource is directed toward a common goal. When all five elements move in sync, organizations can launch facilities with confidence, minimize risk and accelerate value from the very start.

THE ESSENTIALS OF OPERATIONAL READINESS





A PRACTICAL, PROVEN MODEL FOR DAY ONE SUCCESS

The answer to avoiding these typical pitfalls is a consistent model to guide and measure a facility startup process. That's where CAI comes in.

CAI developed its Operational Readiness Framework to align all phases of the operation, ensuring an on-time launch, reducing post-launch errors and achieving optimal production levels immediately upon startup. The Framework is a practical, proven method to drive action, deliver results and give internal teams confidence.

Using the Framework ensures the optimal result from the Tale of Two Startups examples, rather than the error-riddled scenario.

The centerpiece of the CAI Operational Readiness Framework is the Six Pillars of Operational Readiness. Rather than building the framework around siloed functions like QA or training, the Six Pillars are interconnected strategic areas. On-time launch and ideal Day One output occurs when each area is successful and all six are aligned with one another.

All workstreams fall into one or more of the the six pillars. This approach ensures that people, processes, systems and infrastructure are all integrated around a common plan, creating collaboration across functions and ensuring that quality is at the center of all activities.

STRATEGY LEADERSHIP
Unified direction, culture and commitment across teams and systems for alignment and accountability to operational success.

EXECUTION EXCELLENCE
Readiness based on measurable outcomes via planning, risk management and continuous improvement for high-performance operations.

WORKFORCE CAPABILITY
All staff are supported, trained, qualified and clear on their roles—ready to perform on Day One.



EQUIPMENT & FACILITY READINESS
Facilities, equipment, utilities designed, installed, tested and maintained to meet operational needs.

DIGITAL & DATA ENABLEMENT
Digital systems and data flows are strategically designed to support rapid project delivery, better decision-making and efficiency.

QUALITY ADVANCEMENT
Quality and regulatory practices are best in class and phase-appropriate supporting operational agility and long-term performance.

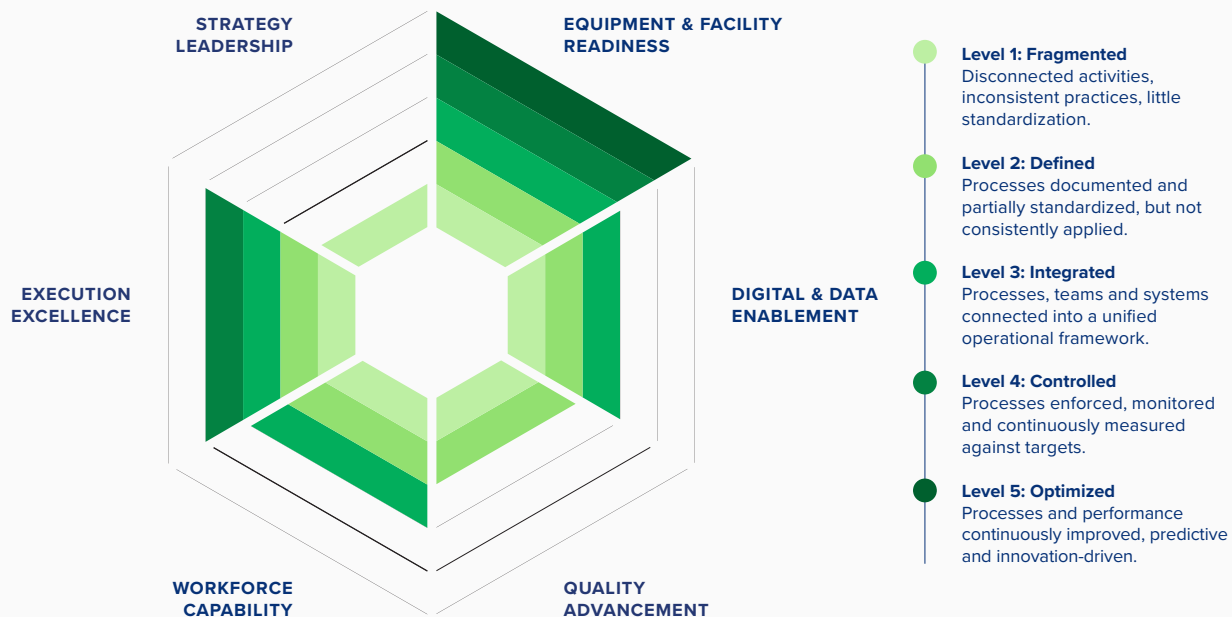


Pillar Maturity Model

Operational Readiness is measured across six foundational pillars, each representing a key domain of life sciences facility startup. The maturity of each pillar is assessed on a five-level scale, from Fragmented to Optimized. This approach helps teams identify strengths and gaps in areas such as leadership,

execution, quality, digital enablement, equipment readiness and workforce capability. The maturity spider graph visually displays your current state across all pillars. When every pillar reaches Level 3 (“Integrated”), your organization achieves basic operational readiness—ensuring people, processes, systems and assets are working together to support a confident launch.

EXAMPLE OF MATURITY LEVELS WITHIN THE SIX PILLARS OF OPERATIONAL READINESS



Program Maturity Roadmap

The Program Maturity Roadmap outlines the stepwise journey organizations follow to achieve and sustain operational readiness. This roadmap guides teams through five critical phases: Discover & Define, Build the Foundation, Execute & Integrate, Deploy at Scale and Sustain & Improve. Each phase

represents a set of coordinated activities and milestones that systematically close gaps, align cross-functional efforts and ensure readiness is built and maintained over time. The roadmap graphic illustrates how these phases create a clear, repeatable path to safe, efficient and compliant operations from Day One.

ROADMAP PHASES





THE INDUSTRY'S TRUSTED EXPERT IN OPERATIONAL READINESS

Often, a lack of a focused operational readiness framework is the biggest factor when facilities struggle at startup. There's a reason companies turn to CAI for support.

As a trusted partner across life sciences and mission-critical industries, CAI turns Operational Readiness into a competitive advantage. We've built our reputation and honed our expertise with decades of hands-on experience in the industry, gaining the knowledge to understand pharmaceutical manufacturing and what it takes to succeed from Day One.

Our Operational Readiness Framework and the integrated Six-Pillar approach did not come about overnight or by accident. It was developed and refined from years of being on the ground, guiding companies through multiple project delivery phases into successful launches.

With CAI as your partner, you get access to all we offer—the practical proven framework and the years of expertise from the top talent in the industry. Additionally, we bring:

- The latest advancements in technology and AI that optimize efficiency and accelerate readiness
- A field-tested process proven to consistently deliver projects on time and on budget
- A rigorous approach that sets industry standards for excellence and client satisfaction

Trusted. Tested. Ready to help ensure a seamless startup and operational success from Day One.

Set your course for success

The best way to lay the groundwork for a successful launch is to start the conversation early. Engaging with our experts gives your team the opportunity to identify gaps, align on priorities and build a clear path to operational readiness.

Operational Readiness Strategy Session: A focused, one-on-one consultation with a CAI expert. Review your current readiness approach, surface improvement opportunities and outline actionable strategies tailored to your project.

Operational Readiness Workshop: A structured, facilitator-led session for your cross-functional team. Align on key objectives, address potential risks and develop an integrated roadmap for a seamless and coordinated startup.





CAI is here to be your trusted partner to accelerate operational readiness and excellence through technology-driven solutions tailored to your business needs.

Let's get started. Contact us today to schedule an Operational Readiness [workshop](#) or [strategy session](#) tailored to your facility.

Call us at **(317) 271-6082** or contact us [online](#).

Are you ready?

