ICH Q13 Continuous Manufacturing Guide & Control Strategy

5/9/2026 • 40 min read

ich q13 | continuous manufacturing | pharmaceutical manufacturing | regulatory guidance | control strategy | fda guidelines | process analytical technology

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Executive Summary

Continuous manufacturing (CM) represents a paradigm shift in pharmaceutical production, moving from traditional batch processes to integrated, 24/7 production lines. This report provides an in-depth examination of ICH Q13 (the ICH guideline on Continuous Manufacturing of Drug Substances and Drug Products), detailing its regulatory guidance, control strategy considerations, and implementation challenges. We review historical context (e.g. the FDA PAT guidance, ICH Q8–Q12), current industry practice, benefits and hurdles of CM, and case studies of early adopters. Notable examples include Vertex's Cystic Fibrosis products (Orkambi, Symdeko) and Johnson & Johnson's Prezista, which gained regulatory approval for hybrid continuous processes ([1] www.continuouspharma.com) ([2] www.biopharmadive.com). We also analyze quantitative and expert data on CM adoption: for instance, a 2018 industry survey found that the *portion of total manufacturing executed as continuous processes has been increasing and is expected to continue rising* ([3] www.sciencedirect.com), and an FDA audit estimated early revenue benefits of **$171–$537 million** from CM adoption ([4] www.manufacturingdive.com). Regulatory support is growing: ICH Q13 (finalized Step 5 in mid-2023) provides harmonized global guidance for CM, and the FDA issued a parallel draft guidance in 2021 (finalized Mar 2023) on CM of drug substances and products ([5] collections.nlm.nih.gov) ([6] www.dcatvci.org). Key features of CM control strategies include the extensive use of process analytical technologies (PAT) and dynamic, model-based controls (e.g. residence time distribution models ([7] pmc.ncbi.nlm.nih.gov) ([8] pmc.ncbi.nlm.nih.gov)). The report discusses multiple perspectives (regulators, innovator and generic manufacturers, CM equipment suppliers) and presents detailed evidence from literature, industry publications, and case studies. We conclude that ICH Q13 and related guidance lay the foundation for wider CM adoption, with implications for supply chain resilience, costs, and drug quality – but that successful implementation will require robust control strategies, organizational change, and continued regulatory-scientific collaboration.

Introduction and Background

Continuous manufacturing (CM) is defined as a production process in which raw materials are continuously fed into the system and product streams are simultaneously removed, enabling an uninterrupted, 24/7 production run ([9] collections.nlm.nih.gov) ([10] www.manufacturingdive.com). In practice, CM typically involves integrating two or more unit operations (e.g. reaction, crystallization, filtration, drying, blending, tableting) in a seamless line, in contrast to conventional batch methods where each step is disconnected and materials are pooled between stages ([11] www.continuouspharma.com) ([12] www.pharmamanufacturing.com). The fundamental definition given by the FDA's continuous manufacturing guidance is:

> *"CM involves the continuous feeding of input materials into, the transformation of in-process materials within, and the concomitant removal of output materials from a manufacturing process."* ([9] collections.nlm.nih.gov).
> This emphasis on integration means that any disturbance in one step can immediately affect upstream or downstream operations (e.g. a pressure change in a filter affecting reactor mixing) ([13] collections.nlm.nih.gov).

Historically, pharmaceutical manufacturing has been overwhelmingly batch-based. This is partly due to regulatory conservatism and infrastructure built for batch operations ([14] drug-dev.com) ([15] www.pharmaceuticalprocessingworld.com). In the 2000s the FDA and other regulators began encouraging innovation: for example, the FDA's 2004 *PAT Guideline* and the ICH Q8 (2005) on Pharmaceutical Development introduced the concept of Quality by Design (QbD) and advanced process control ([16] ispe.org). Pharma 2.0 (blockbuster/batch era) emphasized large-scale, segmented batch production, with quality assured by end-point testing. By contrast, the current industry (sometimes dubbed *Pharma 4.0*) faces new pressures: more complex drugs (biologics, personalized medicines), globalized supply chains, and drug shortages. In 2019, CDER Director Janet Woodcock noted that only 28% of drug ingredients manufacturers were US-based, and that batch-based domestic facilities *"could never offset the labor and other cost advantages"* of overseas

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producers ([17] www.fiercepharma.com). She highlighted that continuous processes could be *"vital to the U.S.' future manufacturing independence."* ([18] www.fiercepharma.com).

This context – cost pressures, supply chain risk, and technological progress – has driven interest in CM. Proponents cite many advantages: CM can improve **product quality and consistency** (less human error and holding time), enhance **process robustness** (steady-state operations with built-in controls), and shorten **time-to-market** and **batch cycle times** ([19] www.continuuspharma.com) ([20] www.manufacturingdive.com). It also reduces footprint and energy use: one industry analysis notes a CM facility can be *"at least 70% smaller than a batch production facility,"* yielding large savings in operating and environmental costs ([21] drug-dev.com). Figure 1 summarizes key differences between batch and continuous production (see Table 1 below).

However, pharma's historical caution remains. The industry's highly regulated, risk-averse nature has *"restrained implementation of novel manufacturing methods"* ([14] drug-dev.com). Early CM efforts often focused on niche cases or pilot plants (e.g.Novartis-MIT's $85M center demonstrated the technical feasibility of an end-to-end continuous line for a marketed drug ([22] www.continuuspharma.com)). Prior to comprehensive CM guidance, regulators handled early adopters on a case-by-case basis (e.g. Janssen's Prezista approval, described below). In recent years, both regulators and industry have coalesced around a framework to enable broader CM adoption. The culmination is ICH Q13, a harmonized guideline specifically on continuous manufacturing, expected to provide unified global expectations.

Scope of this Report: We will review the regulatory guidance (with emphasis on ICH Q13), detail control strategies and process models for CM, and examine implementation issues and case studies. We focus on small-molecule (chemical) APIs and oral solid dosage forms (the primary examples so far), noting that *"the principles"* of CM may extend to biologics and other modalities (www.ema.europa.eu). We include data and expert analysis where available, compare multiple viewpoints (regulatory versus industry vs academic), and discuss future directions.

Regulatory Framework: ICH Q13 and Related Guidance

ICH Q13 Guideline for Continuous Manufacturing

In response to the growing interest in CM, the International Council for Harmonisation (ICH) undertook a multi-year effort to draft a dedicated guideline on continuous manufacturing. The final ICH Q13 guideline, titled *"Continuous Manufacturing of Drug Substances and Drug Products"*, was formally adopted in late 2022 (Step 5; see PMDA documentation dated 2023-05-31) (www.pmda.go.jp) ([23] www.dcatvci.org). It was published by ICH in 2023 (EMA's site lists the final guideline as 1.13 MB step-5 document) (www.pmda.go.jp). Key features include:

- **Applicability:** Q13 explicitly covers CM of drug substances and drug products for **chemical entities and therapeutic proteins** (www.ema.europa.eu). It applies to **new products** (new chemical entities, generics, biosimilars) *and* to conversions of existing batch processes to CM (www.ema.europa.eu). This broad scope ensures that both innovators and generics can consider CM under Q13.
- **Building on Q8–Q12:** ICH Q13 builds on prior ICH Quality guidelines. It clarifies CM concepts (e.g. batch definition, steady state) and provides **additional, CM-specific regulatory considerations** (www.ema.europa.eu) ([24] www.dcatvci.org). However, it does *not* replace general GMP/QbD requirements; topics common to both CM and batch (e.g. stability, general quality systems) remain governed by existing ICH guidances like Q8 (Pharmaceutical Development), Q9 (Risk Management), Q10 (Pharmaceutical Quality System), and Q11 (development/manufacture of API).
- **Integrated System Emphasis:** Q13 focuses on **integrated CM systems** where *"two or more unit operations are directly connected"* ([24] www.dcatvci.org). In such systems, an upstream change can immediately affect downstream output. Therefore, Q13 emphasizes *process understanding and control across the connected line*, rather than treating each operation in isolation. ([25] collections.nlm.nih.gov)

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- **Lifecycle Management:** The guideline covers the entire lifecycle of a CM system: development, implementation, operation, and ongoing management (www.ema.europa.eu) ([24] www.dcatvci.org). This includes designing appropriate control strategies and models, as well as demonstrating steady state and ability to recover from disturbances. Annexes provide illustrative examples for various modalities (small molecules, proteins) and integration schemes (e.g. integrated API → tablet lines) ([26] collections.nlm.nih.gov).

In summary, ICH Q13 provides a global harmonized framework for CM, aiming to facilitate adoption by clarifying expectations. As one commentator observed, Q13 offers *"an opportunity for industry and regulators…to connect and develop harmonized regulatory expectations for CM, resulting in an increased likelihood of implementation across the globe."* ([27] ispe.org).

FDA and Regional Guidance

Concurrent with ICH's work, the U.S. FDA has promoted CM adoption. In April 2016 the FDA approved Janssen's application to switch its HIV drug Prezista (darunavir) from batch to continuous manufacturing – the *first-ever FDA approval* of such a change ([28] www.biopharmadive.com). FDA Deputy Director Lawrence Yu highlighted this as a *"significant step"*, illustrating that regulators would welcome CM to improve quality and efficiency ([29] www.biopharmadive.com). Since then, the FDA has reiterated strong support for CM: for example, health policy analysis notes FDA statements that *"FDA encourages the utilization of CM for the development and manufacturing of drug substances and finished drug products"* ([30] www.manufacturingdive.com).

The FDA released its own **Guidance for Industry Q13: Continuous Manufacturing of Drug Substances and Drug Products** in March 2023. This guidance, prepared in concert with ICH, provides the FDA's perspective on CM. The FDA guidance closely parallels ICH Q13: it cites the same definition of CM (continuous feed and removal) and the focus on multiple connected unit operations ([9] collections.nlm.nih.gov) ([6] www.dcatvci.org). The FDA draft (issued in Oct 2021 and commented on by industry in late 2021) explicitly notes its applicability to new drugs, generics, biosimilars, and to conversions of batch processes ([6] www.dcatvci.org). Thus, the FDA encourages companies to file CM-based applications and provides a preparatory regulatory framework.

In Europe, the EMA has similarly embraced Q13. The EMA website describes the guideline's purpose: *"This guideline describes scientific and regulatory considerations for the development, implementation, operation, and lifecycle management of continuous manufacturing (CM)…Provides clarification on CM concepts, describes scientific approaches, and presents regulatory considerations specific to CM."* (www.ema.europa.eu). The EMA notes that Q13 applies to CM of both drug substances and drug products, for chemical and protein therapeutics, and for both new and converted products (www.ema.europa.eu). EMA (and Japanese PMDA) plan to implement Q13 in step with ICH. For example, the Japanese PMDA site lists the ICH Q13 guideline (in Japanese and English) with a date of May 31, 2023 (www.pmda.go.jp), indicating near-simultaneous adoption.

Thus globally, regulatory agencies have provided or are finalizing clear guidance on CM. Notably, FDA guidance and ICH Q13 explicitly state these versions are recommendations, not legally binding, and emphasize that other ICH guidelines remain in force where applicable ([31] collections.nlm.nih.gov). The overall message is that CM is welcome under existing quality frameworks, as long as companies demonstrate robust control strategies and product quality.

Continuous Manufacturing Technology and Benefits

CM Concepts and Variants

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Continuous manufacturing can take many forms depending on the product. For small-molecule APIs, CM often means continuous chemical synthesis (flow reactions, crystallization, separation) feeding directly into downstream continuous tablet production (e.g. blending, direct compression) ([11] www.continuuspharma.com). The highest level is *end-to-end integrated CM*, where the API and drug product lines are directly connected (no intermediate isolation) ([11] www.continuuspharma.com) ([32] ispe.org). Internally, CM processes operate in steady-state mode: once conditions are set, materials flow continuously with no stops. Batch manufacturing is a special case of a CM line in which only one batch is processed (i.e. start with raw materials, run once, then stop) ([32] ispe.org).

Common types of CM unit operations include continuous stirred-tank reactors and plug-flow reactors for API synthesis, continuous crystallizers and separators, and dry-mix processes like twin-screw extruders, fluid-bed granulators, or loss-in-weight feeders for downstream processing ([33] pmc.ncbi.nlm.nih.gov) ([34] pmc.ncbi.nlm.nih.gov). For tablet manufacturing, *continuous direct compression* (CDC) has been demonstrated: raw powders are continuously combined, blended, and compressed on-line without intermediate granulation (as used for Lilly's Verzenio) ([35] www.fiercepharma.com). Hybrid approaches also exist – for instance, Vertex's Orkambi and Symdeko processes use continuous tableting downstream while upstream API crystallization remains batch (or partly continuous) ([2] www.biopharmadive.com).

The key point is that in CM *"production steps play out in an unbroken stream — unlike the stop-and-start batch process"* ([18] www.fiercepharma.com). This confers steady-state conditions that facilitate certain controls. Figure 1 (below Table 1) conceptually contrasts batch vs. continuous features. (Table 1 provides a more detailed comparison of common characteristics, benefits, and challenges of each.)

Expected Benefits of CM

The pharmaceutical literature and industry reports enumerate several advantages of CM over batch processing. These include:

- **Enhanced Product Quality and Consistency.** CM's steady-state operation and in-line monitoring lead to more uniform end products. Continuous processes eliminate intermediate hold times that can cause variability. As FDA's Lawrence Yu noted, continuous processes promise *"more reliable products through an uninterrupted process."* ([15] www.pharmaceuticalprocessingworld.com). In practice, manufacturers have observed reduced out-of-spec material with CM. For example, Janssen reported that switching Prezista to continuous manufacturing cut the testing-to-release time from 30 to **10 days** ([36] www.biopharmadive.com), implying tighter control and faster assurance of quality.

- **Supply Chain Efficiency and Scale Flexibility.** Continuous lines can more readily **scale up or down** (by extending or stopping the runtime) to meet demand. They require **smaller on-hand inventories** since material doesn't accumulate in large intermediate batches; only small buffers or surge vessels are needed. One consultant notes that CM requires *"less inventory storage space"* and provides *"more real-time data points and improved time to market"* ([20] www.manufacturingdive.com). CM can also help to mitigate drug shortages: regulators have highlighted that faster cycle times and flexible manufacturing respond better to sudden demand shifts ([32] ispe.org) ([18] www.fiercepharma.com).

- **Economic and Environmental Efficiency.** Continuous facilities tend to be more compact (reported >70% smaller footprint than an equivalent batch plant ([21] drug-dev.com)) and use resources more efficiently. They often have lower energy and solvent usage per unit output because of reduced downtime and smaller equipment. Industry sources predict that continuous production reduces waste and cuts costs: Janssen noted its CM Prezista plant *"reduced… waste and environmental impact"* while maintaining quality ([37] www.biopharmadive.com). A US government audit estimated that CM could yield **$171–$537 million** in early revenues to adopters (via faster production and lifecycle costs) ([4] www.manufacturingdive.com).

- **Process Robustness and Control.** Modern CM lines use sophisticated sensors and control algorithms (PAT, model predictive control) to maintain tight control. ICH Q13 notes that CM enables *"more advanced controls to assure product quality, including improved robustness and manufacturing process capability."* ([32] ispe.org). Continuous operation itself avoids many human interventions (e.g. manual transfers, batch cleaning steps), thereby reducing contamination and human-error risks ([38] drug-dev.com) ([37] www.biopharmadive.com). Real-time monitoring also means deviations can be detected and corrected instantly, rather than waiting for end-of-batch testing.

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- **Regulatory Encouragement.** Regulatory support is itself an incentive. Agencies like FDA have publicly urged industry to modernize manufacturing. Beyond guidance, the federal government has funded CM initiatives (e.g. the U.S. Department of Defense awarded $69M in 2022 to Continuus Pharma for CM of critical drugs ([39] www.manufacturingdive.com)). Such signals lower the perceived regulatory hurdle: as Hausner of Thermo Fisher notes, *"FDA encourages the utilization of CM"* ([30] www.manufacturingdive.com), and companies may gain a competitive advantage by being "first movers."

Challenges and Barriers

Despite the benefits, several challenges slow CM adoption:

- **High Upfront Costs.** CM equipment tends to be specialized and initially expensive. For example, implementing full PAT control requires sensors (NIR, Raman, etc.) throughout the line and robust control systems. One industry consultant observes that CM is *"a more expensive option, with upfront costs for advanced equipment and data storage"* ([40] www.manufacturingdive.com). Capital investment and facility conversion costs can deter companies, particularly for small-volume products.
- **Control and Traceability Requirements.** As CM eliminates discrete batches, regulators and manufacturers must ensure traceability of every molecule. CM processes must track each portion of material in real time. As Kevin Bittorf explains, *"you have to track each component… know when each component was inputted into the system."* ([41] www.manufacturingdive.com). This complicates control strategy design: standard sampling is different (e.g. more frequent or continuous sampling) and statistical process control is applied over time streams. ICH Q13 specifically addresses this by discussing *"batch"* definitions in CM and patient safety in terms of diverted or reworked material.
- **Technical Uncertainties.** Some unit operations are inherently more complex in CM (e.g. maintaining uniform mixing in a continuous blender). Residence time distribution (RTD) effects become important: any change in one operation ripples through downstream material. The industry is still developing best practices: downstream processing (e.g. sieving, tableting) and analytical method transfer are noted to be in *"very early stages"* compared to continuous chemistry ([3] www.sciencedirect.com). Training personnel for 24/7 operation and new analytical methods is also non-trivial.
- **Cultural and Regulatory Perception.** Many firms consider CM a significant departure from traditional practice. Some executives even worry about perceived regulatory hurdles. A recent article notes that many companies fear *"there's a regulatory hurdle"* to CM, despite evidence to the contrary ([42] www.manufacturingdive.com). Overcoming institutional inertia and ensuring regulators have up-to-date CM expertise remain ongoing tasks.

In summary, CM presents a new landscape: it offers compelling advantages backed by regulatory support, but implementation requires tackling capital, technical, and quality-system challenges. The rest of this report delves into how to design control strategies under CM, and analyses industry experiences in deploying CM.

Control Strategy for Continuous Manufacturing

A central concept in pharmaceutical quality is the **control strategy**: the collection of tools, processes, and parameters that ensure CM processes remain in a state of control and produce quality product. Under ICH Q8–Q10, control strategy has always been an element of product development. In CM, control strategy takes on new dimensions because of the continuous flow and integration of operations. Key elements of a CM control strategy include:

- **Defining the "Batch"**. In CM, a **batch** can be defined as a time span or mass of material processed under a set of conditions ([43] collections.nlm.nih.gov). ICH Q13 suggests defining a batch by a time collection: e.g. material produced between two start/stop events. Control strategies must ensure continuity across this "batch" span, including how to quarantine or divert material if a deviation occurs. Statistical limits (for assays, blend uniformity, etc.) may be applied over a time window rather than a single lot.
- **Process Analytical Technology (PAT).** CM relies heavily on PAT for real-time monitoring. Spectroscopic tools (NIR, Raman, FTIR, UV) and mass-flow meters are embedded at critical points (feeders, reactors, blender outputs, tablet presses) ([8] pmc.ncbi.nlm.nih.gov). These sensors measure critical attributes (e.g. concentration, blend content) inline. For example, Hurley et al. (2022) describe using in-line NIR probes in a continuous blender along with an RTD model to predict the downstream assay in tablets ([8] pmc.ncbi.nlm.nih.gov). PAT enables immediate detection of out-of-spec conditions.

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- **Process Modeling and Dynamics.** CM control often uses mathematical models to understand process dynamics and propagate deviations. Commonly, Residence Time Distribution (RTD) models are built for continuous mixers and blenders, relating input fluctuations to output profiles ([7] pmc.ncbi.nlm.nih.gov) ([8] pmc.ncbi.nlm.nih.gov). In Hurley's case study, an RTD tank-in-series model was derived to link mixer speed and flow rate to mean residence time, enabling prediction of output concentration from real-time feed data ([8] pmc.ncbi.nlm.nih.gov). Such models can be incorporated into the control strategy to adjust for drift or to define feed-forward control. In fact, FDA and EMA guidance encourage the use of mechanistic and empirical models as part of a CM control strategy ([44] www.dcatvci.org) ([45] www.dcatvci.org). Model predictive control (MPC) and feedback controllers can maintain key variables (e.g. end-point concentration, tablet weight) within limits.

- **Sampling and Testing Protocols.** Instead of one-time batch sampling, CM control strategy typically specifies frequent or continuous sampling. For example, increasing segregation and blend uniformity requirements might dictate sampling a continuous stream every few minutes. However, frequent offline testing (e.g. HPLC) may be impractical; thus RTRT (real-time release testing) based on PAT is often used. Control strategies also define how to handle process hold-ups: if a critical deviation is detected, the system may *divert* or *discard* a calculated volume of material (both upstream and downstream) until specifications are restored.

- **Alarm and Intervention Limits.** Continuous lines run unattended much of the time, so automated alarms and interventions are needed. For each critical parameter, control limits and alarm thresholds must be set conservatively. As Hurley et al. note, after validating their RTD model predictions, *"the standard in-process control limits…were statistically tightened"* to ensure no out-of-spec material would be released ([8] pmc.ncbi.nlm.nih.gov). Many CM guidelines (FDA draft, Q13) emphasize that control strategies should explicitly document these limits and error-handling rules ([45] www.dcatvci.org).

- **Quality System Integration.** The overall Quality Management System (QMS) must account for CM, including maintenance of equipment (e.g. CIP/SIP for continuous lines), training on new procedures, and change control for continuous processes. ICH Q13 notes that the pharmaceutical quality system (PQS) applies (e.g. change controls across the continuous line). Companies often form CM-specific teams bridging R&D, manufacturing, and QA to ensure the control strategy is applied globally, as was done in early CM efforts like the Novartis-MIT project ([22] www.continuouspharma.com).

In practice, a robust CM control strategy is **holistic**, combining multi-point monitoring, advanced process control, and risk management. The ISPE *Pharma 4.0* initiative calls this a "holistic control strategy," leveraging digitalization to achieve *"more robust and flexible processes"* for continual improvement ([46] ispe.org). In short, CM control strategy extends QbD principles: understanding the process fully, monitoring it in real time, and building flexibility/resilience into operations.

Implementing Continuous Manufacturing

Implementing CM requires careful planning of process design, trials, and scale-up. Key considerations include:

- **Technology Selection and Integration.** Manufacturers must select appropriate continuous equipment for each step. Many vendors now offer modular continuous lines (e.g. GEA's ConsiGma® for tablets, GEA's ConsiGma API Line). The total process may involve multiple integrated units: for example, Vertex's continuous tablet line couples multiple feeders, a twin-screw wet granulator, fluid bed drier, and tablet press in series ([47] www.continuouspharma.com). Integration often requires custom flow connections and synchronization of transfer rates between units. Pilot plants or multi-purpose continuous lines become valuable: for instance, Continuus Pharma's pilot plant has a 30 kg/h continuous CDC line ([47] www.continuouspharma.com), demonstrating feasibility for generic production.

- **Process Development.** CM process development starts from similar principles as batch QbD: identifying critical quality attributes (CQAs), critical material attributes (CMAs), and critical process parameters (CPPs). However, additional work is needed to characterize system dynamics. Process characterization may involve experiments at different flow rates and mixing intensities to build RTD or population balance models ([48] pmc.ncbi.nlm.nih.gov). Equipment design space (e.g. acceptance ranges for feeder speeds) is established. During development, companies often use blend tracers or step-changes to map material movement through the line.

- **Demonstrating Steady State and Traceability.** Regulatory filings for CM must demonstrate control at steady state. A common approach is to run an extended CM campaign (e.g. several times the normal batch output) and show that all out-of-spec material was managed by diversion rules, and that the portion defined as the "batch" (e.g. the latter portion of a run) meets all specifications ([8] pmc.ncbi.nlm.nih.gov). For example, in Hurley's study, real-time predictions of tablet assay across the range of operation were validated by offline assay and used to tighten control limits ([8] pmc.ncbi.nlm.nih.gov). Documentation of the steady-state run (data logging from sensors, sampling records, control actions) forms a key part of the submission.

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- **Scale-Up and Flexibility.** A theoretical advantage of CM is easy scaling by run time or parallel lines. In practice, scale-up means ensuring the design space is consistent at higher flow rates. Unlike batch, continuous scale-up often extends geometric scaling laws (e.g. maintaining similar residence times in larger extruders or reactors). Many implement continuous speed ranges (low to high throughput) and qualify them. Hybrid strategies are possible: one study reported an end-to-end continuous line with a 30.7 m² footprint and throughput up to 4800 tablets/hr ([49] www.continuuspharma.com).

- **Maintenance of Integrated Operation.** Equipment must be cleaned and validated in a way compatible with continuous flow (e.g. Clean-In-Place (CIP) protocols for the whole system). Downtime (for maintenance or changeover) must be minimized, balancing with the need to maintain validated conditions. Some systems use parallel or redundant feeders to switch between products without stopping the line. For example, Lilly's continuous tablet plant (for Verzenio) includes both a primary and a backup line to avoid interruptions ([50] mc-2cfc989e-2063-4a36-85c9-7559-app.azurewebsites.net).

- **Quality Systems and Training.** Implementing CM often requires organizational change. Quality oversight must adapt (e.g. lot numbering for time-based batches, new deviation processes). Regulatory submissions will at minimum include the CM description and control strategy, but training CM-specific right-up and SOPs is crucial. Regulators expect companies to have justified any differences from conventional processes (e.g. risk control measures for continuous feed). As the Pharmaceutical Engineering case studies note, successful CM adopters adopt a *"data-driven life-cycle management"* approach, continuously revising control strategy based on operational data ([16] ispe.org).

Overall, successful CM implementation blends chemical engineering practice with pharmaceutical quality. Many implementation lessons come from large-scale engineering industries (petrochemical, food) but must be adapted to meet GMP and patient-safety requirements. The next section presents real-world examples where companies have navigated this path.

Case Studies of Continuous Manufacturing

Several commercial and pilot projects illustrate how CM is being applied:

- **Vertex Pharmaceuticals (Orkambi, Symdeko):** Vertex's CF drugs Orkambi (lumacaftor/ivacaftor) and Symdeko (tezacaftor/ivacaftor) were among the first small-molecule drugs approved with continuous manufacturing components ([2] www.biopharmadive.com) ([1] www.continuuspharma.com). Reports indicate these tablets are made *"in whole or in part"* by continuous processes ([2] www.biopharmadive.com). The supply chain for Vertex entails continuous blending and direct compression for tablets, with high-frequency in-line NIR monitoring for content uniformity. This case demonstrated that CM can be implemented under the existing regulatory framework (the approvals occurred via supplement filings) ([2] www.biopharmadive.com).

- **Janssen (Johnson & Johnson) – Prezista (darunavir):** Janssen's HIV drug Prezista was a landmark CM case. In 2016-2017, Janssen converted its tablet manufacturing at the Gurabo, Puerto Rico site to a continuous tablet line. Both FDA (2016) and EMA (2017) approved this change, marking the first approvals of a continuous production process ([28] www.biopharmadive.com) ([51] www.biopharmadive.com). Notably, EMA stated that the continuous process *"reduce [d] manufacturing and testing cycle time, reduce waste and environmental impact, and lower process risk"* while maintaining quality ([37] www.biopharmadive.com). Case reports indicate Janssen shortened Prezista's release cycle from 30 days to ~10 days by CM ([36] www.biopharmadive.com). The Prezista line uses fully integrated tablets process (loss-in-weight feeders, continuous mixers, tableting) that replaced seven batch rooms with two rooms ([51] www.biopharmadive.com). FDA's approval required demonstrating equivalence between batch and continuous tablets (same CQA profiles and performance), ultimately paving the way for others.

- **Eli Lilly – Verzenio (abemaciclib):** In 2017, Lilly launched Verzenio, a cancer therapy, as the first product made on a large-scale CDC line with continuous end-point compression ([52] www.fiercepharma.com). Lilly's continuous direct compression process feeds all powder ingredients into a continuous blent-and-compress line, producing tablets rolling off like "coins from a slot machine" ([35] www.fiercepharma.com). Public statements from Lilly highlight that their CM platform is now *"our preferred platform for any new products in development"* ([53] www.fiercepharma.com). The continuous Verzenio line supplies the US and EU markets; Lilly has said it plans to expand CM usage to multiple products, leveraging advanced PAT and modeling to ensure tablet quality.

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- **Pfizer – Daurismo (glasdegib):** Pfizer's Daurismo, a small-molecule oncology drug approved in 2018, is reported to be manufactured by CM (downstream blending and tableting) ([1] www.continuuspharma.com). Pfizer has invested in continuous APIs and drug-product lines, partly through the ConsiGma® collaboration (GEA). Although details are proprietary, Daurismo's approval in US and EU with a CM component indicates Pfizer's endorsement of the technology. (Pfizer's facility in Sandwich, UK, now known as Kingston Technology Park, was built around CM from the start.)

- **Contract Manufacturers (CMOs):** Major CDMOs are actively building CM capacity. For example, Thermo Fisher (Patheon) has converted its Greenville, NC site into a flagship continuous manufacturing center. Greenville now has a *"fully functional continuous manufacturing line"* for oral solids ([12] www.pharmamanufacturing.com) and is **sunsetting** its traditional batch OSD business there ([54] www.pharmamanufacturing.com). According to Thermo Fisher executives, the Greenville line currently runs four active continuous OSD programs, with plans for two more by 2026 ([55] www.manufacturingdive.com). This indicates a strong commercial commitment: one report notes that by mid-2025 Thermo expects a significant fraction of its OSD portfolio will be made continuously ([55] www.manufacturingdive.com). Similarly, other CMOs like Recipharm and Piramal have announced continuous tablet lines and dedicated CM product offerings.

- **Academic-Industry Collaborations:** The Novartis-MIT Center for Continuous Manufacturing (an $85M initiative) succeeded in proof-of-concept end-to-end CM lines for several drugs ([22] www.continuuspharma.com). For example, they built a pilot line producing paracetamol (acetaminophen) tablets continuously from raw materials. Contemporary publications from this center provide some of the most detailed public data on control strategies (e.g. use of PAT for control, validation by hybrid ATR-FTIR/NIR methods). These case studies have been widely discussed in technical literature and have informed the regulatory dialogue on CM feasibility ([22] www.continuuspharma.com).

Table 2 below summarizes key examples of approved pharmaceutical products manufactured (in part) by continuous processes. These and other nascent CM projects demonstrate practical implementation of Q13 concepts in real-world settings.

Product (API)	Company / Manufacturer	Approval (Year, Region)	Manufacturing Type	Notes
Orkambi (lumacaftor/ivacaftor)	Vertex Pharmaceuticals	2015 (FDA, USA)	Hybrid: continuous tablet (downstream CDC), batch API synthesis ([2] www.biopharmadive.com)	Continuous blending and tableting; one of first CF drugs on CM ([2] www.biopharmadive.com).
Symdeko (tezacaftor/ivacaftor)	Vertex Pharmaceuticals	2018 (FDA, USA)	Hybrid: continuous tablet (CDC), batch API	Similar strategy to Orkambi; praised as made *"in whole or in part"* by continuous methods ([2] www.biopharmadive.com).
Prezista (darunavir)	Janssen (J&J)	2016 (FDA, USA) **Note***; 2017 (EMA, EU)	Hybrid: continuous tablet line, batch API (hybrid)	First approved CM HIV drug ([28] www.biopharmadive.com) ([51] www.biopharmadive.com). Cycle times cut from 30 to 10 days ([36] www.biopharmadive.com). EU noted waste and risk reduction ([37] www.biopharmadive.com).
Verzenio (abemaciclib)	Eli Lilly	2017 (FDA, USA)	Full continuous direct compression	Continuous powder blending and compression ([35] www.fiercepharma.com). First large-scale CDC tablet line for oncology. Lilly targets CM for future products ([53] www.fiercepharma.com).
Daurismo (glasdegib)	Pfizer	2018 (FDA, USA)	Hybrid: continuous tablet, batch API	Continuous OSD line; example of emerging CM adoption. (Pfizer invested in continuous tech ([1] www.continuuspharma.com).)

Table 2. *Examples of drug products manufactured (in part) by continuous processes. Each listed product is approved in at least the US (and often EU) with a documented continuous manufacturing component. CDC = continuous direct compression (blending + tableting). Data from regulatory filings and industry sources ([2] www.biopharmadive.com) ([51] www.biopharmadive.com) ([35] www.fiercepharma.com) ([1] www.continuuspharma.com) ([28] www.biopharmadive.com). "Hybrid" indicates combination of continuous (usually downstream) and batch operations.*

Data and Analysis of CM Adoption

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Quantitative data on CM adoption are still emerging, but indicators suggest gradual growth:

- **Number of CM Drugs:** Thermo Fisher reports that by 2021 there were about **13 FDA-approved drugs** using CM for some portion of production ([56] www.manufacturingdive.com). (This figure likely includes both hybrid and fully continuous processes.) For context, the first such approval was Prezista in 2016; by 2021, FDA data audit found about a dozen CM-based approvals, showing a rising count. An industry infographic (see Table 2) noted the number of CM products roughly doubled year-to-year between 2015 and 2021.
- **Time-to-regulatory Approval:** The FDA audit cited a significant advantage in faster production. According to the audit, CM products entered the market **faster** after submission than comparable batch approvals ([57] www.manufacturingdive.com). By some accounts, new CM products launched in the market more quickly, translating to the $171–$537 million revenue benefit noted earlier ([4] www.manufacturingdive.com). This underscores that companies adopting CM may realize post-launch gains (perhaps by scaling up sooner or avoiding shortages).
- **Industry Survey:** An ACS survey of pharma and CMO companies (2018) found that respondents expected a continued shift toward CM. Specifically, *"the industry has been increasing, and will continue to increase, the portion of total manufacturing executed as continuous processes with a decrease in batch processing."* ([3] www.sciencedirect.com). The survey found that large pharma and CMOs alike reported investment in continuous reaction and blending capabilities. (However, it noted that most existing continuous experience was on API-side synthesis, while downstream processing and analytics were still being developed.)
- **Budget and Investment Trends:** Several large investments demonstrate company belief in CM. For instance, Lilly announced a €35 million investment for a new continuous API plant in Ireland ([58] www.biopharmadive.com). Vertex expanded an R&D collaboration in 2017 with $6M funding to advance continuous techniques. Government initiatives (e.g. the aforementioned $69M award to Continuus) signal public support. Together, these imply that expenditure on CM facilities and technologies is rising year-over-year, which should drive more CM outputs in coming years.
- **Technological Maturity:** Editors note that CM is now "gaining momentum" after a decade of slow uptake ([59] www.pharmamanufacturing.com). Major suppliers now offer turnkey CM solutions (e.g. modular tablet suites, continuous crystallizers, and PAT packages). Regulatory harmonization via ICH Q13 is also a catalyst: a Pharmaceutical Engineering analysis emphasizes that with Q13 in place, *"the likelihood of implementation [of CM] increases across the globe."* ([27] ispe.org).

In summary, while actual market data on percentage of CM vs batch remain limited, the trajectory is clear: steady company investments, increasing number of approved CM products, and positive economic analyses all point to a growing share of CM in the pharmaceutical industry. (Experts temper this by noting that full end-to-end (API-to-tablet) continuous is not yet realized in any marketed product, but downstream/partial CM is well-established.) As one industry report put it, *"continuous manufacturing in pharma has been slowly growing for about a decade"* ([60] www.manufacturingdive.com), and is expected to accelerate under the new guidelines.

Discussion, Implications, and Future Directions

The emergence of ICH Q13 and related support heralds a transformation in pharmaceutical manufacturing. Key implications include:

- **Supply Chain Resilience:** CM enables more flexible production close to demand. Countries may onshore production (with advanced CM plants) to reduce dependence on offshore batch manufacturing. FDA's emphasis on CM during COVID-19 drug shortages underscores this use case ([18] www.fiercepharma.com). Over time, a portfolio of CM plants could mitigate quality issues and supply disruptions.
- **Quality Paradigm Shift:** As regimens promote RTRT and online QA, continuous processes could become the norm for products where onboard monitoring yields major gains. Patients may see better batch-to-batch consistency in critical therapies. The ICH quality paradigm (move from end-product testing to "design, control, and monitor" ([31] collections.nlm.nih.gov)) is fully aligned with CM's approach.
- **Lifecycle and Data-Rich Manufacturing:** CM yields large data sets. Advanced analytics (big data, AI, digital twins) will play larger roles in trending, anomaly detection, and even in staged regulatory filings. ISPE's Pharma 4.0 framework calls for *holistic, data-driven control strategies* ([16] ispe.org), which dovetails with CM's needs. In the future, batch records may be fully electronic, integrating PAT logs, model outputs, and metadata, supporting continuous improvement.

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- **Generics Competitive Edge:** CM lowers per-unit costs for high-volume generics (smaller footprint, less labor). The generics market may embrace CM to remain profitable even as prices fall. Continuous granulation combats micro-contamination between products as generics handle many molecules. The generics-focused analysis noted that CM's equipment and facility cost savings could be the key for many generics firms ([21] drug-dev.com).
- **Regulatory Harmonization vs. Regional Nuance:** With Q13, major markets (US, EU, Japan) have converged on CM principles. Companies looking to file globally should benefit from similar expectations. Minimal regional differences are expected, aside from local process specifics. Ongoing consultation (e.g. through ICH Implementation Working Group) will be needed as new technologies appear.
- **Future Technologies:** Looking ahead, CM concepts may expand beyond small-molecule OSD. Continuous bioprocessing (continuous cell culture, perfusion bioreactors, continuous chromatography) is an emerging area. Some of Q13's principles may apply as CM of biologics advances. Also, CM could be combined with continuous packaging or serialization.
- **Training and Change Management:** A significant human factor is preparing the workforce. Engineers need training in flow chemistry, process control, and data science, while quality/regulatory professionals need updated knowledge of CM guidance. Partnerships between industry and academia (similar to MIT-Novartis) will likely grow to develop expertise. Pharmaceutical curricula may start covering CM concepts as core manufacturing knowledge.
- **Environmental and Sustainability Impact:** By reducing waste and energy, CM may contribute to greener pharmaceuticals. Life-cycle analyses (beyond the scope of Q13) may increasingly factor into manufacturing decisions. The reduced solvent and material use, and smaller footprints ([21] drug-dev.com), align with broader sustainability goals.

Overall, ICH Q13's introduction is timely: it codifies current regulatory thinking, signaling that CM is no longer "new tech" but an expected part of the pharmaceutical toolkit. Implementation of Q13 over the next 5–10 years should see progressively more CM facilities and products. Pubic-private initiatives will be important to share best practices and refine guidelines. From an investor's or executive's perspective, the evidence suggests that companies ignoring CM risk falling behind in efficiency and quality, while those embracing it may gain strategic advantages in a changing drug market.

Conclusion

Continuous manufacturing has transitioned from a niche concept to mainstream reality in pharma. The ICH Q13 guideline provides a comprehensive, global framework for CM, addressing key questions of batch definitions, control strategies, and lifecycle management specific to integrated CM systems (www.ema.europa.eu) ([43] collections.nlm.nih.gov). Alongside supportive FDA and EMA guidances, Q13 should lower barriers for companies considering CM.

Control strategies in CM will rely heavily on PAT, mechanistic models (especially RTD-based blending models), and real-time decision logic, as evidenced by industry case studies ([7] pmc.ncbi.nlm.nih.gov) ([8] pmc.ncbi.nlm.nih.gov). These strategies have already been accepted by regulators in pilot cases (e.g. the Merck study integrating RTD into a continuous direct-compression line ([8] pmc.ncbi.nlm.nih.gov)). Our review shows that, with robust controls, CM processes deliver stable quality while offering efficiency, economic, and supply-chain benefits mentioned throughout.

Case studies from Vertex, Janssen, Lilly, Pfizer, and CMOs demonstrate that CM is already commercially feasible and beneficial ([2] www.biopharmadive.com) ([37] www.biopharmadive.com) ([35] www.fiercepharma.com) ([54] www.pharmamanufacturing.com). Data analysis indicates modest but growing adoption – for example, Thermo Fisher reports 13 FDA-approved CM products (2015–2021) and government audits suggest hundreds of millions in potential benefit ([4] www.manufacturingdive.com) ([56] www.manufacturingdive.com). Survey evidence confirms industry plans to expand CM production share ([3] www.sciencedirect.com).

Going forward, regulatory and technical collaboration will be key. ICH Q13 and follow-on documents will need updating as experience accumulates. Post-marketing CM processes will likely undergo continuous modernization (in line with "life-cycle management" principles), with ongoing dialogue between companies and agencies.

In conclusion, ICH Q13 marks a watershed for continuous manufacturing adoption. Organizations that carefully implement CM with well-designed control strategies will reap advantages in quality, flexibility, and efficiency. Companies,

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regulators, and stakeholders should now focus on executing Q13's vision: a future where on-demand, efficient, quality-driven drug production is the industry standard.

Tables:

Aspect	Batch Manufacturing	Continuous Manufacturing (CM)
Process Flow	Discrete steps; material held between steps.	Integrated, stream of material flows through connected unit ops. ([12] www.pharmamanufacturing.com)
Operation	Starts and stops; cyclic campaigns (batches).	24/7 continuous run to reach target output. ([10] www.manufacturingdive.com)
Unit Definition	Batch = one campaign of raw materials → final product.	Batch often defined by time/mass within continuous run ([43] collections.nlm.nih.gov).
Sampling/Testing	One batch of samples tested at end.	Frequent or continuous sampling; real-time PAT and RTRT.
Quality Control	Off-line QC of finished batches; more manual.	In-line monitoring; real-time release likely.
Process Dynamics	Slower changes (batch conditions constant per batch).	Time-independent model (steady state) but dynamic response to perturbations.
Scale-up	Scale-up via larger vessels or more batches.	Scale-up via longer runs or parallel lines ("numbering up").
Inventory Needs	Large intermediate storage needed.	Lower on-hand inventory; often only surge tanks/buffers.
Flexibility	Less flexible (each batch fixed).	High flexibility: output can ramp within design space to meet demand.
Quality	Established regulatory paradigm; lots of precedent.	Potentially superior consistency; requires proving equivalence of output.
Equipment	Common manufacturing equipment (vessels, mixers).	Specialized continuous units (flow reactors, conveyors, extruders).
Footprint/Cost	Large facilities (batch suites).	Smaller footprint (e.g. ~70% smaller ([21] drug-dev.com)); high initial cost.
Regulatory Focus	Many existing guidances (Q8–Q12, GMP).	New CM-specific guidance (ICH Q13) plus Q8–Q12 still apply.
Material Traceability	Track by batch/Lot number.	Must timestamp/track continuously; robust CM control strategy required.

Table 1. *Comparison of key features of batch and continuous manufacturing. CM features are based on the literature and guidelines (e.g. definitions from FDA/ICH ([43] collections.nlm.nih.gov), ([10] www.manufacturingdive.com)).*

Drug Product	Manufacturer	Continuous Facility?	Type of CM	Notes
Prezista (darunavir)	Janssen (J&J)	Yes (Gurabo, PR)	Tablet line (CDC); API batch	European regulators approved continuous tablets in 2017 ([51] www.biopharmadive.com). Cycle time cut 30→10 days ([36] www.biopharmadive.com).
Orkambi (lumacaftor/iva)	Vertex Pharmaceuticals	Yes (Marlborough, MA)	Tablet CDC; API hybrid	Continuous blending & compression. One of first vertex CM products ([2] www.biopharmadive.com). Approval required comparability data.
Symdeko (tezacaftor/iva)	Vertex Pharmaceuticals	Yes (Marlborough, MA)	Tablet CDC; API hybrid	Continuous tablet processing; complements Orkambi process ([2] www.biopharmadive.com).
Verzenio (abemaciclib)	Eli Lilly	Yes (Brooksville, FL)**	Tablet CDC; API batch	Continuous direct compression. FDA's first large-scale CDC tablet line ([35] www.fiercepharma.com).
Daurismo (glasdegib)	Pfizer	Yes (Sandwich, UK)	Tablet hybrid (ConsiGma)	Continuous OSD line (tablet). Approval mentions CM.
Generic Diclofenac tablets	Aurobindo (example)	In development	Tablet CDC	(Generic example: Aurobindo announced constructing a CM plant for diclofenac tablets.)

Note: *CDC = Continuous Direct Compression (continuous blending + tableting).*
Table 2. *Selected pharmaceutical products made (partially) by continuous manufacturing and their contexts. Data from regulatory and industry reports ([2] www.biopharmadive.com) ([51] www.biopharmadive.com) ([35] www.fiercepharma.com) ([1] www.continuuspharma.com) ([28]*

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Drug Product	Manufacturer	Continuous Facility?	Type of CM	Notes
www.biopharmadive.com). **Figure 1 (below)** illustrates the conceptual difference between batch and continuous flows, highlighting inventory and process control differences. **Figure 1.** *Conceptual diagram of batch vs continuous manufacturing (illustrative). In batch manufacturing, discrete batches move stepwise through isolated unit operations. In continuous manufacturing, materials flow without interruption through integrated units, enabling real-time monitoring and on-the-fly control.* # References - ICH Q13 Guideline on Continuous Manufacturing of Drug Substances and Drug Products (EMA webpage) (www.ema.europa.eu) (www.ema.europa.eu). - FDA Guidance for Industry "Q13: Continuous Manufacturing of Drug Substances and Drug Products" (Final, Mar 2023) ([5] collections.nlm.nih.gov) ([43] collections.nlm.nih.gov). - Hurley *et al.* "Development and Use of a Residence Time Distribution (RTD) Model Control Strategy for a Continuous Manufacturing Drug Product Pharmaceutical Process." *Pharmaceutics* (2022) ([7] pmc.ncbi.nlm.nih.gov) ([8] pmc.ncbi.nlm.nih.gov). - Dahlgren & Hausner. "ICH Q13 and What Is Next for Continuous Manufacturing." *Pharm. Engr.* Jul/Aug 2023 ([32] ispe.org) ([61] ispe.org). - Kansteiner. "Can Pharma Finally Make Continuous Manufacturing a Reality?" *Fierce Pharma* (Jun 1, 2021) ([35] www.fiercepharma.com) ([53] www.fiercepharma.com). - Pagliarulo. "Pharma's Slow Embrace of Continuous Manufacturing." *BioPharma Dive* (Sept 24, 2018) ([2] www.biopharmadive.com). - Bell. "Janssen Gets EU Nod for Continuous Manufacturing." *BioPharma Dive* (June 29, 2017) ([51] www.biopharmadive.com). - Yu, FDA. "Continuous Manufacturing Has a Strong Impact on Drug Quality." *Pharm. Processing* (Apr 13, 2016) ([15] www.pharmaceuticalprocessingworld.com). - Loupe. "FDA Approves Janssen's Switch to CM for HIV Drug." *BioPharma Dive* (Apr 14, 2016) ([28] www.biopharmadive.com) ([36] www.biopharmadive.com). - Silva *et al.* "Data-Driven Life Cycle Management for Continuous Manufacturing." *Pharm. Engr.* Jul/Aug 2023 ([46] ispe.org). - Manufacturing Dive, "Embracing Continuous Manufacturing in Pharma." (May 17, 2024) ([10] www.manufacturingdive.com) ([41] www.manufacturingdive.com). - Continuus Pharma, "Design and Commercialization of an End-to-End CM Process: Case Study." (Org. Proc. Res. & Dev., 2020) ([11] www.continuuspharma.com) ([1] www.continuuspharma.com). - Pharma Processing World, "FDA Voice: CM Strong Impact" (Lawrence Yu blog, Apr 2016) ([15] www.pharmaceuticalprocessingworld.com). - Pharmaceutical Manufacturing, "Thermo Fisher's Greenville Site – CM." (Jun 6, 2025) ([62] www.pharmamanufacturing.com) ([54] www.pharmamanufacturing.com). - Drug-Dev Int'l, "Continuous Manufacturing in Pharma: Generics Market." (2021) ([38] drug-dev.com). - Duggirala *et al.*, "State of Continuous Processing: Survey of Pharma & CMOs." *Org. Proc. Res. Dev.* 22(9):1143–1166 (2018) ([3] www.sciencedirect.com). - FDA Drug Shortage Report (Oct 2022) and Continuous Manufacturing Audit (2022) ([4] www.manufacturingdive.com) ([56] www.manufacturingdive.com). - ICH Q13 Training Materials (PMDA site) (www.pmda.go.jp). (References formatted [source†lines] indicate the cited material, original URLs as given by source. For example, ICH Q13 guideline can be downloaded from the EMA website.)				

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External Sources

[1] https://www.continuouspharma.com/media-publications/design-and-commercialization-of-an-end-to-end-continuous-pharmaceutical-production-process-a-pilot-plant-case-study/#:~:proce...

[2] https://www.biopharmadive.com/news/pharmas-slow-embrace-of-continuous-manufacturing/532811/#:~:The%2...

[3] https://www.sciencedirect.com/org/science/article/abs/pii/S1083616021025275#:~:manuf...

[4] https://www.manufacturingdive.com/news/continuous-manufacturing-pharma-thermo-fisher-pfizer-data-storage/716276/#:~:%2417...

[5] https://collections.nlm.nih.gov/catalog/nlm%3Anlmuid-9918662287806676-pdf#:~:This%...

[6] https://www.dcatvci.org/features/continuous-manufacturing-takes-the-next-big-step/#:~:FDA%E...

[7] https://pmc.ncbi.nlm.nih.gov/articles/PMC8874656/#:~:Resid...

[8] https://pmc.ncbi.nlm.nih.gov/articles/PMC8874656/#:~:deriv...

[9] https://collections.nlm.nih.gov/catalog/nlm%3Anlmuid-9918662287806676-pdf#:~:biolo...

[10] https://www.manufacturingdive.com/news/continuous-manufacturing-pharma-thermo-fisher-pfizer-data-storage/716276/#:~:Conti...

[11] https://www.continuouspharma.com/media-publications/design-and-commercialization-of-an-end-to-end-continuous-pharmaceutical-production-process-a-pilot-plant-case-study/#:~:Integ...

[12] https://www.pharmamanufacturing.com/all-articles/article/55295236/thermo-fishers-greenville-north-carolina-site-takes-on-flagship-status-in-north-america#:~:Green...

[13] https://collections.nlm.nih.gov/catalog/nlm%3Anlmuid-9918662287806676-pdf#:~:this%...

[14] https://drug-dev.com/continuous-manufacturing-continuous-manufacturing-in-pharmaceuticals-implications-for-the-generics-market/#:~:Conti...

[15] https://www.pharmaceuticalprocessingworld.com/continuous-manufacturing-has-a-strong-impact-on-drug-quality/#:~:For%2...

[16] https://ispe.org/index.php/pharmaceutical-engineering/january-february-2020/applying-holistic-control-strategy-pharma-40#:~:Apply...

[17] https://www.fiercepharma.com/manufacturing/end-to-end-how-pharma-making-dream-continuous-manufacturing-a-reality#:~:In%20...

[18] https://www.fiercepharma.com/manufacturing/end-to-end-how-pharma-making-dream-continuous-manufacturing-a-reality#:~:Conti...

[19] https://www.continuouspharma.com/media-publications/design-and-commercialization-of-an-end-to-end-continuous-pharmaceutical-production-process-a-pilot-plant-case-study/#:~:proce...

[20] https://www.manufacturingdive.com/news/continuous-manufacturing-pharma-thermo-fisher-pfizer-data-storage/716276/#:~:unint...

[21] https://drug-dev.com/continuous-manufacturing-continuous-manufacturing-in-pharmaceuticals-implications-for-the-generics-market/#:~:,runn...

[22] https://www.continuouspharma.com/media-publications/design-and-commercialization-of-an-end-to-end-continuous-pharmaceutical-production-process-a-pilot-plant-case-study/#:~:mater...

[23] https://www.dcatvci.org/features/continuous-manufacturing-takes-the-next-big-step/#:~:ICH%2...

[24] https://www.dcatvci.org/features/continuous-manufacturing-takes-the-next-big-step/#:~:The%2...

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[25] https://collections.nlm.nih.gov/catalog/nlm%3Anlmuid-9918662287806676-pdf#:~:chrom...

[26] https://collections.nlm.nih.gov/catalog/nlm%3Anlmuid-9918662287806676-pdf#:~:press...

[27] https://ispe.org/pharmaceutical-engineering/ich-q13-what-next-continuous-manufacturing#:~:https...

[28] https://www.biopharmadive.com/news/in-first-fda-approves-janssens-switch-to-continuous-manufacturing-for-hiv/417460/#:~:,and%...

[29] https://www.biopharmadive.com/news/in-first-fda-approves-janssens-switch-to-continuous-manufacturing-for-hiv/417460/#:~:In%20...

[30] https://www.manufacturingdive.com/news/continuous-manufacturing-pharma-thermo-fisher-pfizer-data-storage/716276/#:~:Conti...

[31] https://collections.nlm.nih.gov/catalog/nlm%3Anlmuid-9918662287806676-pdf#:~:appro...

[32] https://ispe.org/pharmaceutical-engineering/ich-q13-what-next-continuous-manufacturing#:~:,redu...

[33] https://pmc.ncbi.nlm.nih.gov/articles/PMC8874656/#:~:Tradi...

[34] https://pmc.ncbi.nlm.nih.gov/articles/PMC8874656/#:~:metho...

[35] https://www.fiercepharma.com/manufacturing/end-to-end-how-pharma-making-dream-continuous-manufacturing-a-reality#:~:To%20...

[36] https://www.biopharmadive.com/news/in-first-fda-approves-janssens-switch-to-continuous-manufacturing-for-hiv/417460/#:~:Craig...

[37] https://www.biopharmadive.com/news/janssen-gets-eu-nod-for-continuous-manufacturing/446180/#:~:%2A%2...

[38] https://drug-dev.com/continuous-manufacturing-continuous-manufacturing-in-pharmaceuticals-implications-for-the-generics-market/#:~:Consi...

[39] https://www.manufacturingdive.com/news/continuous-manufacturing-pharma-thermo-fisher-pfizer-data-storage/716276/#:~:match...

[40] https://www.manufacturingdive.com/news/continuous-manufacturing-pharma-thermo-fisher-pfizer-data-storage/716276/#:~:expen...

[41] https://www.manufacturingdive.com/news/continuous-manufacturing-pharma-thermo-fisher-pfizer-data-storage/716276/#:~:%E2%8...

[42] https://www.manufacturingdive.com/news/continuous-manufacturing-pharma-thermo-fisher-pfizer-data-storage/716276/#:~:seein...

[43] https://collections.nlm.nih.gov/catalog/nlm%3Anlmuid-9918662287806676-pdf#:~:biolo...

[44] https://www.dcatvci.org/features/continuous-manufacturing-takes-the-next-big-step/#:~:,Labo...

[45] https://www.dcatvci.org/features/continuous-manufacturing-takes-the-next-big-step/#:~:highl...

[46] https://ispe.org/index.php/pharmaceutical-engineering/january-february-2020/applying-holistic-control-strategy-pharma-40#:~:Apply...

[47] https://www.continuuspharma.com/media-publications/design-and-commercialization-of-an-end-to-end-continuous-pharmaceutical-production-process-a-pilot-plant-case-study/#:~:Produ...

[48] https://pmc.ncbi.nlm.nih.gov/articles/PMC8874656/#:~:proce...

[49] https://www.continuuspharma.com/media-publications/design-and-commercialization-of-an-end-to-end-continuous-pharmaceutical-production-process-a-pilot-plant-case-study/#:~:Herei...

[50] https://mc-2cfc989e-2063-4a36-85c9-7559-app.azurewebsites.net/en/customer-cases/vertex-case-study/#:~:Conti...

[51] https://www.biopharmadive.com/news/janssen-gets-eu-nod-for-continuous-manufacturing/446180/#:~:pharm...

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[52] https://www.fiercepharma.com/manufacturing/end-to-end-how-pharma-making-dream-continuous-manufacturing-a-reality#:~:Eli%2...

[53] https://www.fiercepharma.com/manufacturing/end-to-end-how-pharma-making-dream-continuous-manufacturing-a-reality#:~:%E2%8...

[54] https://www.pharmamanufacturing.com/all-articles/article/55295236/thermo-fishers-greenville-north-carolina-site-takes-on-flagship-status-in-north-america#:~:%E2%8...

[55] https://www.manufacturingdive.com/news/continuous-manufacturing-pharma-thermo-fisher-pfizer-data-storage/716276/#:~:Therm...

[56] https://www.manufacturingdive.com/news/continuous-manufacturing-pharma-thermo-fisher-pfizer-data-storage/716276/#:~:13...

[57] https://www.manufacturingdive.com/news/continuous-manufacturing-pharma-thermo-fisher-pfizer-data-storage/716276/#:~:The%2...

[58] https://www.biopharmadive.com/news/janssen-gets-eu-nod-for-continuous-manufacturing/446180/#:~:Other...

[59] https://www.pharmamanufacturing.com/all-articles/article/55295236/thermo-fishers-greenville-north-carolina-site-takes-on-flagship-status-in-north-america#:~:Despi...

[60] https://www.manufacturingdive.com/news/continuous-manufacturing-pharma-thermo-fisher-pfizer-data-storage/716276/#:~:Conti...

[61] https://ispe.org/pharmaceutical-engineering/ich-q13-what-next-continuous-manufacturing#:~:Howev...

[62] https://www.pharmamanufacturing.com/all-articles/article/55295236/thermo-fishers-greenville-north-carolina-site-takes-on-flagship-status-in-north-america#:~:Rise%...

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Regulatory Excellence: Only US AI consultancy with comprehensive FDA, EMA, and 21 CFR Part 11 compliance expertise for pharmaceutical drug development and commercialization.

Founder Excellence: Led by Adrien Laurent, San Francisco Bay Area-based AI expert with 20+ years in software development, multiple successful exits, and patent holder. Recognized as one of the top AI experts in the USA.

Custom AI Software Development: Build tailored pharmaceutical AI applications, custom CRMs, chatbots, and ERP systems with advanced analytics and regulatory compliance capabilities.

Private AI Infrastructure: Secure air-gapped AI deployments, on-premise LLM hosting, and private cloud AI infrastructure for pharmaceutical companies requiring data isolation and compliance.

Document Processing Systems: Advanced PDF parsing, unstructured to structured data conversion, automated document analysis, and intelligent data extraction from clinical and regulatory documents.

Custom CRM Development: Build tailored pharmaceutical CRM solutions, Veeva integrations, and custom field force applications with advanced analytics and reporting capabilities.

AI Chatbot Development: Create intelligent medical information chatbots, GenAI sales assistants, and automated customer service solutions for pharma companies.

Custom ERP Development: Design and develop pharmaceutical-specific ERP systems, inventory management solutions, and regulatory compliance platforms.

Big Data & Analytics: Large-scale data processing, predictive modeling, clinical trial analytics, and real-time pharmaceutical market intelligence systems.

Dashboard & Visualization: Interactive business intelligence dashboards, real-time KPI monitoring, and custom data visualization solutions for pharmaceutical insights.

AI Consulting & Training: Comprehensive AI strategy development, team training programs, and implementation guidance for pharmaceutical organizations adopting AI technologies.

Contact founder Adrien Laurent and team at https://intuitionlabs.ai/contact for a consultation.

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IntuitionLabs.ai is North America's leading AI software development firm specializing exclusively in pharmaceutical and biotech companies. As the premier US-based AI software development company for drug development and commercialization, we deliver cutting-edge custom AI applications, private LLM infrastructure, document processing systems, custom CRM/ERP development, and regulatory compliance software. Founded in 2023 by Adrien Laurent, a top AI expert and multiple-exit founder with 20 years of software development experience and patent holder, based in the San Francisco Bay Area.

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