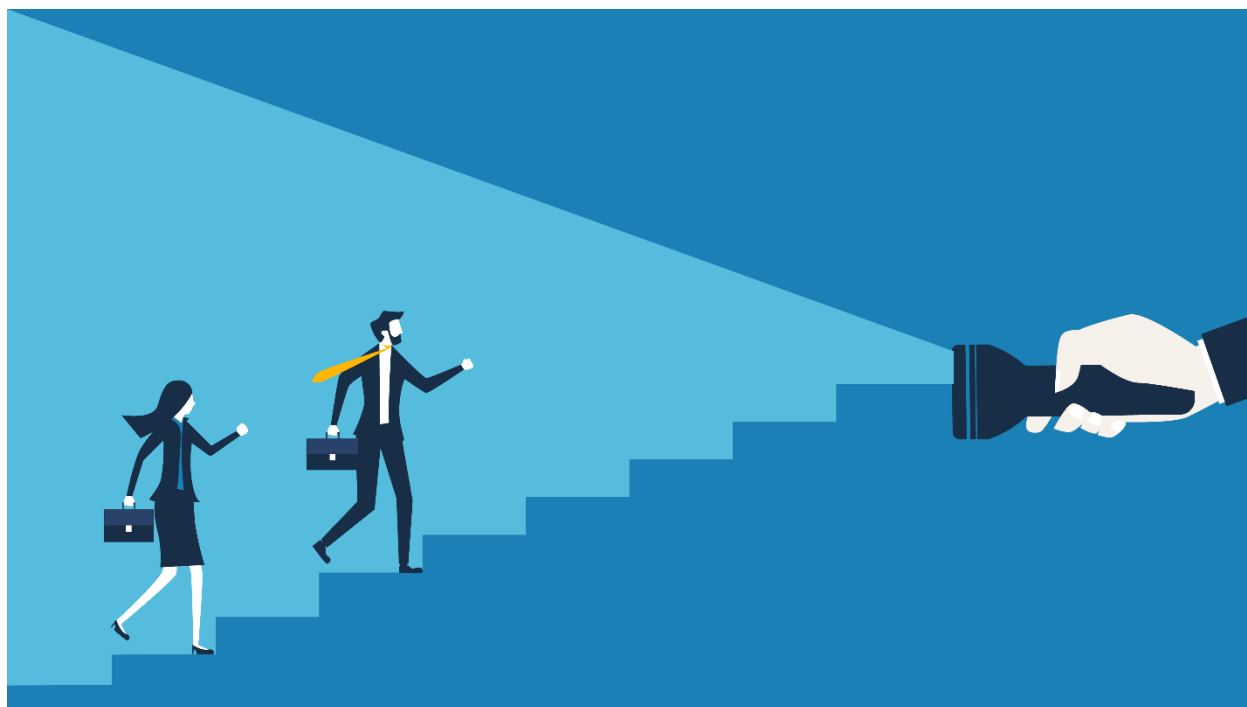


Escaping Pilot Purgatory: Scaling Digital Manufacturing From Proof of Concept to the Plant Floor



A cGMP Consulting White Paper on Production-Ready Design, Scale-Up Economics, and Portfolio Governance – October 29, 2026

Pharma 4.0 | Digital Manufacturing | Operational Excellence | Validation

An educational resource for executive and technical leaders in FDA-regulated life sciences.

Executive Summary

Most pharmaceutical manufacturers can point to a successful digital pilot that never scaled. The proof of concept worked, the results were promising, the demonstration impressed leadership, and then the initiative stalled. The plant-wide deployment never arrived, the projected return never materialized, and the pilot joined a growing collection of validated concepts that changed nothing. The pattern is common enough to have earned a name: pilot purgatory.

The cause is rarely technical. Pilots stall at the transition to production because they were designed as experiments rather than as production systems. A pilot can run in a controlled corner of the operation with manual workarounds, informal data handling, and a small group of enthusiasts. Production requires validation, data governance, integration with existing systems, procedures, training, and adoption by people who did not volunteer. None of that is present in a pilot design, and all of it becomes a wall at exactly the moment the organization wants to move fast.

The regulatory environment has become markedly more favorable to digital manufacturing than it was when many organizations formed their assumptions. The FDA's Computer Software Assurance guidance, finalized in September 2025 and updated in February 2026, establishes that assurance effort should be proportionate to intended use and risk of failure, which makes validating production digital systems far more tractable than the exhaustive approach that once made scaling prohibitive. Organizations still assuming that scaling means validating everything are working from a premise the regulator has retired.

This paper examines why pilots succeed and scale-ups fail, what production readiness actually requires, and how the current regulatory framework changes the economics of scaling. It addresses the design decisions that determine whether an initiative can scale, the ROI models that account for scale-up cost rather than pilot success, and the governance that kills weak pilots early and moves strong ones fast. The objective is not more pilots. It is fewer pilots that reach the plant.

Introduction

Digital transformation in pharmaceutical manufacturing has opened a substantial gap between demonstrated capability and realized value. Organizations have proven that predictive analytics can anticipate deviations, that electronic batch records reduce documentation errors, that advanced process control can tighten variability, and that connected equipment can surface problems earlier. Those demonstrations are real. What is frequently missing is the plant running on any of it.

The gap has a structure. A pilot is optimized to demonstrate that something can work, which is a different objective from making it work in production. The pilot team is chosen for enthusiasm, the scope for tractability, the data gets handled manually where automation would be hard, and the regulatory questions get deferred because the pilot is not making product decisions. Each of those choices is reasonable for demonstrating a concept and disqualifying for running a plant.

When the pilot succeeds and the organization asks to scale, the deferred work arrives all at once. The system has to be validated. The data flows have to be governed. The integration with the manufacturing execution system, the laboratory system, and the quality system has to be built. Procedures have to be written, people have to be trained, and operators who did not choose the technology have to adopt it. The scale-up looks nothing like the pilot, costs multiples of what the pilot cost, and frequently exceeds what the business case assumed, at which point the initiative quietly stops.

This paper is for the manufacturing, engineering, quality, and technology leaders responsible for digital initiatives, and for the executives funding them and waiting for the return. It focuses on the design and governance decisions that determine whether a pilot becomes a plant capability or a well-documented demonstration.

Industry Background

Pharma 4.0 describes applying Industry 4.0 concepts to pharmaceutical manufacturing: connected equipment, data-driven process understanding, advanced analytics, automation, and the integration of information across the manufacturing operation. The ISPE developed the Pharma 4.0 operating model to

provide a structured framework, building on ICH quality frameworks and connecting digital capability to the pharmaceutical quality system rather than treating it as a parallel technical program.

The regulatory foundation for digital manufacturing was laid earlier than many organizations recognize. The ICH Q8 pharmaceutical development framework introduced quality by design, design space, and the idea that process understanding rather than fixed parameters should govern control. ICH Q9 established quality risk management. ICH Q10 defined the pharmaceutical quality system across the lifecycle, and ICH Q11 addressed drug substance development. The FDA's process validation guidance established a lifecycle model whose third stage, continued process verification, presumes ongoing data collection and analysis. Together these frameworks describe an operation that is data-driven by design, which is what Pharma 4.0 implements.

What changed recently is the validation economics. For years, the practical obstacle to scaling digital systems was that each one required exhaustive validation, which made a plant-wide deployment of connected, data-generating technology prohibitively expensive. The FDA's Computer Software Assurance guidance, finalized September 24, 2025 and updated February 3, 2026, formalizes a risk-based approach in which assurance effort matches intended use and risk of failure. Combined with the GAMP 5 second edition published in July 2022, which emphasized critical thinking and addressed the modern software landscape, the frameworks now support scaling in a way they previously did not.

The European framework is moving in a parallel direction, with the draft revision of Annex 11 published in July 2025 treating computerized systems as core GMP-controlled assets and addressing cloud, supplier management, and lifecycle risk in substantially more detail than the 2011 version. Organizations scaling digital manufacturing across global sites should design against both frameworks rather than sequentially, since the technical controls the European draft specifies are more prescriptive than the American guidance requires.

Regulatory Landscape

The frameworks relevant to scaling digital manufacturing address validation, data integrity, process understanding, and the quality system that governs them.

Computer Software Assurance and the Economics of Scale

The Computer Software Assurance guidance addresses software used in production or the quality system, applying a four-step method: define intended use, assess the risk of failure, plan assurance activities proportionate to that risk, and document the basis for confidence. The February 2026 update aligned the guidance with the Quality Management System Regulation, adopted recognized cloud computing definitions, addressed cybersecurity evidence, expanded vendor oversight recommendations, and stated that the approach applies to automation tools, data analytics tools, and artificial intelligence and machine learning tools used in production or the quality system. For scaling, the significance is that a digital deployment spanning many systems and functions need not be validated uniformly. Effort concentrates where failure would affect product quality, patient safety, or data integrity, which is what makes plant-wide deployment economically feasible.

Data Integrity Across a Connected Operation

Digital manufacturing multiplies the volume of electronic records and the number of systems generating them, and data integrity expectations apply to all of it. The FDA data integrity guidance, along with MHRA, PIC/S, and WHO guidance, establishes expectations for attribution, contemporaneous recording, audit trails, and record retention that scale with the operation. A pilot handling data manually in a spreadsheet has deferred these questions; a production deployment cannot. Audit trail review at a frequency aligned with the review of the underlying data, individual user attribution, and protection of original records are design requirements for a production system, not considerations for later.

Process Understanding and the Validation Lifecycle

The ICH quality frameworks and the FDA process validation guidance establish that process control should rest on process understanding, and that validation is a lifecycle rather than an event. Digital manufacturing serves this directly: the data a connected operation generates is the evidence base for continued process verification. Organizations that design digital initiatives with the process validation lifecycle in view build systems that satisfy a regulatory obligation while delivering operational benefit. Those that treat the initiative as a technology project frequently build systems whose data cannot support the validation obligations the operation carries.

The European Framework

The draft revision of Annex 11, published July 7, 2025 with final publication expected mid-2026, addresses computerized systems substantially more prescriptively than its predecessor, including expanded audit trail scope covering data creation, multi-factor authentication for electronic signatures, a dedicated security chapter, and specified supplier contract elements. Organizations scaling digital manufacturing across sites subject to both FDA and EU inspection should design a control set informed by both frameworks, taking the more demanding expectation on each dimension, rather than deploying against one framework and remediating against the other.

The regulatory framework is no longer the obstacle to scaling that it was. Risk-based assurance makes plant-wide deployment tractable, and the process validation lifecycle actively rewards the data a connected operation produces. The obstacle is that pilots are designed as experiments, and experiments do not scale into production no matter how favorable the regulatory environment becomes.

Current Industry Challenges

The reasons pilots stall are consistent across organizations and across technologies, which tells you they are structural rather than incidental.

Experiment Design Versus Production Design

A pilot is designed to answer whether something can work. A production system has to work reliably, under validation, with governed data, integrated with existing systems, operated by people who did not volunteer. The pilot defers every one of these requirements because deferring them is what makes the

pilot fast. When the organization asks to scale, the deferred requirements arrive together and are frequently larger than the pilot itself, which is why the scale-up estimate shocks the sponsors who saw how easy the pilot was.

Deferred Validation and Data Governance

Pilots frequently operate outside the validated environment, handling data manually and making no product decisions, which is appropriate for a demonstration. But a system that was never designed for validation is frequently difficult to validate, because the design choices that made the pilot fast, undocumented data flows, informal interfaces, unconstrained user access, are exactly the choices assurance has to address. Retrofitting validatability costs more than designing for it, and sometimes it means rebuilding what the pilot proved.

Integration as an Afterthought

Pilots typically run alongside existing systems rather than within them, with data moved manually. Production requires integration with the manufacturing execution system, the laboratory system, the quality system, and the enterprise systems that hold the operation's data. Integration is where digital initiatives consume budget and time unexpectedly, because interfaces that did not exist have to be built, and because the data models of systems built at different times for different purposes rarely align cleanly.

Adoption by the Unenthusiastic

Pilot teams are self-selected enthusiasts. The plant is not. Scaling requires that operators, supervisors, and quality reviewers who did not choose the technology, may not trust it, and have workarounds that already function adopt a new way of working. This is a change management problem technology cannot solve, and it is the reason many technically successful deployments produce no measurable benefit: the system gets installed and the old process continues alongside it.

Business Cases Built on Pilot Economics

The business case that justified the pilot frequently extrapolates pilot results across the plant without accounting for the validation, integration, procedure, training, and change management costs scaling requires. When actual scale-up costs emerge, the return that justified the initiative no longer clears the hurdle, and the initiative stops. The failure is in the model rather than in the technology, but the technology takes the blame, which makes the next initiative harder to fund.

No Governance to Stop or Accelerate

Many organizations have no mechanism to kill a weak pilot decisively or to move a strong one quickly. Pilots accumulate, each consuming attention and none reaching production, and the organization mistakes activity for progress. Without a stage gate that requires production-readiness evidence before scale-up funding, and that terminates initiatives that cannot demonstrate it, the portfolio fills with demonstrations.

Risks of Poor Implementation

The risks of pilot purgatory are primarily economic and organizational, though poorly executed scaling creates compliance exposure as well.

Risk Category	Potential Consequence
Unrealized investment	Cumulative pilot spending that produces demonstrations rather than capability, with no operational return to show for years of effort.
Competitive lag	Competitors realizing efficiency, cycle time, and quality benefits from deployed digital capability while the organization accumulates proofs of concept.
Organizational fatigue	Repeated initiatives that never reach the plant, eroding credibility for digital investment and making the next proposal harder to fund.
Compliance exposure from rushed scaling	Systems deployed to production without adequate assurance or data governance because the scale-up was compressed after the pilot consumed the timeline.
Shadow systems	Deployed technology running alongside unchanged manual processes, producing duplicate records and data integrity questions rather than benefit.
Sunk integration cost	Investment in point solutions that cannot integrate, requiring replacement rather than extension when the operation attempts to connect them.

The compounding organizational cost deserves attention. Each initiative that stalls makes the next one harder, because the people who would sponsor it have watched the pattern. Eventually the organization stops proposing ambitious digital work and confines itself to initiatives small enough to complete, which are by definition too small to matter. The capability gap against competitors who solved the scaling problem then widens structurally rather than incidentally.

There is also a specific compliance risk in the pattern's endgame. When leadership finally insists that a long-running pilot reach production, the scale-up is frequently compressed into a timeline that does not permit adequate validation, data governance, or change management. A system rushed into a regulated production environment because the pilot consumed the schedule is a compliance problem created by a governance failure.

Best Practices

Escaping pilot purgatory takes designing for production from the outset, modeling the real economics, and governing the portfolio with the discipline to stop as well as to start.

Design for the Plant on Day One

Every pilot should be designed with the production requirements in view: how the system will be validated, how data will be governed, how it will integrate, and how people will adopt it. This does not mean building the production system first. It means making pilot design choices production can extend

rather than choices production has to undo. A pilot that proves a concept using an architecture production cannot use has proven less than it appears.

Establish Data Architecture Before Scaling

Because digital manufacturing multiplies data and the systems generating it, the data architecture determines whether an operation scales coherently or accumulates disconnected point solutions. Define how data will flow, where it will reside, how integrity will be maintained, and how it will support the continued process verification the validation lifecycle requires. Architecture designed after several systems are deployed is a migration project; architecture designed first is a foundation.

Apply Risk-Based Assurance Deliberately

The Computer Software Assurance framework makes plant-wide deployment feasible, but only for organizations that have actually operationalized it. That means procedures, templates, and quality review criteria that require intended use, risk assessment, proportionate assurance, and documented rationale rather than uniform documentation. Organizations that adopt the guidance in name while keeping volume-of-evidence practice will find scaling as expensive as it was before the guidance existed, and will conclude, incorrectly, that validation is the obstacle.

Treat Adoption as Half the Work

Scaling requires that people who did not choose the technology use it, which means change management is not a communications activity appended to deployment but a substantial portion of the work. Involving operators and reviewers in design, addressing the workarounds the new system displaces, and measuring actual usage rather than deployment are what convert an installed system into a working one. A system that is deployed and bypassed has consumed the cost and delivered nothing.

Model the Real Economics

Business cases should include the validation, integration, procedure, training, and change management costs scaling requires, so the decision to scale is made against real numbers rather than pilot extrapolation. An honest model may show that a promising pilot does not justify plant-wide deployment, which is valuable information delivered before the money is spent rather than after. The model should also account for the compounding value of shared architecture, since the second and third initiatives on a coherent foundation cost substantially less than the first.

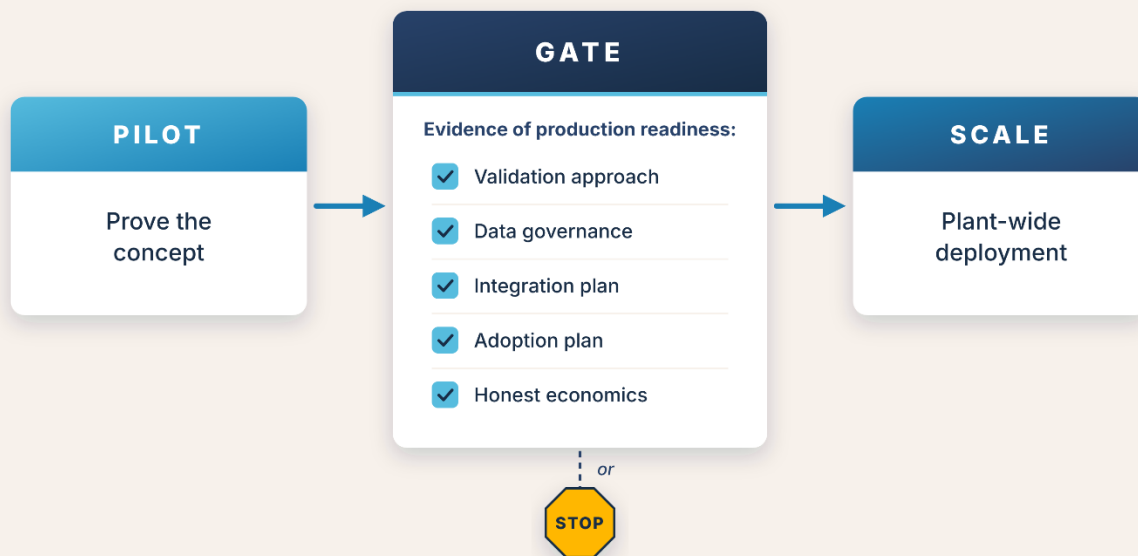
Govern With a Stage Gate That Can Say No

Establish a gate between pilot and scale-up that requires evidence of production readiness: a validation approach, a data governance design, an integration plan, an adoption plan, and an economic model including scale-up costs. Initiatives that cannot produce these should be stopped rather than allowed to persist. The purpose of the gate is as much to terminate weak initiatives decisively as to advance strong ones quickly, because a portfolio that never stops anything cannot concentrate resources on what matters.

Implementation Roadmap

The roadmap below builds the capability to move digital initiatives from concept to plant reliably.

FIGURE 1
The Pilot-to-Production Gate



Step 1: Assess the Current Portfolio

Inventory digital initiatives, their status, their cumulative cost, and how many have reached production. This assessment usually reveals the pattern clearly and provides the case for changing how initiatives are governed.

Step 2: Perform a Gap Assessment

Assess whether the organization has the enablers scaling requires: an operationalized risk-based assurance approach, a data architecture, integration capability, and change management capacity. Gaps here explain why initiatives stall regardless of their individual merit.

Step 3: Establish the Data Architecture

Define how data will flow, reside, and be governed across the digital operation, with integrity and the continued process verification obligation in view. This foundation determines whether subsequent initiatives compound or fragment.

Step 4: Operationalize Risk-Based Assurance

Revise validation procedures, templates, and review criteria to implement the Computer Software Assurance approach in practice rather than in policy, so scaling is economically feasible. Where operations span jurisdictions, design the control set against both the FDA and European frameworks.

Step 5: Implement the Stage Gate

Establish the pilot-to-production gate with defined evidence requirements and the authority to terminate initiatives that cannot meet them. Apply it to the existing portfolio, which will typically stop several initiatives and accelerate one or two.

Step 6: Design Pilots for Production

Require new pilots to demonstrate their production path at inception: validation approach, data handling, integration, and adoption. This changes what a pilot costs and what it proves, and it substantially raises the proportion that scale.

Step 7: Scale With Adoption as a Deliverable

Execute scale-ups with change management as a funded workstream and adoption as a measured outcome, not merely deployment. Track actual usage and the displacement of the processes the system replaces.

Step 8: Measure Realized Value and Compound

Measure the operational benefit actually realized rather than projected, and use the shared architecture to make each subsequent initiative cheaper than the last. Compounding is where digital transformation returns arrive, and it requires that the foundation be built deliberately.

Technology Considerations

The technology choices that determine scalability concern architecture and integration more than the capability of individual systems.

Manufacturing execution systems, laboratory information management systems, and electronic quality management systems form the operational backbone digital initiatives have to integrate with. Point solutions that cannot integrate become islands, and an operation accumulating islands has digitized without connecting, which forfeits most of the benefit. Evaluating integration capability before deployment, rather than after, is what separates an architecture from a collection.

Data platforms and analytics determine whether the data a connected operation produces becomes process understanding or merely storage. The continued process verification obligation in the validation lifecycle requires ongoing analysis, and a digital operation whose data cannot support that analysis has generated volume without value. Analytics infrastructure should be designed with the validation obligations in view, since the same data serves both the operational and the regulatory purpose.

Cloud platforms increasingly host these systems, bringing the shared-responsibility considerations both the FDA guidance and the Annex 11 draft address. Understand and document which controls you own and which the provider owns, and reflect it in agreements, particularly given the contract elements the European draft specifies. Artificial intelligence and analytics tools used in production or the quality system fall within risk-based assurance scope, and organizations operating in Europe should note the draft Annex 22 position limiting artificial intelligence in GMP-critical applications to static, deterministic models.

Future Outlook

The conditions for scaling digital manufacturing are more favorable than they have ever been. Risk-based assurance has changed the validation economics, the regulatory frameworks actively reward data-driven process understanding, and the technology has matured past the point where capability is the constraint. What remains is the organizational discipline to design for production and to govern a portfolio with the willingness to stop.

The frameworks will keep developing in this direction. The final Annex 11 text expected mid-2026 will formalize expectations for computerized systems in a connected operation, and continued convergence between the FDA guidance, the European framework, and the GAMP model reduces the ambiguity that once made organizations cautious. Advanced manufacturing, continuous processing, and increasingly connected operations will make the data architecture question more consequential, not less.

The organizations that escape pilot purgatory will separate from those that do not, and the separation will compound. Each initiative deployed on a coherent foundation costs less than the last and delivers more, while each pilot that stalls consumes resources and produces nothing. That divergence is already visible, and the difference is not technology access or regulatory environment, both of which are broadly shared. It is whether the organization designs for the plant and governs the portfolio with the discipline to say no.

How cGMP Consulting Can Help

Scaling digital manufacturing takes knowing what production readiness actually demands, having operationalized risk-based assurance so the economics work, and governing a portfolio with discipline. cGMP Consulting helps organizations convert digital initiatives into deployed capability.

Our consultants assess digital portfolios and the enablers that determine whether initiatives can scale, including data architecture, assurance approach, integration capability, and change management capacity. We help organizations operationalize the Computer Software Assurance framework so plant-wide deployment is economically feasible, revising procedures and templates rather than restating policy, and we design control sets that satisfy both the FDA and European frameworks for organizations operating across jurisdictions. We help establish data architecture with the continued process verification obligation in view, design pilots that can scale, and implement the stage gate that advances strong initiatives and terminates weak ones. We support scale-ups with validation, data governance, and adoption treated as the substantial work they are.

Our approach is consultative and grounded in how digital systems are actually validated and inspected. We aim to leave organizations with capability in the plant rather than demonstrations in the portfolio.

Conclusion

Pilot purgatory is not a technology problem. Organizations have proven repeatedly that digital manufacturing works. What they have not built is the path from a demonstration to a plant, because pilots are designed as experiments and experiments do not extend into production. The validation, data governance, integration, and adoption the pilot deferred arrive together at the scale-up and stop it.

The regulatory environment has changed in the organization's favor. Risk-based assurance makes validating a plant-wide deployment tractable, and the validation lifecycle actively rewards the data a connected operation produces. Organizations still assuming that scaling means validating everything are working from a premise the regulator retired, and they are declining an opportunity on the basis of an obstacle that no longer exists in the form they imagine.

What remains is discipline. Design pilots with the production path in view. Build the data architecture before the systems accumulate. Operationalize risk-based assurance in procedures rather than in policy. Treat adoption as half the work, because it is. Model the real economics including scale-up costs. And govern the portfolio with a gate that can stop a weak initiative decisively, since a portfolio that never stops anything cannot concentrate on what matters. The organizations that do these things will have capability in the plant. The others will have a very well documented collection of things that worked once.

If your organization is scaling digital manufacturing beyond proof of concept, or reassessing a portfolio of initiatives that have not reached production, the experienced consultants at cGMP Consulting can help assess your current state, identify the enablers you are missing, and develop practical solutions tailored to your business objectives. To start a confidential conversation, complete the Contact Us form at cgmpconsulting.com/contact-us.

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