

WHITE PAPER

Bridging the Digital Divide in Pharmaceutical Tech Transfer

A Joint Perspective from NGT BioPharma Consultants & DTG

Table of Contents

04	Introduction
06	Executive Summary
07	Section 1: Tech Transfer: The Hidden Bottleneck in Pharmaceutical Value Realisation
08	Section 2: The Digital Divide: Systems Exist, But Data Does Not Flow
10	Section 3: Where Value Is Lost: Hidden Inefficiencies
13	Section 4: The Persistence of the PDF Economy
16	Section 5: The Real Barrier: Mindset, Leadership, and Operating Model
18	Section 6: Rethinking the CDMO Ecosystem: From Fragmentation to Platforms
22	Section 7: Sustainability: From Constraint to Catalyst
23	Section 8: The Future State: A Fully Integrated, Data-Centric Pharma Ecosystem
26	Section 9: A Practical Roadmap for Tech Transfer Digital Transformation
27	Section 10: Conclusion: From Fragmentation to Orchestration
29	Section 11: Enabling the Next Generation of Tech Transfer
31	References

Authors



Rob Innes

Director, Data Analytics & AI



Mark Buswell

Head of Digital Innovation



John Arthur

Director, Sustainability



Nicola Clear

Strategic Business Development



Introduction: A Convergence of Perspectives

Recognizing a growing convergence between strategic consulting and digital execution in the pharmaceutical industry, NGT Biopharma Consultants (NGT) and Digital Technologies Group (DTG) identified a shared opportunity: to explore, challenge, and reframe how digital transformation can unlock value across a critical CMC interface between R&D and Commercial Product Manufacturing during **'tech transfer'** as part of Phase II-III drug development.

Both organizations bring complementary strengths. NGT's core service area includes; CMC, Quality and Regulatory strategies, tech transfer optimization, and operational excellence for pharmaceutical industry. DTG brings deep expertise in digital architecture, data integration, and the practical implementation of modern, flexible technology platforms required for pharmaceutical manufacturing. Together, this creates a powerful lens through which to examine one of the industry's most persistent and complex challenges.

To explore this topic, a private panel discussion was convened, bringing together senior perspectives from both organizations: Mark Buswell and Nicola Clear (NGT), alongside Rob Innes and John Arthur (DTG). The discussion was deliberately structured to challenge conventional thinking by examining the same problems from different sides of the organizational and technical divide.

What emerged was not simply a restatement of known issues, but a set of shared insights and creative perspectives that cut across strategy, technology, operations, and sustainability. The conversation highlighted a critical truth: **while the challenges in tech transfer are widely acknowledged, the underlying causes, and therefore the solutions, are often misunderstood.**

This white paper captures the essence of that discussion. It reflects a collective view that:

- 1 The need for transformation is real and urgent
- 2 The enabling digital technologies are already available
- 3 There is a lack of clarity on why change must happen, and how it can be achieved in practice

CONTINUED INSIGHT

By combining strategic insight with digital pragmatism, this paper aims to provide both a compelling case for change and a set of practical, thought-provoking pathways forward. We believe the perspectives shared here will resonate not only with pharmaceutical innovators, but also with CDMOs navigating increasing complexity, competitive pressure, and the need to differentiate through digital capability.

This paper follows the logic of a diagnostic before a prescription.

It opens by establishing why tech transfer represents a hidden but significant drag on pharmaceutical value realization, before examining the root causes in detail — from data fragmentation and the persistence of document-based exchange to the validation burden, leadership capability gaps, and the structural complexity of the modern CDMO ecosystem. Sustainability is explored not as a separate topic, but as a lens that sharpens the case for data integration. The paper then turns to the future state: the platforms, standards, ontologies, and partnership models that are beginning to make seamless digital tech transfer achievable. It closes with a practical roadmap and a call to action framed around the specific capabilities that NGT and DTG collectively bring to this transformation.

Readers primarily interested in the strategic case will find it in Sections 1 through 5. Those focused on ecosystem and platform solutions should turn to Sections 6 through 8. The roadmap and service offer are in Sections 9 through 11.



Executive Summary

Pharmaceutical organizations are facing a convergence of pressures: accelerating time-to-market expectations, increasing manufacturing complexity, growing reliance on CDMOs, and intensifying sustainability and regulatory demands. At the center of this challenge lies a persistent and often underestimated bottleneck, the technology transfer step (tech transfer) between R&D and commercial manufacturing.

Despite decades of investment in digital systems such as LIMS, MES, and ERP platforms, tech transfer continues to be characterized by delays, duplication, and inefficiencies. Data is repeatedly reinterpreted, reformatted, and re-entered across organizational and system boundaries. The result is not only operational inefficiency, but also loss of critical knowledge, increased risk, and missed opportunities for optimization.

This white paper, developed jointly by NGT and DTG, argues that the root cause of these challenges is not a lack of digital tools, but **a failure to ensure data continuity across the pharmaceutical value chain**. While the industry has digitized individual systems, it has not effectively enabled the seamless flow of data and knowledge between them.

What is now becoming clear is that this is no longer just an operational inefficiency, it's a strategic risk. The industry is experiencing the convergence of four critical pressures:

- 1 Fragmented digital systems and data
- 2 Sustainability demands across global supply chains
- 3 A lack of end-to-end transformation ownership
- 4 Rapid evolution of CDMO partnerships toward digitally enabled models

These pressures increase the number of touchpoints between business units and between organizations. As Rob Innes observed:



The point of interface between two systems is always where you see waste, delay, and error.

— Rob Innes, DTG

We propose a shift toward a data-centric operating model, enabled by integrated data architectures, workflow orchestration, and shared data exchange platforms across sponsor and CDMO ecosystems. This represents not an incremental improvement, but a fundamental structural transformation.

KEY INSIGHT

The challenge is not technology alone but how systems, data, teams, and ecosystems interact.

01

Tech Transfer: The Hidden Bottleneck in Pharmaceutical Value Realization

Tech transfer is the critical bridge between R&D and commercial manufacturing, where scientific innovation must be translated into robust, scalable, and compliant production processes. Yet it is also the stage at which many programs struggle with CMC knowledge flows; proactive planning and communication from the outset are essential to mitigating this.

Across the industry, organizations report consistent challenges:

Extended timelines driven by iterative rework

Limited visibility across functional and organizational boundaries

Duplication of analytical and process development activities

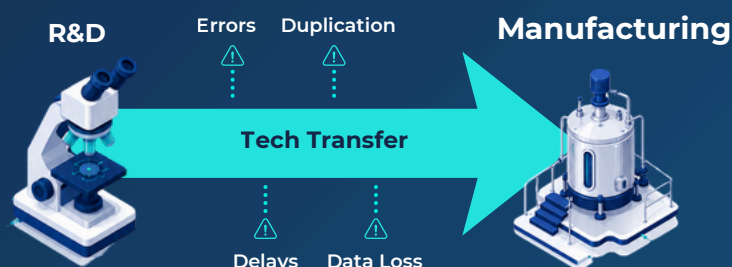
Delays in decision-making due to fragmented information flows

These challenges are not merely operational, they are structural. Tech transfer is not constrained by isolated inefficiencies, but by how the industry fundamentally manages and transfers information and, by extension, knowledge.

The implications are significant. Delays in tech transfer directly impact time-to-market, the single most important driver of commercial value in pharmaceutical development. In an increasingly competitive and cost-constrained environment, such inefficiencies are no longer sustainable.

This contradiction sits at the heart of the industry's digital challenge. Pharmaceutical organizations have invested heavily in digital systems over the past two decades. Laboratory systems (LIMS), manufacturing execution systems (MES), supply chain tools, and data repositories such as Veeva Vault are now embedded across the value chain. Yet tech transfer, one of the most critical processes in the lifecycle, remains persistently inefficient.

“Tech transfer is where value is either realized or silently lost.”



02

The Digital Divide: Systems Exist, But Data Does Not Flow

A key insight emerging from this discussion was the distinction between **digital systems** and **digital readiness**. While most organizations have invested heavily in systems, these environments do not operate as an integrated whole.

R&D environments are inherently exploratory, with data generated in flexible, evolving formats that reflect early-stage development uncertainty. Manufacturing environments, by contrast, depend on highly structured, validated, and standardized data models.

This mismatch creates a fundamental barrier to data continuity. Information generated in R&D must be extracted from local systems, reformatted, manually curated, and re-entered into manufacturing systems. This process is inefficient, introduces risk, and reduces the fidelity of the underlying data.

The result is a digital divide that is not technological, but architectural. Systems exist, but they do not share a common data language or structure. As Mark Buswell observed:

“

“R&D systems are designed for flexibility... manufacturing systems are designed to lock things down for compliance.”

— Mark Buswell, NGT BioPharma Consultants

These differing priorities have often led to separate systems (LIMS, MES, ERP), separate data structures, and separate operating models. While logical in isolation, they create a structural discontinuity at the point of tech transfer. As Rob Innes highlighted:

“There’s no continuous integration across that divide... and that becomes problematic as point solutions and bespoke integrations solve project-level challenges, but compound organizational level issues as teams juggle multiple different approaches, applications and standards.”

— Rob Innes, DTG

CONTINUED INSIGHT

What should be a seamless progression becomes instead a translation exercise. Data is reformatted. Context is lost. Decisions are revisited.

This structural divide is not unique to pharmaceuticals. Industries such as automotive and aerospace also operate across complex, multi-stage lifecycles, yet they have invested heavily in maintaining a continuous digital thread from design through to production. In those sectors, the expectation is that knowledge is preserved, not reconstructed, at each stage.

The contrast raises an important question: why has pharmaceutical development, despite its scientific sophistication, not yet achieved the same level of digital integration?

Part of the answer lies in economic structure. Industries such as automotive and aerospace operate under tighter margins, creating stronger incentives to optimize efficiency and reduce waste. Pharmaceutical organizations, particularly in innovative therapeutics, have historically operated under higher margins, reducing the immediate pressure to address operational inefficiencies in areas such as tech transfer. However, that context is changing rapidly.

Much of the pharmaceutical industry's investment in digital data infrastructure has, understandably, been concentrated on clinical operations.

Platforms such as Medidata Solutions have become industry benchmarks for managing the complex data flows between sponsors, contract research organizations (CROs), and clinical sites — streamlining trial management, regulatory submissions, and patient data integration at scale.

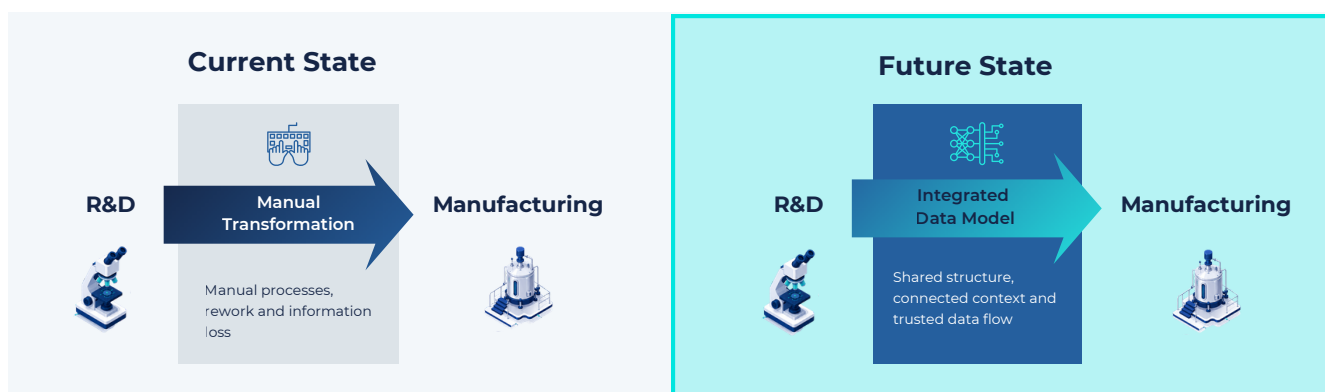
This focus is justified: clinical development accounts for approximately **70% of total R&D expenditure**, and the regulatory stakes demand rigorous data governance. Yet the same logic that drove that investment, the need for seamless, standardized data exchange across organizational boundaries, applies equally to the non-clinical and manufacturing space.

The industry has been slow to recycle those hard-won lessons into tech transfer, CMC development, and commercial supply chain operations, where fragmented data flows between sponsors and CDMOs remain the norm rather than the exception. Closing that gap is not a technical stretch; it is a matter of strategic will.

“

We don't have a technology problem. We have a data continuity problem.

-Rob Innes, DTG



03

Where Value Is Lost: Hidden Inefficiencies

Across organizations value leakage is pervasive, but hard to measure explicitly. The inefficiencies in tech transfer are recognized but what is not acknowledged is how deeply they are embedded into tech transfer systems and processes. As Mark Buswell captured:



Tech transfer is effectively a knowledge workflow but it's not managed as one.

— Mark Buswell, NGT BioPharma Consultants

This observation reframes the problem. Tech transfer is not simply a sequence of tasks; it is the movement and application of knowledge. Yet it is rarely treated as a structured, orchestrated workflow.

Data is repeatedly re-entered manually, transferred via PDFs, and reformatted across systems. There is no continuous integration across the divide, so point solutions and bespoke integrations that solve project-level challenges yet compound organization-level issues exist, by creating multiple different approaches, applications, and standards to manage.

Lack of Workflow Orchestration

Tech transfer is not managed as a structured digital workflow. Even today, co-ordination often relies on email and meetings; tasks are sequential rather than parallel; and visibility is limited across functional and organizational boundaries.

The industry has demonstrated it can move faster when circumstances demand it. During COVID-19, vaccines and treatments were delivered at unprecedented speed by starting each development phase early, taking exceptional financial risks, and bypassing typical stage gates before proceeding to manufacturing.

As Nicola Clear observed: *“Pharma delivered quality products through front-loading investment and heroics — not possible to replicate across the entire portfolio.”* The COVID model was not built on better systems; it was built on emergency-scale willpower and resource mobilization to ensure data flowed to the right next step.

The case for digital transformation is precisely to make that kind of speed consistently accessible, without requiring heroics every time.

CONTINUED INSIGHT



“Email creates queues.
Workflows create
flow.”

— Mark Buswell, NGT BioPharma
Consultants

The contrast with other industries is striking. Mark Buswell drew an analogy to selling items on a secondhand marketplace app, photographing them, uploading metadata, dropping them at a collection point, and instantly receiving confirmation through an end-to-end automated supply chain. *“I was absolutely blown away by the supply chain aspect,”* he noted. *“That’s e-commerce. In pharma process development and manufacturing, we’re lacking that disruptive force, we don’t have many disruptor companies in the manufacturing supply chain.”* The observation raises a pointed question: pharma has the complexity to justify sophisticated workflow orchestration yet lacks the competitive pressure that has driven it elsewhere.

“You don’t typically have
full data-level visibility
across the pharma product
value chain.”

— Rob Innes, DTG

This constrains decision-making, risk management, supply chain optimization, and environmental reporting. External research reinforces this point: organizations derive most digital transformation value when they focus on end-to-end domains or value streams, rather than isolated systems or functions. Yet Pharmaceutical tech transfer is rarely managed as such a domain.

The Validation Tax

Computer system validation represents one of the most underappreciated drains on digital progress in pharmaceutical manufacturing. In practice, validation can consume up to half of the total cost of implementing a new system and **approximately 90% of that cost is documentation** rather than testing. Major platforms such as LIMS and MES require full re-validation cycles every three to four years simply to maintain technical currency, often with minimal functional improvement for the end user. The result is a high cost of change, institutional reluctance to innovate, and slow adoption of modern digital tools.

The emerging concept of Validation 4.0 (using data-driven, behavior-based approaches rather than document-heavy static requirements) offers a credible path forward, and AI-assisted validation is beginning to make this practical. However, industry adoption remains limited. Until validation practices modernize, they will continue to act as a structural brake on the pace of digital transformation across the manufacturing and CMC space

Partnership Value Loss

As Pharmaceutical innovators increasingly rely on CDMO partnerships, managing multiple dissimilar CDMO relationships across the drug portfolio adds a challenge of complexity, non-standard systems and data. Poor digital capability leads to slower CDMO onboarding, reduced transparency, and lower strategic value.

The depth of this fragmentation becomes visible at the supply chain level. As Mark Buswell observed from extensive consulting work: *"You talk to most pharma material suppliers / CDMO's, and they'll tell you they know their clients' forecasts better than the clients do. So much so they don't rely on the pharma industry's forecasts to manage their own capacity. They use their own."*

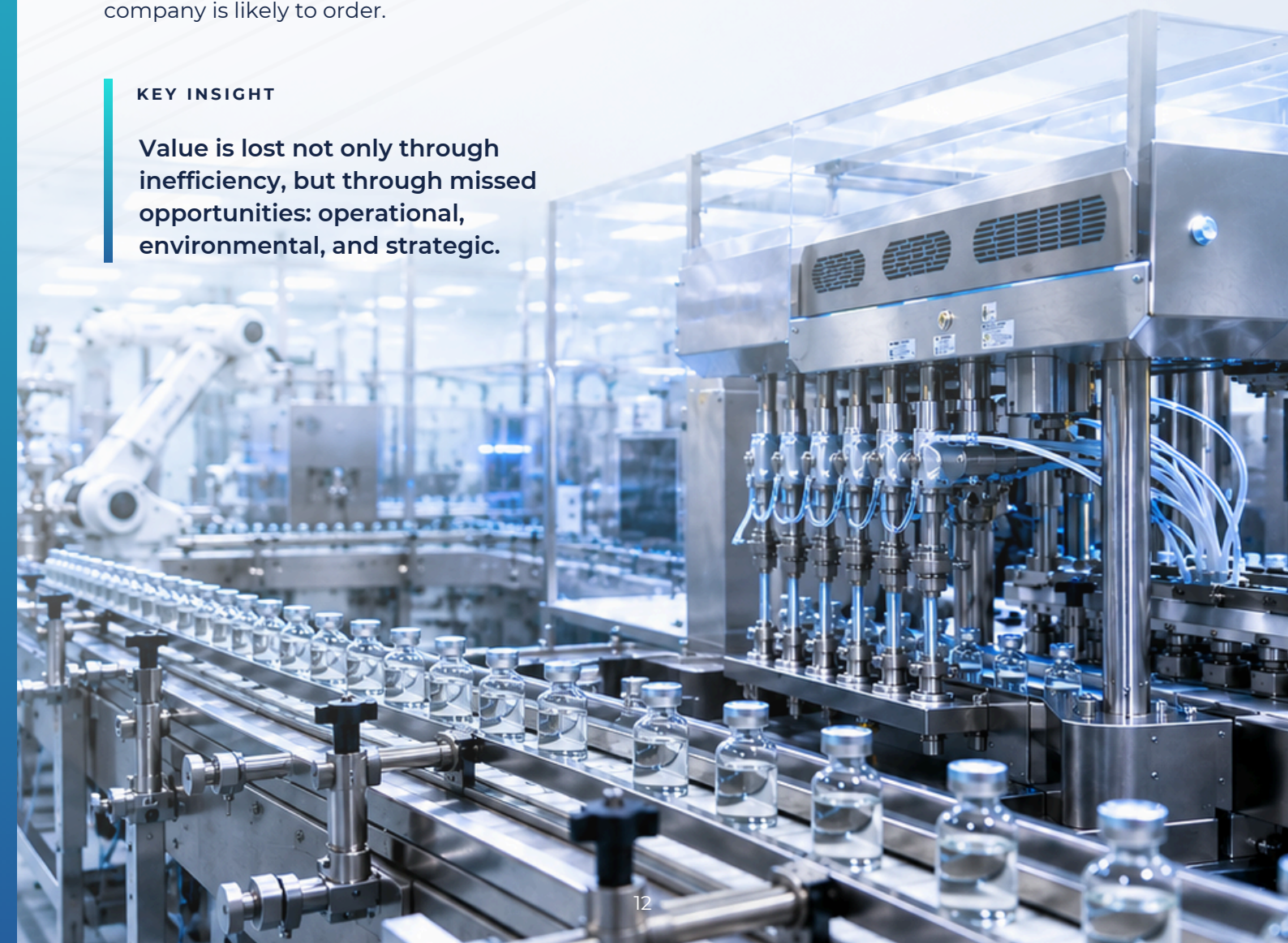
Suppliers plan capacity and stock based on their own models of what a given pharma company is likely to order.

The irony is that the data to enable accurate, shared forecasting already exists in the pharma's own systems, it simply does not flow. The opportunity is not just to reduce manual data entry at the certificate of analysis level, but to achieve something far more ambitious: a just-in-time supply model in which materials arrive pre-cleared, driven by integrated data rather than manual coordination.

For both CDMOs and their customers, it is a many-to-many challenge: each party must adapt to different data systems, standards, and quality procedures, adding significant complexity. This is one reason why strategic CDMO partnerships are gaining more favor and open the door for changing the data flow paradigms for those who invest.

KEY INSIGHT

Value is lost not only through inefficiency, but through missed opportunities: operational, environmental, and strategic.



04

The Persistence of the PDF Economy

Perhaps the most visible and persistent symptom of data fragmentation across the pharmaceutical value chain is the continued reliance on document-based data exchange. Despite operating increasingly sophisticated internal systems, organizations routinely export data into static formats such as PDFs for external communication.

Certificates of analysis (CoAs), batch records, and specifications are still commonly shared via email as documents. These files are then reviewed, interpreted, and often manually re-entered into receiving systems — hence reintroducing friction into what should be a seamless digital process.

This creates several well-understood challenges:

Latency: materials may remain in quarantine while documents are reviewed and approved

Errors: manual transcription introduces risk and variability

Lack of traceability: data lineage becomes fragmented and difficult to audit

Inefficiency: the same data is handled, interpreted, and processed multiple times

In effect, the industry has digitized internally but continues to operate externally as if it were paper based.



“We generate data digitally, but we exchange it like it’s 1995.”

— Mark Buswell, NGT BioPharma Consultants

Beyond Process: The Psychology of Trust in Data

However, the persistence of the “PDF economy” is not purely a technical or process issue, it is also our own human one. There is a subtle but important psychological dynamic at play in how individuals assess and trust information.

CONTINUED INSIGHT

Static documents, particularly those that resemble traditional paper records carry an inherent sense of authority and finality. A PDF is perceived as fixed, reviewed, and complete. It cannot easily be changed and therefore feels trustworthy. By contrast, data presented within digital systems, such as a LIMS driven dashboard or dynamic data views, can feel more fluid and questionable. Values may update, filters may change outputs, and different users may see slightly different representations of the same underlying data. While this flexibility is one of the strengths of digital systems, it can also create discomfort.

Even experienced professionals often express a preference for reviewing a “paper-on-glass” version of a document:

“

“There is something reassuring about checking a PDF of a CoA, compared to viewing the same data dynamically in a system.”

— Mark Buswell, NGT BioPharma Consultants

This highlights a critical tension at the heart of digital transformation:

- 1 Trust in pharma is historically built on immutability and documentation
- 2 Digital systems, by design, emphasize flexibility and real-time data
- 3 Control vs. Agility, or Certainty vs. Dynamism

Digital Transformation Must Address Trust

This insight has important implications for digital transformation initiatives. Moving from document-based to data-driven exchange is not simply a matter of technical integration, it requires a deliberate effort to rebuild trust in how data is presented, validated, and consumed.

Future solutions must therefore balance the flexibility of digital systems with the assurance traditionally associated with static documentation. This means:

- Embedding strong principles of data integrity and auditability
- Ensuring clear versioning and the ability to generate stable “snapshots” of data at specific points in time
- Designing user interfaces that convey clarity, consistency, and confidence
- Ensuring full transparency of data lineage so users understand where data originated, how it has been transformed, and whether it can be relied upon

In this context, digital systems must not only be technically robust, they also need to feel trustworthy to the people who depend on them.

From Documents to Trusted Data Exchange

The objective is not to eliminate documents entirely, but to move beyond them as the primary mechanism of data exchange. In a more mature model, information flows automatically between systems in structured, machine-readable formats, supported by embedded validation and approval workflows that ensure compliance without manual intervention. Human-readable outputs still have a role but they are generated as certified snapshots derived from live data, rather than serving as the source of truth themselves. This model preserves the reassurance of fixed records while enabling the efficiency, scalability, and responsiveness of true digital integration.

The logical endpoint of this evolution is the digital twin. Rather than transferring knowledge through static documentation, the twin allows process understanding to travel as a dynamic, data-rich model that manufacturing teams can interrogate directly.

As Mark Buswell posed the question:

"Could the digital twin become the knowledge container passed from R&D to manufacturing?"

In practice, this means that instead of a manufacturing scientist picking up the phone to ask an R&D colleague what temperature the mixer should run at, they log into a portal and interrogate the twin — a model that already knows, because it was built on the data that R&D generated. That is what genuinely paperless tech transfer looks like. Combined with advances in AI, the same infrastructure opens further possibilities: predictive process optimization, faster scale-up, and sustainability-by-design. The prerequisite, however, is the same in both cases — structured, connected, trusted data. Without that foundation, neither seamless data exchange nor meaningful digital twins are achievable.

Current state

System → PDF → Email → Manual Review → Manual Entry → System

Future state

System → Data Exchange Layer → System

KEY INSIGHT

The transition from documents to trusted data exchange is as much a cultural challenge as it is a technical one.

“

“Many companies are still accepting PDFs as the data exchange mechanism... even though the data originates in digital systems.”

— Rob Innes, DTG

05

The Real Barrier: Mindset, Leadership, and Operating Model. The 'Second Muscle'

Digital transformation is often seen as a technology issue, but in reality, it is a leadership and operating model challenge.



“Projects don’t fail because of technology. They fail because of mis-alignment.”

— Rob Innes, DTG

Industry evidence consistently shows that transformation succeeds when end-to-end domains are owned and actively led, yet many pharmaceutical organizations lack clear ownership of the full tech transfer lifecycle.

By its nature, tech transfer straddles R&D and commercial divisions, each with separate operating budgets, competing priorities, and different definitions of success. This structural ambiguity is compounded by the increasing specialization of CDMOs, where multiple partners, each focused on specific drug substance or drug product technologies, are routinely involved across the lifecycle of a single product.

Market Authorization Holders frequently manage portfolios spanning numerous specialist CDMOs, each operating with different systems, processes, and data models, producing a fragmented landscape of non-standardized interfaces that complicates and slows every handoff.

The result is a "spaghetti" network of data flows and, more consequentially, a spaghetti network of accountability.

What fills this structural gap is not, in most organizations, a transformation leader with end-to-end ownership.

It is an ownership vacuum.

CONTINUED INSIGHT

Leaders recognize the potential value of a more integrated, data-driven environment; awareness of the problem is not in short supply. What is scarce is the combination of deep domain knowledge and digital fluency required to translate that awareness into action — to determine where to begin, to define what good looks like, and to take accountability for delivering it.

In the absence of that leadership, organizations default to familiar patterns: transformation is delegated to IT functions that may not grasp the end-to-end nature of drug development; initiatives emerge in isolation across functions or sites; and progress remains incremental rather than structural.

Mark Buswell tells a story that captures both the problem and its remedy precisely. Early in his career as a process engineer, he worked in a pilot plant where the standard service level agreement for introducing a new process was four weeks. A progressive pilot plant director decided to challenge that, proposing three days instead. *"We thought, how do we crunch four weeks' work into three days?"* Buswell recalls. *"And actually, it was a successful challenge, because what we realized is that a lot of the work we did in the four-week time period was self-serving and not a true barrier to starting."*

Two decades later, as a senior consultant, he encountered the same pattern at a far larger scale: an 18-month tech transfer timeline, and a team debating whether they could reduce it to 16 months. He remembered the pilot plant. *"I thought we should be talking: can we turn it into one month? Everybody was shocked. No way, no way. And I said — hear me out. Are you sure there's no way?"* The reaction, he reflects, is itself the problem.

“

“Being digitally creative in manufacturing is not something that was traditionally encouraged or rewarded.”

Mark Buswell – NGT BioPharma Consultants

The barrier was not technological. It was a failure of imagination, compounded by an organization that had never been required to ask a different question.

What Mark Buswell was exercising in both cases was what has been described as a "second muscle": the ability to combine deep process domain expertise with the digital understanding needed to reimagine how that process could work. Leaders with this capability can translate business needs into digital solutions, own transformation outcomes end-to-end, and ask the questions that organizationally siloed teams are structurally prevented from asking.

Their absence is not a personal failing; it is a predictable consequence of an industry where R&D and commercial have long operated as separate worlds, and where the career paths that would build this combined capability have rarely existed. Developing it deliberately, at scale is one of the most consequential investments a pharmaceutical organization can make.

KEY INSIGHT

The industry does not lack technology — it lacks technology-enabled business leadership.

05

Rethinking the CDMO Ecosystem: From Fragmentation to Platforms

When tech transfer extends beyond internal organizational boundaries, fragmentation intensifies. The increasing use of CDMOs has transformed the industry, enabling flexibility and scalability, but also introducing new layers of relationship, data, and knowledge flow complexity. For a small biotech managing one or two CDMO relationships, this complexity is manageable. For mid- to large-sized pharma sponsors overseeing portfolios of specialist partners, each operating with different systems, processes, and data models, it becomes a structural challenge.

Data integrations across sponsor-CDMO boundaries are typically managed on a case-by-case basis. Each connection becomes a bespoke effort, resulting in a network of point-to-point integrations that are difficult to scale and maintain. Industry analysis highlights persistent gaps in digital CMC and manufacturing data flows, limited forecasting and supply chain digitization, and poor collaboration infrastructure across the ecosystem. Economic incentives reinforce the problem: CDMOs operate on tight margins and require clear returns on digital investments, while pharma sponsors often prioritize speed and cost over long-term data integration. The result is a structural digital transformation deadlock.

There is a counter-intuitive dynamic worth acknowledging here. In Mark Buswell's experience, CDMOs are often more motivated to shrink tech transfer timelines than internal manufacturing teams. *"CDMOs don't get paid until they start manufacturing, and they want to shrink that tech transfer time. With internal capacity, it's easier for companies to agree to extended timelines."* When a CDMO is competing for business, time is genuinely money.

The paradox, however, is that CDMOs have yet to fully leverage digital tools to act on that motivation. *"Just imagine what they could achieve if they invested in disruptive digital technology,"* Buswell observed. *"We are just starting to see that thinking as part of strategic vendor relationship selection."*

CONTINUED INSIGHT

In fact, a recent paper to Pharma Source, 2026 by MasterControl has published some startling statistics:

92%

of CDMO's report that sponsors now raise digital capabilities during partnering discussions.

35%

of CDMO's report digital capabilities are a RFP requirement

27%

of CDMO's have implemented electronic batch records and only 25% use a digital Manufacturing Execution System.

The regulatory environment is more receptive than many assume. In discussion with the MHRA innovation office, about a prospective supply chain integration project, DTG received encouragement relating to digital-first information exchange. As Rob Innes recalled: *"They indicated that work which improves the surety of supply, maintains data integrity and shortens decision time at each supply node will be viewed positively."* The technical work remains, but the regulatory direction of travel is clear.

As the panel discussion progressed, the concept of a different data model started to emerge. **A shift from point-to-point system integrations to platform-based connectivity**, whether purely internal or between sponsors and CDMOs resonated strongly.

Mark Buswell offered an analogy that captures the opportunity with disarming clarity. *"I pay for parking on my phone and have about nine different parking apps, one for each operator, each specific to a specific set of parking locations."* Then, in his local town, he discovered that the parking locations could now be paid for by any parking app. The app provider no longer had a monopoly on a specific location. Essentially the different parking apps had been integrated into some sort of shared umbrella back-end platform. *"That umbrella approach is transformational."*

Now think about the same analogy in the CDMO space." Every pharma sponsor and CDMO currently builds its own point-to-point integration for every relationship. A shared industry data exchange layer would solve the problem once, for everyone, rather than having each pair of organizations solve it independently and maintain it indefinitely.

“

“Why integrate company by company, when we could integrate the industry once?”

— Rob Innes, DTG

An industry-level data exchange platform providing a secure, yet shared infrastructure layer would enable standardized data exchange protocols, reduced integration complexity, improved scalability across networks, and faster onboarding of new partners.

CONTINUED INSIGHT

Are such neutral, open, industry-governed exchange layer models a utopia?

No, they are a reality, and are well established in other industries, including finance (payment networks) and logistics (tracking platforms). The pharmaceutical industry has yet to adopt a comparable approach; the opportunity exists, and the question is whether the impetus is there.

Strategic pharma partnerships with CDMOs are evolving rapidly. Key expectations now often include shared goals on operational transparency and digital integration. As Nicola Clear noted: *“Leading CDMOs are already responding to digital CMC opportunities impacting R&D tech transfer, the panel highlighted two recent examples below:*



AstraZeneca's CMC Data Hub offers a compelling proof point that this transformation is already underway. Shortlisted for the Pistoia Alliance's 2026 Data Science Team of the Year, the CMC Hub, led by Sophie Bailes and developed in partnership with Amino Data and Slalom, reportedly **reduced CDMO data transfer time from four weeks to under 24 hours.**

Built on a foundation of structured data and shared ontologies, it also underpins AI-assisted authoring tools that simplify how scientists create and format CMC data tables for regulatory submissions.

Notably, the team moved from hackathon concept to deployed technology in just five months — a pace that would have been unthinkable under traditional validation and integration approaches.

<https://pistoiaalliance.org/news/2026-data-science-talent-awards-finalists-announced/>

Lonza

The CDMO Lonza and its membership of CMAC (the University of Strathclyde's internationally recognized medicines manufacturing research hub) signals a broader industry shift toward **pre-competitive collaboration on CMC digitalization.**

As a Translation to Industry Collaborator, Lonza gains access to CMAC's network of academic and industrial leaders working on **continuous manufacturing, crystallization, and digital CMC strategy**, with the explicit goal of translating research outcomes into scalable solutions for its pharma and biotech customers.

<https://www.cmac.ac.uk/news-database/lonza-joins-cmac>

CONTINUED INSIGHT

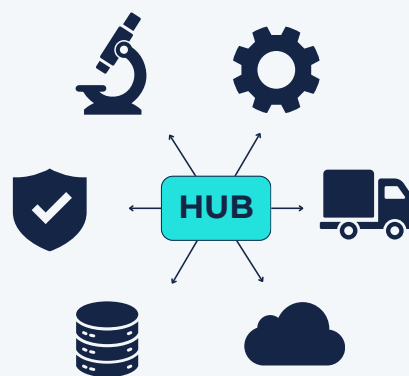
Where AstraZeneca's CMC Data Hub demonstrates what is achievable within a single organization, the Lonza-CMAC partnership illustrates the next step: embedding those capabilities across the CDMO relationship itself, so that digital CMC best practice travels with the molecule through tech transfer rather than being rebuilt from scratch at each handoff. Just two clear signals of a different alliance driven connected future.

SPAGHETTI ARCHITECTURE

Bespoke point-to-point integrations

**HUB-AND-SPOKE MODEL**

Data exchange platform

**KEY INSIGHT**

Digital maturity is becoming a differentiator in CDMO selection and partnership strategy and a competitive requirement.

07

Sustainability: From Constraint to Catalyst

The tech transfer process takes on an additional dimension when viewed through a sustainability lens. John Arthur of DTG highlights a critical but often overlooked issue: the fragmentation of sustainability data across the product lifecycle. In R&D, decisions are made that directly influence environmental impact, from solvent selection to process efficiency, yet those insights are rarely transferred effectively into manufacturing.

The result is that sustainability assessments already conducted in R&D are frequently repeated downstream, not by design but by default, due to a lack of data continuity. This duplication is both wasteful and consequential: by the time manufacturing teams revisit these questions, the window to meaningfully influence process design has often closed.

The conclusion is clear: **sustainability cannot be achieved without end-to-end data integration.**

In this sense, environmental ambition may prove to be the catalyst that drives the digital infrastructure investment that operational arguments have so far failed to secure. Digital transformation becomes not only an operational imperative, but an environmental one and the foundation for the kind of cross-organizational collaboration that both goals require.

The data gap has strategic as well as operational consequences. Without integrated data flows, procurement cannot optimize supplier selection, manufacturing cannot build on R&D insights, and organizations cannot effectively measure their Scope 3 emissions — the hidden bulk of the supply chain, representing over **70%**, and often up to **90%**, of total carbon footprint. These are precisely the areas where data visibility upstream and downstream is weakest. Global misalignment compounds the problem: Western organizations face increasing regulatory and ESG pressures, while suppliers in cost-sensitive markets often lack the incentives to invest in the same direction.

“

Sustainability could force the data integration that efficiency alone could not.”

— John Arthur, DTG

KEY INSIGHT

Sustainability is constrained not by intent, but by data fragmentation. Embedding it requires end-to-end data integration.

08

The Future State: A Fully Integrated, Data-Centric Pharma Ecosystem

All discussions to this point highlighted the future lies not in integrating systems, but in integrating data. As Rob Innes put it:



“Integrate data. There’s a world of pain in trying to integrate systems.”

— Rob Innes, DTG

A data-centric approach shifts the focus from systems to interoperability, from integration to accessibility, and from structure to flow. This aligns with approaches already established in industries such as fintech, where real-time data exchange and shared platforms underpin collaboration.

If competing global banks can agree on a neutral shared infrastructure (SWIFT) for something as sensitive as financial transactions, there's no fundamental reason pharma sponsors and CDMOs cannot do the same for manufacturing data exchange.

Existing frameworks lay the groundwork. The concept in Quality by Digital Design (QbDD) demonstrates how data should be structured, connected, and leveraged across the product lifecycle. Key components of this future state would include:

Data fabrics enabling seamless integration across systems

Standardized ontologies supporting interoperability

Digital twins linking development and manufacturing

Real-time data exchange across supply chains

CONTINUED INSIGHT

The goal, as Nicola Clear put it, is not to force system convergence but to agree on a shared data vocabulary: *“Allow the systems to be separate but focus on ontologies. Let’s all call an orange an orange across the R&D-to-manufacturing divide.”*

Industry initiatives such as the Pistoia Alliance CMC ontology project and Allotrope are already working toward developing standards. The challenge, as Mark Buswell acknowledged, is follow-through: *“We’re quite good at starting these sorts of initiatives, not so good at necessarily having them progress through to commercial impact. Maybe we just need to double down and drive them through.”*

A platform-based approach would enable real-time collaboration between sponsors and CDMOs, improve supply chain visibility and forecasting, and reduce duplication and integration cost. Rather than building multiple point-to-point integrations, organizations would connect to a common layer that standardizes data exchange across the ecosystem.

In a data-centric integrated model, tech transfer would no longer be a discrete event. It becomes a continuous flow of data and insight. Decisions are made faster, with greater confidence. Processes are optimized earlier. Sustainability is embedded from the outset.

“

“Tech transfer should disappear. Not because it’s gone, but because it’s continuous.”

— Rob Innes, DTG

As digital capability evolves, so does the nature of partnership. Traditional CDMO relationships have been transactional. The future is increasingly strategic. This raises new questions: Will digital platforms become jointly funded? Will data become a shared asset? How will value be distributed across the ecosystem?

Future partnerships may involve shared digital infrastructure, joint investment models, and collaborative data environments. What is clear is that organizations that cannot support this level of integration risk being excluded from higher-value partnerships.

CONTINUED INSIGHT

One emerging approach to this challenge is illustrated by **Plvs Ultra**, a UK-based company developing ontology-driven data infrastructure for pharmaceutical manufacturing, CMC, and supply chain operations. Rather than replacing existing systems of record, the platform is designed to sit across them — connecting data from sources such as LIMS, MES, ERP, and regulatory systems through a shared semantic layer that provides context and relationships between data points.

The practical intent is to make enterprise data searchable and queryable across organisational and system boundaries, reducing the manual effort currently required to locate, reconcile, and interpret information dispersed across siloed platforms. For tech transfer and CMC applications, the stated use cases include faster dossier preparation, regulatory submission readiness, and more efficient data exchange with CDMOs.

The approach is broadly analogous to adding a semantic and ontology layer on top of existing data infrastructure, addressing not the storage of data, but its contextualisation and accessibility across the enterprise.



“If your data isn’t live, contextual, and governed, your AI won’t deliver.”

— Nicola Clear, NGT BioPharma Consultants

KEY INSIGHT

The future of tech transfer is data-driven, dynamic, and integrated. The organizations that master data flow will define the next era of pharmaceutical manufacturing.

09

A Practical Roadmap for Tech Transfer Digital Transformation

To move toward this future state, organizations should adopt a structured approach. These steps do not require a complete system overhaul, they require a shift in mindset, from systems to data, and from projects to platforms.

- 1 Define a clear data strategy aligned with business outcomes
- 2 Invest in modern data architecture, including data fabrics and standardized ontologies
- 3 Pilot digital-to-digital integration platforms with key CDMO partners
- 4 Leverage industry consortia to explore shared platform models that enable ecosystem connectivity
- 5 Implement workflow orchestration tools to replace email-based coordination
- 6 Embed sustainability metrics into early-stage process design decisions
- 7 Evolve validation approaches to support greater agility and iterative development

All this on top of delivering the medicines to patients safely, hence effective transformation requires the right leadership as much as the right technology. Organizations should invest in their leaders by building their **“second muscle.”**

Once you bridge domain expertise and digital capability, ensure that the tech transfer lifecycle has clear, accountable data ownership from end-to-end, then your organization is set up for success.

KEY INSIGHT

The question is no longer whether the industry will transform... but who will lead it.

10

Conclusion: From Fragmentation to Orchestration

Tech transfer sits at the intersection of science, engineering, operations, and increasingly, digital capability. When viewed in isolation, the challenges can appear incremental: issues of efficiency, coordination, and system integration. When viewed in a cross-sector context, they appear more fundamental.

Other industries facing comparable complexity have already demonstrated that seamless data flow, integrated workflows, and digitally enabled ecosystems are achievable and essential. The pharmaceutical industry now faces a choice:



“To continue managing fragmentation, or to redesign tech transfer as a truly integrated, data-driven process.”

— Nicola Clear, NGT BioPharma Consultants

The industry is experiencing four interconnected challenges: digital & data fragmentation, sustainability misalignment, a leadership capability gap, and the rapid evolution of partnership expectations. The opportunity is equally significant.

Organizations that succeed will:

Enable data to flow across the lifecycle — shifting focus from systems to data

Align ownership around end-to-end processes — moving from silos to ecosystems

Develop leaders who own transformation end-to-end, building the “second muscle”

Embed sustainability into decision-making from the earliest stages

Build digitally integrated partnerships grounded in shared data environments

CONTINUED INSIGHT

There is also a new economic force entering this equation.

For decades, CDMOs in cost-competitive markets could rely on cheaper labor costs as a substitute for digital efficiency by manufacturing in lower-cost geographies rather than investing in operational productivity.

As Mark Buswell observed: *“Globalization actually worked against us here.”* As Western governments accelerate the reshoring of pharmaceutical manufacturing to Europe and North America, that option narrows considerably. Operating costs in those geographies are substantially higher, and the margins that were already thin by pharma standards will come under further pressure. The companies that have invested in digital efficiency will be far better placed to absorb this shift than those that have not. Reshoring may prove to be a new geopolitical catalyst to invest in digital technologies for tech transfer; the case for transformation is no longer just strategically compelling, but economically unavoidable.

The organizations that win will not be those with the best systems, but those with the foresight to recognize that as clinical development accelerates, through synthetic data arms, adaptive trial designs, and AI-driven discovery, then CMC and manufacturing execution will become the critical bottleneck. The pipeline moves only as fast as its slowest stage. Those who invest now in orchestrating data, technology, and collaboration across the full pharmaceutical ecosystem will be the ones who redefine how medicines move from discovery to patients."

“

“The organizations that master CMC data flow will define the next era of pharmaceutical manufacturing.”

— Nicola Clear, NGT BioPharma Consultants

11

Enabling The Next Generation of R&D to Commercial Technology Transfer

One Data Thread, End to End

The challenges outlined in this paper are not theoretical, they are being experienced across the pharmaceutical industry today. From fragmented data and inefficient workflows to sustainability pressures and evolving CDMO partnerships, organizations are navigating an increasingly complex and interconnected landscape.

Addressing these challenges requires more than incremental improvement. It requires a coordinated transformation across teams, process, data, technology, and operating model. This is where the combined strengths of NGT BioPharma Consultants and DTG offer a differentiated and holistic approach.

DTG



DTG is a specialist life sciences advisory and software company focused on manufacturing transformation. Unlike traditional consultancies, DTG combines deep technical expertise with extensive hands-on experience leading pharmaceutical manufacturing, supply chain and digital transformation programmes. DTG help organisations solve complex operational challenges through strategic advisory, industry-specific software products and bespoke digital solutions.

DTG supports organisations to:

- Accelerate digital and autonomous operations
- Unlock value from data, analytics and AI
- Transform manufacturing and supply chain performance
- Deliver industry-specific software and digital products

NGT BioPharma Consultants



NGT is a senior-led biopharma consultancy with over 200 consultants across four continents. Its experts bring deep industry experience to support pharmaceutical and biotech organisations across R&D, CMC, Regulatory, Quality and Clinical Development. NGT combines senior judgement with precisely matched expertise to guide clients through complex decisions and deliver practical support where timing, scrutiny and execution affect programme progress and value.

NGT supports organisations to:

- Strengthen Clinical Development and R&D decision-making
- Optimise CMC, Quality, Digital Innovation strategies, including and tech transfer execution
- Improve collaboration with CDMOs and external partners
- Increase clarity, control and decision quality at critical development stages

CONTINUED INSIGHT

A Combined Approach: Bridging Science and Digital

Individually, both organizations bring significant expertise to tech transfer:

NGT'S STRENGTH

Understanding the science, the process, and the operational realities of pharma organizations, to enable grounded, practical, and achievable transformation roadmaps.

DTG'S STRENGTH

Translating clients strategic ambition into practical, scalable digital solutions that improve manufacturing performance.

Together, they offer a powerful combination of expertise to guide both pharma and CDMO leaders in:



PROCESS + DIGITAL INTEGRATION

Aligning scientific workflows with digital infrastructure



STRATEGY + EXECUTION

From vision and roadmap through to implementation



INTERNAL + ECOSYSTEM TRANSFORMATION

Supporting both organizational change and CDMO collaboration models



DATA + SUSTAINABILITY ENABLEMENT

Embedding sustainability into digitally enabled decision-making

The need for this integrated approach reflects the central theme of this paper: **transformation does not happen within systems alone, it happens across the full lifecycle, the full organization, and the full ecosystem.**

Pharmaceutical organizations are at a critical inflection point. We invite organizations to engage in a focused discussion on:

- 1 Identifying the key sources of **value leakage** in current tech transfer processes
- 2 Defining a **data-centric strategy** aligned to business and sustainability goals
- 3 Assessing **digital maturity** across internal operations and external partnerships
- 4 Exploring the role of **shared data platforms** and next-generation collaboration models

References

McKinsey & Company (2025). Building the AI Muscle of Your Business Leaders.

PharmaSource Global. CDMO Digital Maturity and Capability Gaps.

PharmaSource Global. Strategic Pharma Partnerships Insights (2025–2026).

PharmaSource Global. How to Build Resilient Pharma CDMO Partnerships in 2025.

Pharmaceutical Online. MES is Still in the CD-ROM Era, But the Data Architecture Has Moved On.

NGT BioPharma Consultants & DTG (2025). Digital Challenges Across the Pharmaceutical R&D–Manufacturing Divide: Panel Discussion Guide.

Quality by Digital Design (QbDD) Framework: CMAC/CMDO Digital Integration Perspectives (2025).

Pharma Source: Industry Brief by MasterControl. Why Compliance-Driven CDMOs Win Sponsor Contracts (2026)

Whether your organization is at the beginning of this journey or seeking to accelerate progress already underway, we welcome the opportunity to explore how these themes apply in your specific context.

CONTACT US



DTG
digitechgroup.com

Century Court, Riverside Way
Suite 3 & 4, First Floor
Irvine, KA11 5DJ
United Kingdom



NGT BioPharma Consultants
ngtbiopharmaconsultants.com

4 Jeremy Drive
East Lyme
Connecticut, 06333
United States