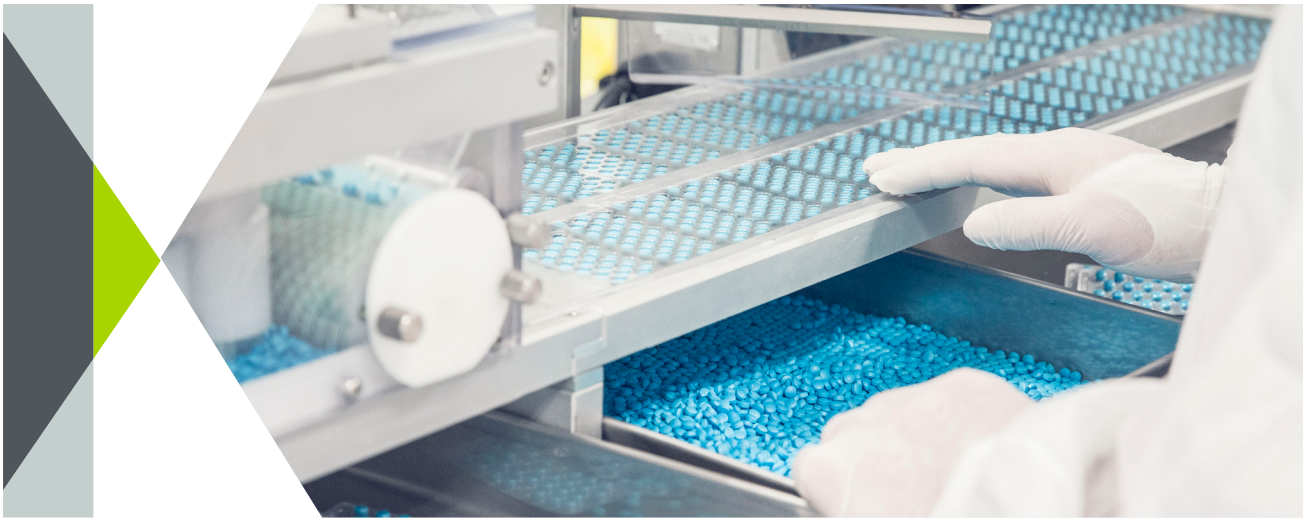


EXECUTIVE INSIGHTS

A View Into the Promise of Continuous Manufacturing

Key takeaways

1. Continuous manufacturing (CM) has the potential to transform pharma production by cutting costs, improving quality and speeding up timelines. It replaces fragmented batch processes with an integrated, real-time system that reduces waste, uses less space and ensures consistent product quality.
2. High upfront costs, complex tech and limited product compatibility — as well as the pharma industry's cautious mindset — make implementation challenging. Many products cannot yet be tested in-line, regulatory frameworks are still evolving and CM expertise is scarce.
3. CM is on the rise, with projected growth of 10%–15% per year, starting from a relatively low base of $2-3bn. Big Pharma is leading with high-volume drugs, while CDMOs are building platforms or partnering up with biopharma on specific projects.
4. CM has mostly been applied to small molecule and oral tablets, but near-to-mid-term adoption for biologics is starting, on a selective number of suitable products, with clear business cases.

Introduction

Pharmaceutical manufacturing is evolving. As the industry looks for ways to enhance efficiency, improve quality and strengthen supply chains, continuous manufacturing (CM) is emerging as a powerful alternative to traditional batch production.

Though adoption has been gradual, CM is gaining momentum across pharma and CDMOs — backed by growing regulatory support and real-world successes.

This *Executive Insights* explores the interesting advantages and opportunities that CM offers to the pharmaceutical industry, the challenges of adapting production processes, and the evolving regulatory landscape. It also provides an outlook on CM adoption.

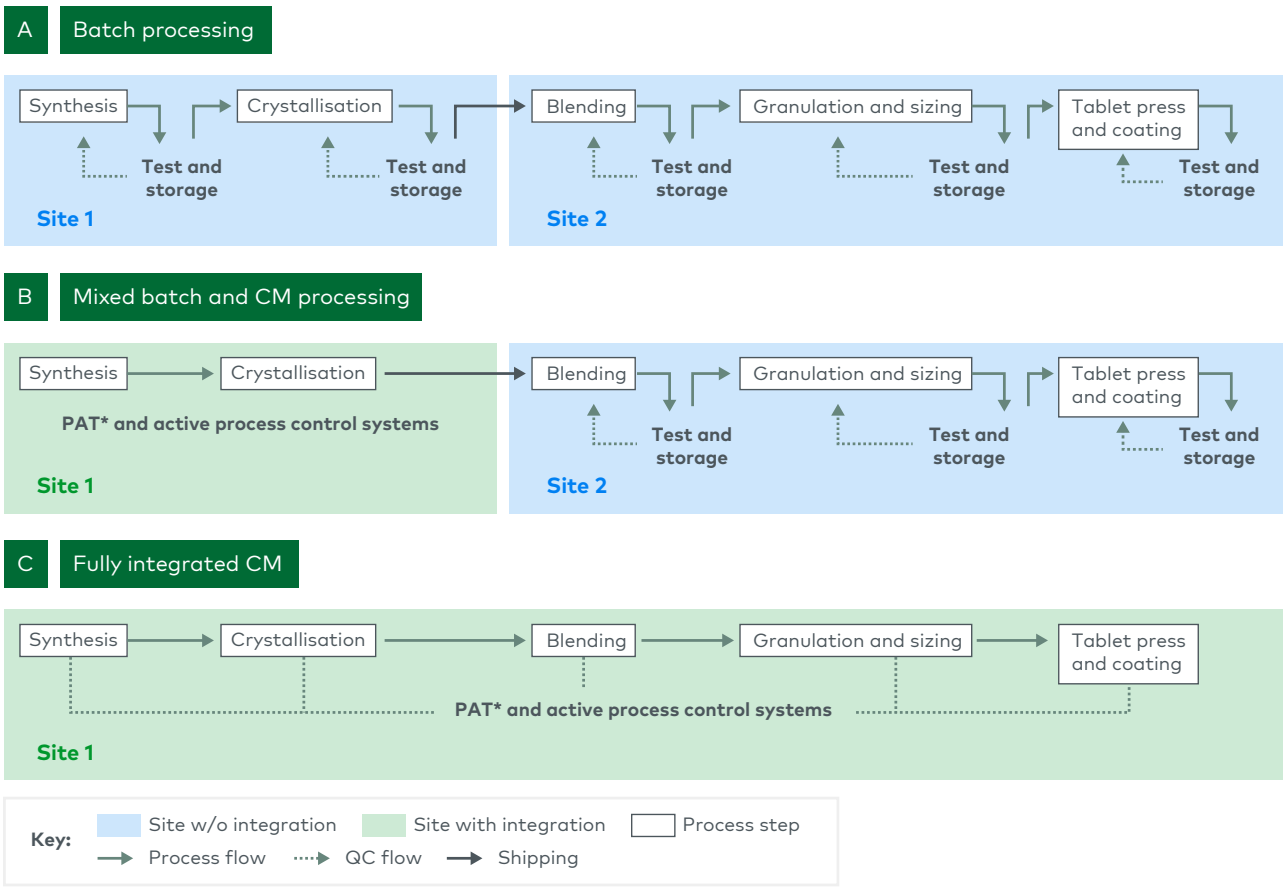
What is continuous manufacturing?

Continuous manufacturing is a fully integrated production process, where pharmaceuticals are created through an uninterrupted flow (see Figure 1). In its more integrated adoption, it covers the full process from production of pharmaceutical ingredients (APIs) to finished dosage form (FDF), streamlining everything into one cohesive system. This is a stark contrast to traditional batch processing, which is sequential, modular and often spread across multiple sites with significant downtime between each stage of the process.

In batch manufacturing, materials are processed in discrete steps, often with testing and storage between each of them, leading to inefficiencies, warehousing needs and batch-to-batch variation. Production volumes are not easily adjustable, and bottlenecks can arise when shifting between production lines.

Figure 1

Process flow representation for tablet manufacturing



Note: PAT=process analytical technology; CM=continuous manufacturing
Source: L.E.K. research and analysis

In CM, all steps are integrated into a closed-loop system, within a single facility. Process analytical technologies (PAT) and real-time quality control tools ensure continuous monitoring of product quality throughout the process.

CM can be applied to both drug substances or APIs, and drug products or finished dose formulations (FDFs). While most applications today focus on one end of the value chain, a few fully integrated examples exist.

In addition, there are emerging hybrid approaches that combine continuous and automated manufacturing process with batch-to-batch operational control elements (for quality and compliance monitoring).

One example is small-volume continuous (SVC) manufacturing, a setup that enables uninterrupted flow of materials while traceability is tight to a batch record (often defined as specific time frame). SVC is ideal for testing new configurations during early development phases and allows for flexible, frequent production cycles, and companies are increasingly mixing batch and continuous processes.

Why and when is CM interesting?

Continuous manufacturing can provide a strategic advantage to pharmacos, driving efficiency, speed, precision and resilience. In some cases, it also accelerates time-to-market and innovation.

By using less APIs and operating within facilities that can be up to 70% smaller than traditional batch lines, CM reduces waste, lowers inventory requirements, cuts operational costs by as much as 50%, and shortens production timelines. Its ability to operate with smaller volumes in combination with fully enclosed modular systems makes it suitable for handling production of highly potent API (HPAPI), reducing exposure risks for products with sensitive chemistries.

Integrated, real-time quality monitoring speeds up delivery, enhances consistency across production runs and reduces error rates, delivering superior product quality. CM is scalable by nature, which allows companies to flex production in line with demand by simply feeding frequency of materials and adjusting run times, without major infrastructure changes.

Proprietary CM processes can serve as a long-term differentiator (i.e. manufacturing efficiency, product quality, ability to scale up or down), reinforce competitive positioning (i.e. better costs and service pricing, improved timing, increased flexibility) and, in some cases, create barriers to generic competition (i.e. hard-to-replicate originator efficiency for new players).

For contract development and manufacturing organisations (CDMOs), CM efficiencies impact pricing power and operational appeal, improving the competitiveness of the service offering through faster, more cost-effective delivery.

Use cases

Real-world adoption of CM has occurred across the biopharma and pharma service industry (see Figure 2).

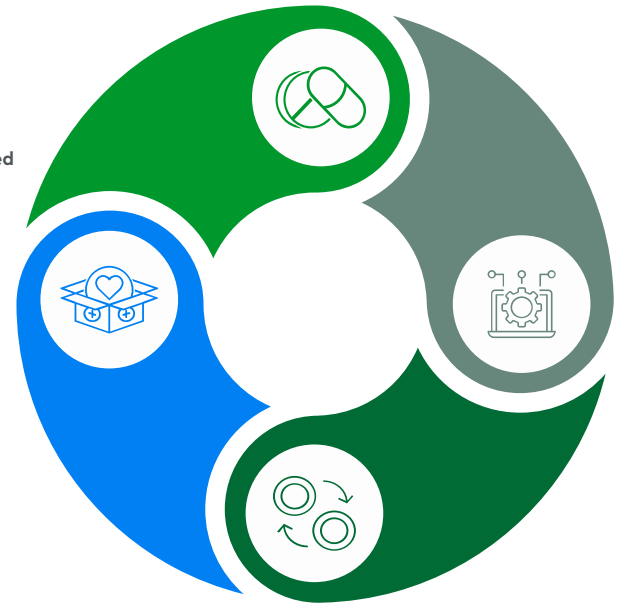
Pharma companies have internalised CM for both APIs and FDFs. However, in most cases, they have kept the two ends of the manufacturing process separate. CDMOs have developed fully owned CM solutions as well as developed partnerships between pharma and CDMOs, with most use cases focusing on API CM.

One of the most ambitious initiatives comes from Janssen, which set a target to produce 70% of its high-volume products using CM by 2025. The company has invested in dedicated facilities and transitioned key products (PREZISTA, TRAMCET), with regulatory approvals secured from the FDA and Japan's PMDA.

Pfizer has similarly set a target of manufacturing approximately 70% of its small molecule, solid oral dose portfolio using CM by 2030, leveraging its Portable, Continuous, Miniature and Modular (PCMM) technology — featuring a footprint 60%–70% smaller than traditional systems — already implemented at its facilities in Groton, Connecticut and Freiburg.

Figure 2

Industry examples



Pharma internalised processes
Continuous manufacturing for API

- Merck, for KEYTRUDA
- GSK, for JESDUVROQ and TRIUMEQ
- Eli Lilly, SVC for GLP-1s
- Dr. Reddy, for Atorvastatin-based products
- Sanofi, undisclosed biologics*

CDMO internalised processes

- Cambrex,** for Lumakrastm
- Continuus Pharmaceuticals, undisclosed
- ThermoFisher, undisclosed

Pharma internalised processes
Continuous manufacturing for FDF

- Janssen, for PREZISTA
- Pfizer, for DAURISMO
- Eli Lilly, for VERZENIO

Pharma and CDMO partnerships

- Hovione and Vertex, for ORKAMBI and SYMDEKO

*In collaboration with Sartorious
**Through the acquisition of Snapdragon Chemistry
Note: SVC=small volume continuous manufacturing capabilities
Source: L.E.K. research and analysis

Challenges for adopting CM

While continuous manufacturing holds significant promise, its widespread adoption is limited by a combination of economic, technical and regulatory challenges, as well as industry conservatism towards altering well-established and validated production processes.

The capital investment required can be substantial, making upfront costs a major hurdle. For generics manufacturers, the return on investment can be particularly difficult to meet given thin margins and high pressure on timing of product launch.

Technically, CM demands advanced process automation and robust PAT, creating complexity in both design and operation. Physical and chemical compatibility is a key limiting factor, as CM works best with APIs and formulations with appropriate potency, moisture sensitivity, particle size and toxicity. Recent technological advantages have made CM more suitable for OEB ≥4 and HPAPI manufacturing.

Regulatory uncertainty remains a challenge. Global frameworks are still evolving and relatively few precedents are available, with regulators and industry alike still building experience with CM submissions.

Compounding these issues is a widespread shortage of talent with the necessary capabilities and experience to operate CM production lines, with many organisations also lacking expertise to start and manage the transition from batch-to-batch to CM processes. Moreover, the deeply conservative industry culture continues to act as a brake on transformation towards newer, more agile approaches.

Opportunities to adopt CM

Although CM presents several challenges, there are numerous incentives and opportunities for companies considering its adoption (see Figure 3).

CM is particularly well-suited for new molecular entities (NMEs) and reformulations, as it allows integration of continuous processes from the earliest stages of development. This enables production lines to be designed specifically for continuous operation, eliminating the need to retrofit traditional batch systems and aligning manufacturing strategy, efficiency goals and product lifecycle planning.

NMEs have a multi-year development and commercialisation runway, providing time for CM process refinement, cost optimisation and enhanced quality control. The flexibility to begin production with smaller volumes and scale up efficiently during the ramp-up phase further supports CM suitability. Additionally, the long lifecycle of NMEs ensures that efficiency gains from CM can be fully realised while the product is generating significant revenue.

Reformulations developed for CM processes have the additional advantage of lower production costs and shorter timelines. This can create meaningful differentiation compared to existing marketed formulations, enhancing their competitive value.

During clinical development, CM can be built into the process early, streamlining scale-up and accelerating timelines. Single-use or SVC pilots offer a critical opportunity, enabling companies to test and refine CM systems, while gathering data to support a strong business case before committing to full-scale implementation.

In select cases, the cost benefits of CM can justify its use for commercialised products with stable, high-volume demand and a clear five-to-seven-year market outlook. These products typically offer a more reliable return on investment, providing sufficient time for the CM process to reach optimal efficiency while the product remains profitable.

As innovation in system design and analytics continues, the range of products suitable for CM is expected to expand, opening new pathways for adoption across the industry.

Figure 3

Challenges and opportunities in continuous manufacturing

Challenges for adoption

Economic barriers

- High upfront capital investment required
- Difficult to estimate return on investment
- Limited flexibility on marginality for most pharmaceuticals

Technical challenges

- System design is complex and requires advanced automation
- Needs robust process analytical technology
- API needs to be of appropriate potency and toxicity
- Formulation requires optimal particle size and low moisture sensitivity

Regulatory challenges

- Regulatory frameworks for CM are still evolving globally
- Few precedents exist for CM regulatory submissions
- All stakeholders are still gaining experience with CM

Workforce limitations and cultural barriers

- Shortage of CM-ready talent across the industry, with lack of in-house expertise for many players to manage the transition
- Conservative industry culture slows adoption of newer, agile manufacturing approaches

Opportunities

New molecular entities

- Possible to test set-up during clinical development
- Potential to shorten development timelines and to help streamline production scale-up in early launch
- SVC pilots can further reduce risks before full-scale implementation

Reformulations

- Provides opportunities to support lifecycle planning activities
- Efficiency gains can protect from generic competition
- Processes are easy to modulate (i.e. accelerate or slow down) to adapt to commercial success of the reformulation

Longstanding products and generics

- Ideal for products with stable, high-volume demand with a clear five-to-seven-year product horizon
- Data collection is easier to build the business case for CM
- Best suited to achieve long-term efficiency and operational goals

Note: API=active pharmaceutical ingredient; SVC=small volume continuous manufacturing capabilities; FDF=finished dosage form; CDMO=contract development and manufacturing organisation
Source: L.E.K. research and analysis

Criteria to determine CM suitability

When evaluating continuous processes for manufacturing pharmaceuticals, there are five main elements to consider:

1. **Product lifecycle alignment.** Ideal candidates are products in clinical development, where processes can be optimised early, before commercialisation. Reformulations or indication expansions, particularly when aligned with new branding or market strategies, also present natural inflection points for transitioning to CM. Switching existing commercialised products or generics is generally less favourable due to potential supply disruptions, but may be justified for high-volume, stable-demand products.
2. **Long-term demand visibility.** CM requires substantial capital, organisational and developmental commitment. A five-to-seven-year horizon tends to be a minimum requirement to offset the high costs of CM processes, justify the investment, and ensure ROI and resource commitment.
3. **Process control compatibility.** CM is the most efficient for products with consistent and well-defined chemical/physical characteristics (e.g. potency, humidity sensitivity, controlled substances).
4. **In-line testing feasibility.** Effective use of CM depends on the ability to conduct in-line quality testing, with current limitations in real-time analytical capabilities restricting CM's applicability for products that require off-line, destructive assays (e.g. modified-release formulations), have complex formulations (e.g. bi-layer tablets, combination drugs), have low compatibility with PAT methodologies (e.g. low-dose drugs or colourless/odourless APIs), or are highly sensitive or unstable (e.g. some biologics, peptides or light-sensitive APIs).
5. **Clarity on efficiency gains.** CM adoption must be supported by clear efficiency improvements in speed, cost or quality consistency as compared to batch-to-batch processes.

Adoption momentum and outlook for continuous manufacturing

Market analysts project 10%–15% annual growth in the CM landscape over the next five years, starting from a relative low base of $2-3bn, driven by advancing technologies, emerging use cases, growing regulatory alignment and overall confidence in the approach.

Several key trends are shaping this momentum:

- Leading regulatory bodies have shifted from cautious observers to active supporters. The FDA has approved multiple CM-based applications and published a self-audit in 2022 to show that CM applications can gain market access faster than comparable batch processes.[1] The WHO's forthcoming 2025 guideline will establish a framework

for CM, addressing best practices, risk management, process validation and system digitalisation.

- Big Pharma is leading the charge, with Janssen, GSK, Eli-Lilly, Sanofi and others making strategic investments, typically starting with high-volume, oral solid dose products.
- The emergence of small-volume continuous setups is lowering barriers to adoption by enabling experimentation in early development, helping build business cases before commercial-scale implementation.
- Technological advancements in the isolation of reactors and the adoption of single-use systems are expanding CM applicability to HPAPI products, while the miniaturisation and increasing modularity of CM systems are reducing both the time and cost required to set up new production lines.
- CDMOs' co-developing of CM lines with pharmacos or launching in-house platforms offers more flexible, efficient services to pharma clients.
- An expansion into biologics, with companies like Sanofi and Sartorius collaborating on continuous processes for biologics, is opening new frontiers and developing new use cases for CM.

Looking ahead, CM adoption will not happen overnight, and will likely remain product-specific and incremental, focusing most likely on assets with high-volume and long-term demand visibility that allow companies and CDMOs to build a business case that offsets capital expenditure and organisational effort.

How L.E.K. can help

With more than 25 years of experience, L.E.K. Consulting is a trusted advisor to leaders across the pharmaceutical and CDMO landscape, offering strategic guidance tailored to the complexities of pharmaceutical manufacturing.

We work closely with clients to evaluate the business case for continuous manufacturing, and identify the products and assets best suited for transition. Our support extends to shaping go-to-market strategies, as well as facilitating the partnerships and investment decisions critical to successful implementation.

Connect with us to explore how we can help you stay ahead of the curve and drive growth through continuous innovation.

Endnotes

[1]FDA, "An FDA Self-Audit of Continuous Manufacturing for Drug Products." https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/fda-self-audit-continuous-manufacturing-drug-products

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