Before the Next Digital Investment

Seven Case Studies from Pharmaceutical and Biotechnology Digital Investment, Organised by the FC Model™

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For the benefit of the pharmaceutical and biotechnology industry.

All organisations described are anonymised.

FREE INDUSTRY RESOURCE

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The FC Model™ is the original intellectual work of the author. All cases are anonymised. No organisation, system, vendor, or individual is identified by name. See the Disclaimer on the following pages for full terms.

Executive Summary

A collection of seven cases illustrating three levels of maturity every decision-maker needs to know before approving the next digital investment.

1. Start with the end in mind.

Before any digital investment is approved, the decision maker should be able to describe — clearly and specifically — how the digital systems will help the business after go-live. What customer improvement will the system bring about? What product quality insight will manufacturing gain? What operational decision will be faster and more data-driven than before?

These are not technology questions. They are business questions. And in most of the organisations described in this book, nobody asked them. Most investments were approved for a system that automates the business process compliantly. This is the minimum value realisation, instead of enabling the business with a step-change.

2. It is all about the business — systems and data are the enablers, not the goal.

Digital investment creates no value by itself. The value is in what the organisation does with the digital data in the system, including the customer improvements it can now make, the product enhancements it can now pursue, the operational waste it can now eliminate.

In each of the four cases that met the minimum value realisation, the technology worked. Nobody took the next step to translate the system data and capability into tangible business improvements. Nobody asked: now that the system and data exist, what does it reveal about our customers, our products, our operations?

The two cases that went further were driven by business leaders who asked that question. One CFO saw that a harmonised, compliant ERP was also a chance to consolidate Finance Shared Services globally — and drove both decisions as one. One Lean Sigma project leader, tasked with consolidating MES systems across sites, looked, found and eliminated operational wastages leading to S$120,000 in recurring annual savings.

3. The way forward is one question at a time, asked at the right moment.

The FC Model™ provides you with three diagnostic questions — one for each level of maturity. They take minutes to answer. They change what gets designed, what gets built, and what the investment will ultimately deliver.

Ask these questions before the investment is approved: what level of business value is this system designed to reach — considering Customer Value, Product Value, and Operational Value? Ask again six months after go-live: what has the integrated systems and data revealed that can help improve the value realisation? Ask again at every moment of organisational change: which planned investments are enabling the organisation to reach the desired maturity level?

The most valuable moment to use this book is just before the next digital investment approval.

Contents

Disclaimer

All organisations, projects, and deployments described in this book are drawn from the author's professional experience across the pharmaceutical and biotechnology industry. All organisations, sites, and individuals have been anonymised and are described by industry sector and functional role only. No organisation, system, vendor, or individual is identified by name.

The cases presented are intended to illustrate general patterns and principles of digital investment maturity in regulated industries. They represent the author's professional observations and interpretations, not official statements, representations, or disclosures by any employer, client, or organisation the author has been associated with.

Nothing in this book constitutes the disclosure of confidential, proprietary, or trade secret information belonging to any organisation. Specific details — including numerical figures, system descriptions, timelines, and project characteristics — have been generalised or altered to prevent identification of any organisation, project, or individual. Any resemblance to the specific proprietary systems, processes, strategies, or outcomes of any named organisation is coincidental.

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This book is for educational and knowledge-sharing purposes. It does not constitute legal, regulatory, financial, or professional advice. Readers should seek independent professional advice before making decisions based on the content herein.

A Note to the Reader

This book is a resource for our industry. If it helps you make better decisions about digital investment in your organisation, it has done its job. Pass it on.

It was written for people who make, or influence, investment decisions about digital systems in pharmaceutical and biotechnology organisations — whether that is a manufacturing plant, a commercial office, a quality control laboratory, an R&D facility, or the supply chain connecting them. That boundary is imaginary. It does not matter to our customers (eventually, patients), our products (life-saving medicines), or our operations (the productivity behind both). The FC Model™ questions apply wherever digital systems operate.

Every organisation described in these pages is real. Every case is drawn from direct experience. All organisations are anonymised — described by industry and characteristics rather than by name. The patterns repeat across organisations of every size, in every region, at every level of digital maturity.

A note on how this book was made: the case studies, the FC Model™, and the ideas in this book come from direct professional experience. An AI writing tool was used throughout the writing and editing process — for prose editing, consistency checking, and manuscript structuring. All content was reviewed and verified, and the author takes full responsibility for it.

Start with the FC Model™ foundation chapter. Read the cases in any order. Come back when a new decision is in front of you.

The FC Model™ — The Foundation

Read this first. Everything else in this book is an example of it in action.

Here is the problem this book exists to solve.

Pharmaceutical and biotechnology organisations invest heavily in digital systems. Most systems do exactly what was approved for — automating processes compliantly. That is the minimum value realisation. Why isn't anyone asking for more?

Not through incompetence. Not through poor judgment. Through a pattern so consistent across organisations of every size, in every region, that it must be structural: once the investment is approved financially, the focus switches to project delivery on time, within budget and compliantly. However, the organisation needed systems that deliver more. Nobody in the room noticed the gap, because there is no shared language to "ask for more".

The FC Model™ is that language.

It maps organisational maturity across two axes: three levels of maturity, and three dimensions of value. Every digital investment your organisation makes sits somewhere on this map. The FC Model™ tells you where.

Three dimensions of value.

★ **Customer Value:** Does your digital investment create value for the customers who depend on your operations — external customers, patients, and the internal teams who serve them?

◆ **Product Value:** Does it help you improve your products — through better quality, through learning and not making the same mistakes, through the intelligence your systems accumulate about what works?

✚ **Operational Value:** Does it make your organisation measurably more productive, faster, and more capable than it was before?

Three levels of maturity.

Most organisations are not equally mature across all three dimensions. And most investments improve one dimension without asking what it would take to improve all three.

Level 1 — Compliant

Systems validated. Risk managed. Standards met.

- Able to prove delivery to standards
- Passes inspections
- Stable but largely reactive

→

Level 2 — Capable

Systems integrated. Decisions evidence-based.

- Data drives decisions across the organisation
- Customer needs shape operations
- Measurably better than before

→

Level 3 — Competitive

Systems create the advantage. Transformation is how you operate.

- Operations delight customers and build loyalty
- Products improve through systematic learning
- Productivity compounds continuously

The full matrix.

Each cell is a diagnostic indicator. Read across a row to see what one level of maturity looks like across all three value dimensions. Read down a column to see how one dimension progresses from Compliant to Competitive.

FC Model™ Value × Maturity	**Customer Value**	**Product Value**	**Operational Value**
Level 1 — Compliant *Systems validated. Risk managed. Standards met.*	Supply reaches customers to specification. Delivery reliability is tracked and auditable. **Indicator:** *"We can prove we delivered what we promised."*	Products consistently meet validated quality standards. Quality is demonstrated, not assumed. **Indicator:** *"We can prove our products meet the standard we validated."*	Systems are validated, change-controlled, and defensible. Operations are documented and repeatable. **Indicator:** *"We can pass an inspection today."*
Level 2 — Capable *Systems integrated. Decisions evidence-based.*	Customer requirements actively shape manufacturing and commercial decisions. Issues surface before they reach customers. **Indicator:** *"Our operations respond to what customers need, not just what the contract specifies."*	Operating data drives product improvement. Quality is built into the process, not tested in at the end. **Indicator:** *"Our products are getting better because of what our systems tell us."*	Systems integrate across the organisation. Decisions are faster and more evidence-based than before. **Indicator:** *"Our systems make us measurably more capable than we were before."*
Level 3 — Competitive *Systems create the advantage. Transformation is how you operate.*	Operating reliability is a source of customer loyalty and competitive differentiation. Customers choose you because of how you operate. **Indicator:** *"Our operations create customer value our competitors cannot easily replicate."*	Product innovation is systematically enabled by operating intelligence. Each cycle generates knowledge that improves the next. **Indicator:** *"Our products improve faster (e.g. higher yield, lesser failures) than the industry norm because of how our systems learn."*	Productivity improvement is continuous and measurable. The organisation learns from every system decision. **Indicator:** *"We are more productive than our peers and we know exactly why."*

Three diagnostic questions.

One question determines which level your organisation is operating at. Be honest. The honest answer is the starting point.

Level 1 — Compliant	*Can you prove, today, that your systems are delivering to the standards your customers, your products, and your regulators require?*
Level 2 — Capable	*Are your systems making your organisation genuinely better at serving customers, improving products, and operating efficiently — or are they only documenting that you are?*
Level 3 — Competitive	*Is your digital investment creating measurable advantage across Customer Value, Product Value, and Operational Value that your competitors cannot easily replicate?*

How this book is organised.

Seven cases, plus a bonus chapter looking ahead. Organised by FC Model™ level. Each case is labelled with the level it reached and the primary value dimension it most illustrates. Read straight through for the full picture, or go directly to the level most relevant to your organisation right now.

	Level	Cases	What this part shows
Part I	**Level 1 — Compliant**	**4 cases**	Most organisations here. Not through incompetence — through approval processes that only gated at Level 1 values.
Part II	**Level 2 — Capable**	**2 cases**	Two organisations that asked what the system could enable beyond the obvious — and found it.
Part III	**Level 3 — Competitive**	**1 case**	One architectural decision, made before the first system was selected, changed what was possible for a decade.
Bonus	**Frontier**	**1 chapter**	An ongoing project exploring the accountability question autonomous systems force upon our industry.

Four of the seven cases sat at Level 1 — Compliant. That is not a selection bias. It reflects the actual landscape of pharmaceutical and biotechnology digital investment, as observed across manufacturing plants and commercial operations, in Asia, Europe, and Australia.

Part I

Level 1 — Compliant

Systems validated. Risk managed. Standards met.

Level 1 — Compliant is not failure. It is the minimum viable state — the point at which an organisation can prove its systems are operating to the required standard. Four cases, drawn from commercial offices, production plants, startup sites, and multi-site deployments across the pharmaceutical and biotechnology industry. Four different faces of Level 1 — across the Customer Value, Product Value, and Operational Value dimensions of the FC Model™ — and four different ways the cost of staying there accumulates.

Case 1 — The IT Greenfield That Stayed at Level 1

A clean slate for IT is the rarest opportunity in digital investment. Level 1 — Compliant is still possible even when you are building from scratch. The waste compounds for a decade.

Organisation	Level	Dimension	Lesson
Biopharmaceutical manufacturer — startup manufacturing and commercial site	**Level 1 — Compliant**	All three dimensions	*Greenfield IT with no shared data intent.*

The physical site was brownfield — buildings, utilities, and some existing infrastructure were already in place. But a deliberate decision was made to treat the IT and digitalisation layer as a complete greenfield: no legacy systems to carry forward, no existing data definitions to preserve, a genuine opportunity to design the digital landscape from scratch.

That opportunity is rare. Most organisations spend years untangling the consequences of digital decisions made by people who have since moved on. Here, for once, nothing had been decided yet.

And the organisation still ended up at Level 1 — Compliant across all three FC Model™ dimensions.

What Level 1 IT greenfield looks like

Multiple critical systems were deployed — for the laboratory, for quality, for supply chain, for labelling, for manufacturing. Each was implemented in isolation to solve one team's problem, with no consideration of how data would flow between them. The warehouse operated on a mix of digital systems and paper, because nobody had made a decision about the warehouse digitalisation landscape.

The global technology team, coordinating from outside the region with the local site team, had no global roadmap. Different global functional groups drove different system selections, and those groups did not speak to each other about data standards, naming conventions, or what the site's digital landscape was supposed to look like in the future.

★ *Freedom to choose does not guarantee good choices. The IT greenfield opportunity was real. What was missing was a shared intent — an agreement, across all functions and before the first system was selected, about what the organisation should eventually be able to learn from its data. Without that agreement, each team made a sensible decision that was collectively incoherent.*

The result across all three dimensions

Customer Value at Level 1: supply reached customers to specification.

Product Value at Level 1: products met validated quality standards.

Operational Value at Level 1: systems were valid and defensible.

All three dimensions at Level 1 — not because the systems failed technically, but because no one had asked what Level 2 would look like before the first line of scope was written.

The FC Model™'s Level 2 — Capable ask on the Customer Value dimension is whether customer needs actively shape manufacturing and commercial decisions. At this site, there was no infrastructure to answer that question. The data to answer it was siloed before the site had produced its first batch.

Contrast: the same opportunity used differently

Case 7 describes a different biopharmaceutical manufacturer on a comparable IT greenfield — where every system was connected by a single architectural decision made before the first vendor was selected, and the end goal was a data lake feeding near-real-time manufacturing intelligence to scientists worldwide. Same opportunity. One design decision made differently. Two completely different FC Model™ levels.

A greenfield IT landscape without a shared data architecture across all three FC Model™ dimensions is just a collection of individual projects wearing a site's name. The FC Model™ level it achieves is determined before the first system is chosen, not after the last one goes live.

Ask yourself

- *For the last major new site or digital programme your organisation ran, was there a shared data architecture agreed — across all functions — before the first system was selected?*
- *On the FC Model™'s Product Value dimension, could someone at your site today trace which process parameters produced which quality outcome for a specific batch or lot?*
- *If your last IT investment had been designed for Level 2 — Capable from the start, what is the single decision that would have been made differently before the first vendor was shortlisted — and who in the room had the authority to make it?*

Case 2 — The Forced Migration That Created Two New Problems

A forced migration reaches Level 1 — Compliant by definition. What it rarely does is ask what Level 2 — Capable would have required, and whether any of it was still possible.

Organisation	Level	Dimension	Lesson
Japanese pharmaceutical manufacturer — production plant	**Level 1 — Compliant**	Operational Value	*Stability is not strategy.*

The existing manufacturing execution system had been customised heavily over more than ten years. By the time the migration investment was approved, the current system was generating at least one deviation every two to three weeks, the rate of creation outrunning the rate of closure. The system was creating more compliance risk than it was managing. That is Level 1 — Compliant in distress: an organisation that cannot reliably prove, today, that its systems are operating to standards.

A forced migration is still a choice

Migrating to a new manufacturing execution system was necessary. But 'forced migration' and 'strategic investment' are not the same thing — and the difference shows in what gets designed. What got designed: the technical migration. On schedule, on budget. Formally accepted by Quality and Finance. What didn't get designed: what the system would do for the business beyond restoring Level 1 — Compliant on the Operational Value dimension.

One more thing, the Line A / Line B problem

Manufacturing and product supply constraints meant Line A migrated first. Line B stayed on the old system. The plant now supported two manufacturing execution systems simultaneously — a new one still being learned, and an old one already decided to be unfit for purpose in the future. Two sets of validation documentation. Two sets of procedures. Two systems in production at once.

The migration that was supposed to reduce risk created a new category of risk. On the FC Model™'s Operational Value dimension, the plant moved from Level 1 in distress to Level 1 — stable, while also operating a dual-system overhead that reduced the measurable capability gain to near zero.

What Level 2 — Capable would have asked

A Level 2 migration would have asked a different question from the start: not just 'how do we stop the deviations' but 'now that we have a stable platform, what can we do with it that we could not do before?' Shorter deviation closure cycles. Real-time batch visibility. Cross-line data comparison. The stable system was the precondition for those capabilities. The migration delivered the precondition and stopped.

On the FC Model™'s Operational Value dimension, Level 2 — Capable asks: are your systems making the organisation genuinely better at operating efficiently — or are they only documenting that you are? At this plant, after the migration, the honest answer was still: documenting.

Level 1 wants the system to stop failing — and for Line A, it did. Level 2 asks what winning looks like. Most forced migrations never get to the second question.

Ask yourself

- *On the FC Model™'s Operational Value dimension, was your last major system replacement a move from Level 1 to Level 2 — or a move from Level 1 in distress back to Level 1 stable?*
- *Can your current system tell you whether deviation closure times have improved since the migration — and if not, who is measuring that, and how?*

Case 3 — The ERP Upgrade That Left Data Silos Intact

An ERP upgrade that connects systems without connecting data achieves Level 1 — Compliant. Everything the investment was supposed to enable depends on data that still cannot speak across sites — or across the supply chain.

Organisation	Level	Dimension	Lesson
Regional specialty pharmaceutical company — commercial offices and contract manufacturing	**Level 1 — Compliant**	Operational Value	*ERP connected systems. Not data.*

A regional specialty pharmaceutical company in Asia-Pacific was acquired by a Venture Capital firm, which moved the headquarters to a tax-optimised jurisdiction to improve the bottom line. The move came with budget for an ERP upgrade — a rare chance to reach Level 2 — Capable across all three Value dimensions. The chance was missed: the ERP upgrade delivered only Level 1 — Compliant, because nobody made the call on data standards before the investment was approved.

What fragmented actually looks like

The business had a contract manufacturer in India and commercial offices in Australia, Singapore, Japan, and several other markets. Each had its own way of naming products, classifying customers, recording complaints, and logging transactions. The ERP upgrade connected them all to the same platform. It collated the data. It did not transform the data into useful information.

★ *Data silos do not need different systems to survive. They can live inside the same ERP if nobody makes a decision about data standards. The FC Model™'s Operational Value dimension at Level 2 — Capable requires systems that integrate across the organisation and make decisions faster. An ERP with fragmented data provides neither.*

The questions that became expensive

How much stock across all markets? What is the true margin on this product when manufacturing cost and commercial cost are consolidated? Which market is the most efficient route to a patient? Which product had the most complaints and how were they handled? Each answer required custom extraction, manual reconciliation, and usually a spreadsheet maintained in parallel by several people. Nobody measured the cost of those spreadsheets.

The project was declared complete at go-live and never revisited. On the FC Model™, the organisation moved from one ERP version to another — remaining at Level 1 — Compliant on the Operational Value dimension, while the gap between what was promised and what was delivered kept widening, going unnoticed.

The missed opportunity: connecting the CMO

The contract manufacturer in India was not just a supplier in an address book. It was the source of every unit of product that the commercial teams in several countries were selling. If the ERP had been designed with standardised data definitions from the start — harmonised product codes, batch identifiers, quality status fields recognised by both the CMO and all commercial sites — the organisation could have connected manufacturing data to commercial performance data for the first time.

With those connections in place, some strategic questions become answerable. What is the actual cost to serve each market, when the CMO's manufacturing cost per batch is accurately attributed to each product and SKU? Which products manufactured at the CMO are most profitable across which commercial markets — and does that change the production allocation decision? What quality trends are appearing at the CMO, in deviation rates or yield profiles, before they become complaints in market?

None of those questions became answerable, because the data standards decision was not made. The CMO remained a separate data kingdom inside the same ERP — connected by the platform but isolated by the data. The opportunity to link the supply chain end-to-end, from manufacturing through to commercial performance, was present at the moment of go-live and silently closed when nobody asked for it.

The cost of avoiding a data standards decision does not appear on go-live day. It appears in every quarterly review where the supply chain and commercial teams are reconciling numbers that should already agree — and in every strategic question about the CMO relationship that cannot be answered without a week of manual work.

Ask yourself

- *On the FC Model™'s Operational Value dimension, could your organisation answer 'what is the true cost to serve each market, including CMO manufacturing cost' in one working day — using only existing systems?*
- *Is your contract manufacturer's data connected to your commercial systems in a way that allows strategic decisions — or is the relationship managed on spreadsheets and quarterly meetings?*
- *The data standards decision that was not made before go-live is still costing your organisation time and money every quarter, in reconciliation work that nobody has measured. Has anyone put a number on that cost — and who would need to see it to act?*

Case 4 — When Each Site Writes Its Own Rules

A platform deployed at every site is not the same as a platform governing every site. The gap between those two outcomes is a single decision — made before deployment begins or quietly deferred until it becomes expensive.

Organisation	Level	Dimension	Lesson
Large generic pharmaceutical manufacturer — multiple production plants	**Level 1 — Compliant**	Operational + Product Value	*Every site a data kingdom.*

A large generic pharmaceutical manufacturer deployed a manufacturing execution system across multiple production sites. The business case was solid: paperless batch records, reduced manual effort, improved data accuracy. A genuine improvement over paper. But the deployment method guaranteed that Level 2 would remain out of reach.

The first site's configuration was thorough: product codes, equipment IDs, batch naming conventions, workflow sequences. When Site 2 deployed, the team extended Site 1's configuration and adjusted for local needs. By Site 3, the pattern was established: each site ran what was technically the same system, configured differently enough that comparing data across sites required a translation step. Technically, one platform. In practice, multiple dialects of the same language that could not understand each other. Freedom to deploy does not guarantee coherence — the system was technically correct at every site, and the network, collectively, still could not answer the most basic cross-site question about product performance.

The governance decision that was never made

Level 2 — Capable on the Product Value dimension requires operating data to drive product improvement across the network: which plant has the best yield profile for this product family? Which site's deviation rate is lowest — and what are they doing differently? Neither question was answerable from a single system query. The data existed at every site. But with each site speaking its own dialect, aggregating it into a network view required manual extraction, translation, and reconciliation.

The governance decision was simple in hindsight: standardise the configuration template before the first site deployed, and require every subsequent site to use it. That decision was available at design stage. It was not made. By the time the fourth site was live, making it retroactively would have cost more than the original deployment.

A validated deployment at every site is not the same as a validated global platform. The gap between those two outcomes is one decision — made before the first site goes live, or deferred until the cost of not making it becomes undeniable.

One question worth asking

- *What is the single data standards or governance decision, currently unmade, that is keeping your multi-site deployment at Level 1 — Compliant rather than Level 2 — Capable?*

Part II

Level 2 — Capable

Systems integrated. Decisions evidence-based.

Level 2 — Capable is the level at which systems integrate and decisions become evidence-based. Data drives decisions across the organisation. Customer needs shape operations. The two cases in this part show what happens when someone inside the organisation sees that opportunity, inside a project approved for other reasons, and drives it to completion.

Case 5 — How a Standardisation Project Found Almost S$120,000 in Savings

The move from Level 1 — Compliant to Level 2 — Capable on the Operational Value dimension is often hiding inside a project that was only approved on Level 1 grounds.

Organisation	Level	Dimension	Lesson
Global pharmaceutical manufacturer — multiple production plants	**Level 2 — Capable**	Operational Value	*Standardisation inconsistency and waste live in the same places.*

Most digital investment approvals look like this: the system will save X hours. It costs Y. ROI = X/Y. Approved. That is a Level 1 — Compliant argument. It is the floor, not the ceiling. That is the minimum value realisation.

A global pharmaceutical manufacturer was running multiple manufacturing execution systems across different sites — each technically sound, each solving the same problem in a slightly different way. An ERP upgrade forced all of it into the open, because an upgrade is exactly the moment when every quiet local accommodation has to be reconciled against one shared system.

A Lean Sigma project followed. Not to check a box, but to find the waste in concrete, measurable terms. Result: almost S$120,000 in recurring annual savings from consolidating overlapping systems onto a single platform.

That was the smallest thing the project delivered.

★ *Follow the trail of standardisation inconsistency and you will find operational waste — every time. They live in exactly the same places. This is what the FC Model™'s Operational Value dimension at Level 2 — Capable looks like in practice: systems integrated across the manufacturing environment, decisions faster and more evidence-based than before. That saving was the visible tip of a much larger organisational capability gain.*

What the S$120,000 actually came from

The savings came from three sources: software licence consolidation as overlapping applications were retired; hardware server reduction as systems combined onto a shared platform; and the internal time no longer spent reconciling separate systems by hand across sites. Combined, these produced a recurring annual saving of close to S$120,000.

What each identified saving had in common: it was invisible until someone looked across all sites at once. The waste existed in the gaps between team-level views, compounding for years, unmeasured.

The question the project never returned to ask

After go-live: nothing strategically. No follow-up on whether the productivity gains held. No question about what the harmonised data was now revealing about the business. The platform was now capable of answering Level 2 questions across the Product Value dimension — where are yields drifting, which sites are outperforming — but nobody asked for those questions in the original investment approval, and nobody asked for them afterward.

The most common way to waste a Level 2 — Capable investment is to declare victory at go-live and never ask what the integrated data is now telling you across the other dimensions.

What the integrated data was already telling them

After consolidation, the harmonised platform could in fact answer questions it was never asked. The data to answer them existed the day after go-live.

Before consolidation, reviewing production yields across both sites meant logging into two separate systems, downloading the data independently, and translating it into a common format before any comparison was possible. After consolidation, the comparison report was available on demand, in real time, from either site.

What followed was what integrated data makes possible: each site could see what the other was doing differently — and improvement moved in both directions. Yields that were drifting at one site were stabilised against the performance profile of the other. The organisation had not designed for this outcome. It arrived as a consequence of making the data visible. The platform had been capable of answering Level 2 questions across the Product Value and Customer Value dimensions from the day after go-live. None of those questions were in the original business case, and none were asked afterward. The data existed. The question did not.

In a comparable MES investment, the Level 2 question was asked — and answered. Key quality analytical attributes were identified and streamed to a data lake in near real time after go-live. The manufacturing process could then be monitored continuously against those parameters, with the ability to intervene before a batch failure rather than after. In a biologics or specialty pharmaceutical environment, a single batch failure can cost millions and disrupt the downstream supply chain for weeks and months. The data to prevent it existed in the first example too. Nobody asked the question.

Ask yourself

- *On the FC Model™'s Operational Value dimension, was your last major investment approved on Level 1 grounds when it had the potential to deliver Level 2 — Capable value?*
- *After your last major platform go-live, did anyone return to ask what the integrated data was revealing about Product Value or Customer Value?*
- *The day after your last major platform went live, what was the first question asked of the integrated data — and how long did it take to get an answer? If it required a manual step, the platform worked. The data architecture did not.*

Case 6 — When the CFO Got Personally Involved

The difference between Level 1 — Compliant and Level 2 on the Operational Value dimension is often one senior leader who sees the capability the technology makes possible — and personally drives the organisation to capture it.

Organisation	Level	Dimension	Lesson
One of the world's largest pharmaceutical companies — commercial offices, four countries (Asia-Pacific)	**Level 2 — Capable**	Customer + Operational Value	*CFO saw the Level 2 opportunity and drove it.*

Most ERP upgrades reach Level 2 — Capable on the Operational Value dimension at best: data harmonisation, version compliance, faster decision-making than before. The only reason this Asia-Pacific commercial rollout reached Level 2 was because the CFO was personally in the room.

The CFO's question

The CFO saw something most ERP project sponsors miss: an opportunity to consolidate Finance Shared Services globally, with the harmonised ERP as the infrastructure that made it possible. The same process. The same data standard. The same shared service centre across every commercial office and manufacturing plant. Appropriate local headcount reduced accordingly. A business transformation decision that required a technical project to execute. Without the CFO's personal involvement, this programme would have delivered Level 2 — Capable harmonisation and stopped there. With it, the organisation got a permanently lower cost base in Finance, and a Customer Value gain besides: commercial and manufacturing operations that responded to what customers needed across markets, not just what each country's contract specified independently.

What Level 2 still did not reach

This reached Level 2 on the Operational Value and Customer Value dimensions. But the Level 3 — Competitive question was not asked: what is the harmonised commercial data now telling us about our customers — their behaviour, their preferences, their unmet needs? Level 3 would have built the architecture to answer those questions. Level 2 captured the strategic moment. Level 3 creates the infrastructure to keep finding those moments.

The FC Model™'s Level 3 — Competitive diagnostic asks: is your digital investment creating measurable advantage that competitors cannot easily replicate? Level 2 created the foundation for that and stopped — because nobody had asked for Level 3 in the original approval, and nobody asked afterward.

What Finance Shared Services consolidation actually required

The CFO's business case was not an IT project. It was a business transformation project that needed a technical project to execute. The ERP — with harmonised data standards applied consistently across every commercial office and every manufacturing plant — was the infrastructure that made it possible. Without the data standards work, the platform would have produced the same result as Case 3: a technically sound ERP with locally interpreted data that could not speak across markets.

The scale of the full global programme puts the ambition in context. The Asia-Pacific rollout that drives this case — the four countries where the CFO's personal involvement made the difference — was one regional deployment inside that larger consolidation, with the same onboarding and training rolled out identically across the US and every other region. Across the full programme, more than 150 sites in over 100 countries were brought under a single shared service centre. Before the programme, preparing consolidated group financial reports required two to three months of manual work — a team of finance specialists collating figures from disparate local systems, translating between formats, and reconciling errors. By the time the CFO received the report, the numbers were already two to three months old.

After go-live, financial reporting became available on demand — accurate to the last completed transaction in the system. The finance specialists who had spent their careers reconciling data were redeployed to analysis and strategic work. Barring human input errors, the numbers could be trusted as soon as they appeared. The CFO could, for the first time, make strategic decisions based on a report that reflected the current state of the business — not what it had looked like three months ago.

What the CFO had seen — and what most ERP project sponsors miss — was that the harmonisation work and the business transformation were the same decision, not two sequential ones. Seeing them as one decision, and driving both simultaneously, was the judgment that created the Level 2 outcome.

What Level 3 would have required from here

The harmonised commercial data that existed across all markets after go-live was the raw material for Level 3 — Competitive on the Customer Value dimension. The architecture was in place. The question was whether anyone would ask what it could now tell the organisation about its customers.

The Level 3 opportunity was market intelligence — integrating external market data with the now-harmonised internal ERP platform. With sales forecasts, supply chain, and fulfilment data sitting alongside commercial performance across all markets, the executive team could finally ask questions that had previously required weeks of manual analysis: the true profitability of each product across each market, demand patterns that predicted where to invest in supply, which markets responded fastest to new product introductions. The infrastructure to answer all of these questions existed from go-live. The decision to ask them was never made.

★ *Level 3 — Competitive is rarely a technology gap. It is an ambition gap — the decision to use what the system now knows to learn continuously about customers and products, not only to operate more efficiently. This programme had earned the right to ask the Level 3 question. It was not asked.*

At every ERP and Finance Transformation kick-off meeting, the CFO — or a trusted delegate — addressed the elephant in the room directly: "Our ERP ship has sailed. You are either on board or you will be left behind." The message was blunt and consistent. Pushback from project teams was close to zero.

The same meeting delivered a second message: junior headcount for manual tasks — accounts payable, accounts receivable, routine journal entries — would be removed at each site. Site finance teams had been briefed beforehand, so nobody was caught off guard. Some sites gave up the headcount outright, in teams as small as one or as large as ten. Others redeployed it to more strategic work — the kind that helps maximise product and investment cost allocation.

Ask yourself

- *In your current major programme, is there a senior leader who has seen the Level 2 — Capable opportunity inside the technical project and is personally driving to capture it?*
- *On the FC Model™'s Customer Value dimension, does your commercial operation respond to what customers actually need — or only to what each market's contract independently specifies?*
- *If your commercial organisation could ask the harmonised ERP data one question today that would change a strategic decision — about where to invest, which products to prioritise, or how to allocate supply — can your current data architecture answer it in one working day, without a spreadsheet?*

Part III

Level 3 — Competitive

Systems create the advantage. Transformation is how you operate.

Level 3 — Competitive is the level at which digital investment creates durable advantage across all three FC Model™ dimensions simultaneously. Manufacturing reliability that customers choose you for. Product innovation that systematically improves with every production cycle. Operational productivity that compounds. One case — designed for Level 3 from the first architectural decision, using a greenfield IT investment to build a virtuous learning cycle from manufacturing data all the way back to R&D — and ultimately to the patients who depend on it.

Case 7 — The Only Level 3 in the Room

Level 3 — Competitive across all three FC Model™ dimensions is not a destination reached by upgrading Level 1 systems. It is a design intent — declared before the first vendor is shortlisted and protected at every decision that follows.

Organisation	Level	Dimension	Lesson
Global biopharmaceutical manufacturer — greenfield biologics plant	**Level 3 — Competitive**	All three dimensions	*One identifier. All systems connected. Virtuous cycle.*

Every case in this book up to this point sat at Level 1 — Compliant, or at Level 2 — Capable on one or two dimensions. Only one was designed from the start for Level 3 — Competitive across all three.

A global biopharmaceutical manufacturer building a greenfield biologics plant made one decision that almost no organisation makes at design stage: every system would be connected, every batch identifier would propagate across every platform, and all the data would eventually flow to a place where scientists could learn from it.

What connected end-to-end actually means

From the distributed control system on the manufacturing floor, through the manufacturing execution system, into a process data historian, through a production data warehouse, and into a real-time statistical process monitoring system. At every layer, the same batch identifier connected the record. The same batch number the distributed control system knew about at Monday 3am was the identifier that appeared in the laboratory system when quality released the batch on Thursday 3pm.

★ *This sounds like a data architecture decision. It is. It is also the decision that determines whether Level 3 is ever possible — because you cannot learn across systems from data that cannot be connected.*

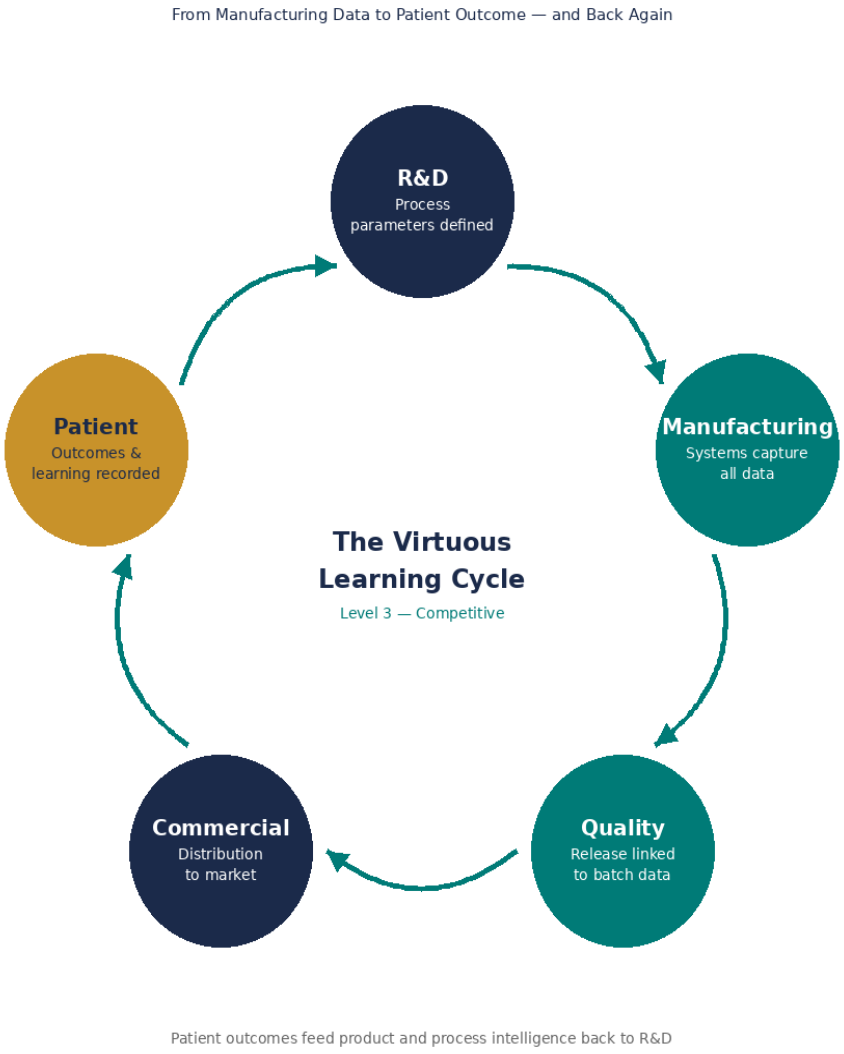
The interface that almost stopped everything

Five months before the regulatory inspection, the success rate of automated handoffs between the distributed control system (DCS) and the manufacturing execution system was dangerously below threshold. Not a technical metric. The number that determined whether the plant received regulatory approval, which determined when product could reach patients, which determined the revenue timeline the board had committed to.

The fix was finding the specific interfacing messages between systems producing different accounts of the same event and correcting those errors at root causes, rather than patching symptoms. Within five months, the interface success rate had improved by close to 30 percentage points, reaching above 95% — well above the threshold needed for a defensible validated state. During the inspection, a regulatory inspector asked to trace a non-conformance in real time across DCS and MES data, the batch record, the deviation system, and the relevant SOP. Every system told the same story.

Reliability is not a technical metric. It is a trust metric on the Customer Value dimension. What you cannot see, you cannot defend. And what you cannot defend, you have not truly validated.

The virtuous cycle — Level 3 across all three dimensions



The production data warehouse aggregated data from the manufacturing floor, the laboratory, and quality release. Process development scientists anywhere in the world could monitor manufacturing performance in near real time. That is Level 2 — Capable on the Operational Value dimension. Powerful. But not yet Level 3.

Level 3 begins when the manufacturing data, connected to quality release data, tells the organisation something about patient outcomes. Which process parameter profiles correlate with which clinical results? The answer does not just improve the current product. It tells R&D which parameters to investigate in the next generation. Each production cycle generates knowledge that improves the next one.

That is the FC Model™'s Level 3 — Competitive on the Product Value dimension: product innovation systematically enabled by operating intelligence, each cycle generating knowledge that improves the next. Manufacturing learns from itself, connects what it learned to what patients experienced, and feeds it back to the scientists designing tomorrow's therapies.

The one decision that made it possible

One architectural commitment, made before the first system was selected: every batch identifier would propagate across every system. That single decision — made early, with the right foresight — is what made the data connectable years later. Compare this to Case 1: same IT greenfield opportunity, multiple systems deployed, no shared identifier, data siloed before the first batch was produced. Same opportunity. One architectural decision. Two completely different FC Model™ levels.

Carry one question out of this chapter, not three: what is the single architectural commitment you would need to make today, before the next system is selected, to make Level 3 — Competitive possible five years from now?

All Seven Cases on the FC Model™

A quick-reference map of every case in this book — and the pattern they collectively reveal.

Seven cases. Four at Level 1 — Compliant. Two at Level 2 — Capable. One at Level 3 — Competitive. The distribution is not a selection bias. It reflects the actual landscape.

Organisation & Sector	FC Level	Dimension	Key Lesson
Biopharmaceutical manufacturer — startup site	**Level 1 — Compliant**	All three dimensions	*IT greenfield with no shared data intent.*
Japanese pharmaceutical manufacturer — production plant	**Level 1 — Compliant**	Operational Value	*Stability is not strategy.*
Regional specialty pharmaceutical company — commercial + CMO	**Level 1 — Compliant**	Operational Value	*ERP connected systems. Not data. CMO link missed.*
Large generic pharmaceutical manufacturer — multiple production plants	**Level 1 — Compliant**	Operational + Product Value	*Every site a data kingdom.*
Global pharmaceutical manufacturer — production plants	**Level 2 — Capable**	Operational Value	*Standardisation inconsistency and waste hid S$120,000 in recurring savings.*
World's largest pharmaceutical company — commercial offices	**Level 2 — Capable**	Customer + Operational Value	*CFO saw the Level 2 opportunity and drove it.*
Global biopharmaceutical manufacturer — greenfield plant	**Level 3 — Competitive**	All three dimensions	*One identifier. All systems connected. Virtuous cycle.*

What the pattern reveals

Four of the seven cases stayed at Level 1 — Compliant. Not because those organisations were incompetent. Not because they lacked budget. Because the approval process only asked for the minimum Level 1 value across one dimension. Because nobody asked what Level 2 looked like before the build began. Because the systems were validated without building the organisation capable of using them at the level the investment intended.

The one Level 3 — Competitive case shares a characteristic that distinguishes it from every other case in this book: an architectural decision was made at the very beginning, before the first system was selected, about what the organisation should eventually be able to learn from all of this data. Not a later decision. A first decision.

Level 3 — Competitive is not a destination reached by upgrading Level 1 systems across three dimensions. It is a design intent — declared before the first vendor is shortlisted, and protected at every decision point that follows.

The FC Model™ in one question

Every case in this book, whatever its level, whatever its primary dimension, ultimately illustrates the same gap. The gap between what the approval assumed and what the organisation needed. Between what was validated and what was capable. Between what the system proved and what the organisation learned.

The FC Model™ closes that gap with one underlying question, asked honestly before investment is approved and asked again after go-live:

Across Customer Value, Product Value, and Operational Value — is your digital investment creating the level of maturity your organisation actually needs? And does everyone in the room agree on what that level is?

In every case where that conversation happened clearly and jointly, the outcome improved. In every case where it did not, the gap showed up eventually — in a spreadsheet nobody should still be maintaining, in a data warehouse that could not answer a basic cross-site question, in a cloud platform where every site had built its own version of the standard, in an IT greenfield that produced a set of disconnected systems instead of a connected digital landscape.

The Pattern Beneath the Cases

Seven cases. Many different countries. Organisations ranging from startup biotechnology sites to some of the world's largest pharmaceutical manufacturers. Different systems, different geographies, different eras, different FC Model™ levels.

The same pattern in every one of them.

The level your digital investment reaches is determined before the first system is selected — not after the last one goes live.

In Case 1, the IT greenfield produced a set of isolated systems not because the technology was wrong, but because no shared data intent was established before the first vendor was shortlisted. In Case 7 — the same type of greenfield, the same scale of investment, the same regulatory environment — a single architectural commitment made before any vendor was selected produced a decade of compounding advantage. The technology in both cases was comparable. The business question asked before the technology was the difference.

This pattern appears in every case. Case 2: the forced migration produced a stable system rather than a capable one because the Level 2 question was not asked before scope was written. Case 3: the ERP connected systems but not data because the data standards decision was not made before go-live. Case 4: the single MES platform became a collection of local variations because global governance was not followed strictly after the first site deployed. The decision not made at the beginning does not go away — it becomes the decision you make later, expensively and reactively, for years afterward.

The cost of the wrong level is never measured, so it is never managed.

Every case in this book carries an invisible cost that does not appear in the project budget, the post-implementation review, or the annual report. In Case 1, it is the decade of questions about patients and products that cannot be answered because the data was siloed before the first batch. In Case 3, it is the spreadsheets maintained in parallel because the ERP cannot answer a basic cross-supply-chain question. In Case 4, it is the manufacturing intelligence that could exist across the network but does not, because each site is a data kingdom with its own dialect.

None of these costs are measured. All of them are real. Measuring the cost of staying at Level 1 is not a technical exercise. It is a leadership exercise — asking, for every system currently running, what would Level 2 look like here, and what is the cost per quarter of not having it. Most organisations have never asked that question in the right room. Asking it once, clearly, changes the conversation permanently.

The move from Level 1 to Level 2 is almost always hiding inside a project already approved.

Case 5 found almost S$120,000 in recurring annual savings inside a compliance project. Nobody approved it as a cost-reduction programme. The savings were there before the project started, invisible because no one had looked across all sites at once.

Case 6 delivered a Finance Shared Services consolidation inside an ERP upgrade. Nobody approved it as a business transformation. The CFO saw what was possible, asked for it at the right moment, and it was delivered. The same project, without that question, would have produced a harmonised ERP and nothing more.

The Level 2 value is in the project. It requires someone who knows what to look for, when to ask for it, and how to frame it for the approval room — before the scope is fixed, and again after it is delivered.

★ *These three patterns run through all seven cases. They are not peculiar to pharmaceutical and biotechnology manufacturing. They are the structural reality of digital investment in any regulated, complex, multi-site organisation. The FC Model™ names them. The cases illustrate them. What an organisation does with that recognition is the question that matters next.*

Look back across all seven cases and the technology never once let anyone down. What ran short, case after case, was the nerve to ask for more with a shared language, before the approval was signed.

Bonus Chapter — When the Operator Isn't Human

A question our compliance frameworks were never designed to answer — and why a new regulatory framework now begins, but does not complete, the response.

★ ⚠ *Looking ahead: The seven cases describe completed deployments at known FC Model™ levels. This chapter is different. It describes an ongoing project at the frontier of regulated manufacturing — and the first dedicated regulatory framework for AI in pharmaceutical operations, published for consultation in July 2025 and not yet finalised. Results from both are still emerging.*

Every case in this book rests on an assumption so fundamental it was never stated: a human performs the action, a human reviews it, a human is accountable for it. That assumption is being tested at scale. In July 2025, the European Commission published EU GMP Annex 22 on Artificial Intelligence for stakeholder consultation — the first regulatory framework dedicated to AI in pharmaceutical manufacturing. It acknowledges the question this chapter has been asking since a cleanroom robot project began. It does not yet fully answer it.

The project

A national government research institute, through a biomanufacturing innovation programme, is developing an autonomous, 21 CFR Part 11 compliant cleanroom robot designed to operate inside a regulated pharmaceutical manufacturing environment — making process decisions and executing steps without direct human initiation of each individual action.

Early in the project, a question surfaced that stopped the room:

★ *"When the robot makes a decision inside a regulated process — without a human directly initiating that specific action — who signs the batch record?"*

Why the existing frameworks were not built for this

21 CFR Part 11 and EU Annex 11 share one foundational assumption: a human performs the action, a human's identity is captured, a human is accountable. An autonomous system breaks that chain by design. Requiring a human signature on every robot decision eliminates the reason to build the robot. This is not a flaw in the design. It is a gap in the framework — one that was never anticipated because autonomous actors in regulated manufacturing environments did not previously exist.

What EU GMP Annex 22 says

EU GMP Annex 22, published for consultation in July 2025 and expected to be finalised in 2026, is the first official European GMP guidance dedicated to AI in pharmaceutical manufacturing. Drafted by the EMA GMDP Inspectors' Working Group with PIC/S — with the FDA and MHRA as observers — it is designed as a globally harmonised framework extending Annex 11 into the AI era.

Its core answer to the accountability question: the Qualified Person remains accountable. AI does not replace the QP. It changes the nature of the evidence trail the QP relies on. Annex 22 requires:

- *Static, deterministic AI models only for GMP-critical operations. Adaptive or generative models are prohibited in critical applications. The system that makes the decision must be fixed, testable, reproducible.*
- *Full lifecycle validation: from training and testing through deployment, monitoring, and change control. Any model change requires formal change control, identical in principle to any validated system update.*
- *Explainability: the AI's reasoning must be traceable. A human reviewer must be able to reconstruct why the system acted as it did and assess whether that reasoning met the required standard.*
- *Defined intended use before testing begins. Drift monitoring during operation. Independent test datasets for validation. Cross-functional accountability across QA, data science, and IT.*

Annex 22's answer to who is accountable is, in the end, the same person who was always accountable. What changes is the evidence trail. Instead of a human signature on each action, accountability is demonstrated through explainability, traceability, and lifecycle governance of the AI system itself. The Qualified Person does not disappear — they shift from approving individual actions to governing the system that takes them.

Where Annex 22 stops — and where the cleanroom robot begins

Annex 22 was written primarily with AI-assisted human decisions in mind: systems that recommend, flag, or predict, with a human reviewing before action is taken. The cleanroom robot raises a harder question. What does meaningful human oversight look like when the system is making thousands of micro-decisions per hour, each individually below the threshold of human review, but collectively constituting the regulated manufacturing process?

Annex 22's explainability requirement is achievable in principle. In practice, for an autonomous system at manufacturing scale, it requires capturing not just what the system did and when, but the specific decision logic and input conditions at each moment — with enough fidelity that a reviewer can reconstruct why the system acted as it did. The architecture for that level of traceability at autonomous scale does not yet exist as a validated standard. The cleanroom robot project is exploring exactly this.

Why the industry should be paying attention now

AI-assisted decisions are already embedded across the industry: process monitoring, anomaly detection, scheduling, release support. In most cases, they operate in a regulatory grey area — tolerated because consequences are limited, or because a human is nominally in the loop without meaningfully reviewing each decision.

Annex 22 closes that grey area. From 2027–2028, when enforcement is expected to begin, any AI system affecting patient safety, product quality, or data integrity must meet Annex 22's requirements. Organisations designing now for explainability, lifecycle governance, and static model validation will be ready. Organisations relying on nominal HITL (Human-In-The-Loop) will face remediation.

There is a FC Model™ dimension here that goes beyond compliance. On the Customer Value dimension at Level 3, manufacturing reliability differentiates. An autonomous manufacturing capability — operating continuously, at specification, with full Annex 22-compliant traceability — is a Level 3 competitive position most organisations cannot yet credibly claim. The ones that establish a credible governance model first will have access to that capability first.

Level 3 — Competitive is where digital investment creates advantage that competitors cannot easily replicate. For the next generation of pharmaceutical manufacturers, that advantage will be built on AI governance — not just AI capability. Annex 22 is the framework's foundation. Build on it before it is required.

Questions worth carrying

- *If an AI or autonomous system in your operation made a consequential process decision today, could you demonstrate — against EU GMP Annex 22's explainability requirements — that the decision was governed, traceable, and within the system's validated scope?*
- *Which AI-assisted systems in your current environment — process monitoring, anomaly detection, scheduling, release support — would satisfy Annex 22's static, deterministic model requirement today? Annex 22 enforcement begins 2027–2028.*
- *What would it mean for your competitive position to establish a credible Annex 22-compliant governance model for AI-assisted manufacturing decisions — before your competitors are required to?*

Where to Go From Here

If your honest answer to the Level 2 diagnostic question is “we are only documenting that we are capable, not demonstrating it,” you are in company with most of the industry. That is not reassurance. Safety in numbers does not lead to business longevity.

The question that follows the diagnosis is not “which framework should we apply?” It is: what decision, currently unmade unknowingly, is holding us here — and who in our organisation is positioned to make it?

In more than twenty years of working through this question with pharmaceutical and biotechnology leaders, three moments emerge consistently where outside perspective adds the most value.

Before investment is approved.

The window between “we have identified a system we want to buy” and “we have written the scope” is where the FC Model™ level gets determined — usually by omission. A diagnostic conversation at this point costs very little compared to discovering the answer three years into deployment. The most important question in any digital investment is the one nobody is asking in the approval room.

After go-live, when the data is finally integrated.

Six to twelve months after a major platform goes live, the data that was never previously available is sitting in the system, unused. This is the most consistent waste in Level 2 deployments. The platform is capable. The questions are not being asked. A structured review at this point reliably surfaces value that was paid for and never captured — across all three FC Model™ dimensions.

At the moment of organisational transition.

A new site head. A merger. A platform replacement. A regulatory inspection outcome that forces a rethink. These moments open decision windows that are otherwise closed. They are the moments when Level 3 becomes possible for organisations that have spent years at Level 1. They are also the moments that pass most quickly — absorbed by operational pressure before the strategic question is asked.

In practice, four questions open every first conversation with every new initiative:

Who is this system for — and how will it help patients? Does the whole team agree on that?

How will we measure success — before go-live, at go-live, and after?

Does this make us better at today’s products — and tomorrow’s?

What if we do not make the investment?

These questions surface the real project — which is almost always different from the approved one.

Why the pattern keeps repeating even in well-run organisations

The organisations in this book are not poorly run. Several are among the world's most sophisticated pharmaceutical manufacturers. They arrived at Level 1 not because they lacked technical skill but because the people who could see the full picture were not in the room at the right moment — and the people in the room were not positioned to say what needed to be said.

An internal team carries two constraints an external advisor does not. The first is altitude: the people who understand the technical landscape are rarely the same people who can challenge the investment case at CFO or site head level. The second is organisational social standing: pointing out that the approved scope was insufficient, even before the project has started, requires credibility and independence that is difficult to sustain from inside an organisation, regardless of how right the observation is.

In another case, a MES migration project was on track for go-live in three months when an external crisis hit. A sister site producing the same product had a supply issue caused by unforeseen line contamination. The site faced two hard choices: delay the migration a full year to help the sister site, or proceed as planned. The arguments on both sides were strong — the IT Director wanted to go live as scheduled, the Supply Chain Director wanted to reconfigure the site to support the crisis — and the site head was undecided. The question landed on me, the external consultant in charge of the migration. I gave my honest view as an independent observer and recommended delaying go-live by a year, which the IT Director — my own sponsor — did not want to hear. I then mapped out the consequences and mitigation measures, and made the case that the crisis was, in other ways, helping the migration project, and that it was manageable overall. The site head and IT Director both agreed to the mitigation plan. Looking back, I believe the site head had already made the decision. He just needed to hear it from someone with nothing to lose either way.

What distinguishes principal advisory from implementation consulting is not primarily technical knowledge. Every organisation I work with has technically capable people. It is the cross-case pattern — having seen this scenario in multiple variations across different organisations and regulatory environments — and the organisational social standing to name what the internal team already suspects but cannot say in the approval room.

The most valuable conversation is the one before the next digital investment approval.

Glossary

Key terms used in this book, defined in the context of pharmaceutical and biotechnology digital investment.

21 CFR Part 11

The United States Food and Drug Administration regulation governing electronic records and electronic signatures in regulated industries. It establishes requirements for the trustworthiness, reliability, and equivalence of electronic records to paper records. Relevant to any pharmaceutical or biotechnology system that creates, modifies, maintains, archives, retrieves, or transmits regulated electronic records.

Batch Record

The complete documentation of the manufacture of a specific batch of a pharmaceutical or biotechnology product. A batch record captures every step, parameter, deviation, and signature associated with production and is the primary evidence of GMP compliance for that batch. Electronic batch records (EBRs) in an MES must meet 21 CFR Part 11 requirements.

Change Control

A formal process for reviewing, approving, and implementing changes to validated systems, processes, or procedures in a regulated environment. Any change that could affect the validated state of a system requires documented change control before implementation. Insufficient change control is one of the most common sources of regulatory findings.

CMO — Contract Manufacturing Organisation

An organisation that manufactures pharmaceutical or biotechnology products under contract for another company. The contracting company (the sponsor) retains quality accountability for the CMO's output. Data connectivity between CMO systems and sponsor commercial or quality systems is a common challenge described in Case 3.

Computer Systems Validation (CSV)

The documented process of establishing evidence that a computer system consistently produces a result meeting predetermined specifications and quality attributes. CSV is required by GMP regulations for systems used in manufacturing, quality, and laboratory environments. A validated system is defensible to regulatory inspection; an unvalidated or poorly validated system is a compliance liability.

DCS — Distributed Control System

An automated control system used to monitor and control manufacturing equipment and processes across a plant. In pharmaceutical and biotechnology manufacturing, the DCS interfaces directly with production equipment and feeds process data to the MES. The integrity of the DCS–MES interface is critical to the reliability of the batch record, as described in Case 7.

Data Integrity

The completeness, consistency, and accuracy of data throughout its lifecycle — from creation through to archiving or disposal. Regulators expect data to be ALCOA+: Attributable, Legible, Contemporaneous, Original, Accurate, plus Complete, Consistent, Enduring, and Available. Data integrity failures are among the most serious regulatory findings an organisation can receive.

Deviation

A departure from an approved procedure, standard, or specification during manufacturing, testing, or storage. Deviations must be documented, investigated, and closed through a formal quality management process. A system that generates deviations faster than they can be closed — as in Case 2 — is operating in a state of Level 1 — Compliant in distress.

EMA — European Medicines Agency

The European Union's regulatory agency for medicines, responsible for coordinating GMP inspection standards across the EEA. Its GMP/GDP Inspectors' Working Group, together with PIC/S, drafted EU GMP Annex 22 on Artificial Intelligence, with the FDA and UK MHRA participating as observers. See the Bonus Chapter.

ERP — Enterprise Resource Planning

A category of integrated business management software that manages core organisational processes including finance, supply chain, procurement, and production planning. In pharmaceutical and biotechnology organisations, the ERP typically interfaces with the MES and quality management systems. ERP upgrades and implementations are described in Cases 3, 5, and 6.

EU Annex 11

The European Union's GMP guideline for computerised systems, equivalent in purpose to the FDA's 21 CFR Part 11 but with some different requirements and scope. Organisations selling products in European markets must comply with Annex 11 for their regulated computerised systems. Multi-jurisdictional manufacturers must satisfy both 21 CFR Part 11 and Annex 11 simultaneously.

FC Model™

The value maturity framework developed by FC Lim for pharmaceutical and biotechnology organisations. The FC Model™ maps digital investment maturity across three levels — Compliant, Capable, and Competitive — and three dimensions of value: Customer Value, Product Value, and Operational Value. It is used as a diagnostic tool to assess where an organisation's digital investment sits today and what is required to reach the next level.

GMP — Good Manufacturing Practice

The regulations and guidelines that govern the manufacture of pharmaceutical and biotechnology products. GMP requirements cover facilities, equipment, materials, personnel, processes, and documentation. Regulatory agencies including the FDA, EMA, HSA, MHRA, and TGA conduct inspections to verify GMP compliance. Digital systems used in GMP environments must be validated.

HSA — Health Sciences Authority

The regulatory authority of Singapore responsible for regulating health products including pharmaceuticals, medical devices, and health supplements. HSA conducts GMP inspections of pharmaceutical manufacturing facilities in Singapore and reviews applications for product registration. HSA inspections follow guidelines aligned with international GMP standards.

LIMS — Laboratory Information Management System

A software system used to manage laboratory samples, data, workflows, and instruments. In pharmaceutical and biotechnology environments, LIMS must be validated under GMP requirements and typically interfaces with the MES and quality management systems. The integrity of data flowing between LIMS and other systems is a common source of regulatory risk.

MES — Manufacturing Execution System

A software system that manages, monitors, and controls manufacturing operations on the production floor. In pharmaceutical and biotechnology manufacturing, the MES manages electronic batch records, equipment status, material tracking, and process instructions. MES is described extensively across Cases 1, 2, 4, and 7. The MES sits between the ERP (planning layer) and the DCS (control layer) in the typical manufacturing IT architecture.

MHRA — Medicines and Healthcare products Regulatory Agency

The regulatory authority of the United Kingdom responsible for regulating medicines and medical devices, including GMP inspection. The MHRA participated as an observer, alongside the FDA, in the EMA/PIC/S drafting of EU GMP Annex 22 on Artificial Intelligence. See the Bonus Chapter.

PIC/S — Pharmaceutical Inspection Co-operation Scheme

A scheme through which regulatory authorities across dozens of jurisdictions co-operate on GMP standards and inspection practice, working toward global harmonisation. PIC/S collaborated with the EMA's GMDP Inspectors' Working Group to draft EU GMP Annex 22 on Artificial Intelligence. See the Bonus Chapter.

Process Data Historian

A software system that captures and stores time-series data from manufacturing processes — including equipment readings, sensor values, and process parameters — at high frequency and with high fidelity. In the Case 7 architecture, the process data historian sits between the DCS and the production data warehouse, enabling near-real-time process monitoring and retrospective analysis by scientists.

SOP — Standard Operating Procedure

A documented procedure describing how a task or process is to be performed in a regulated environment. SOPs are subject to change control, version management, and training requirements. In an MES or electronic document management system, the linkage between SOPs and the batch record — as described in Case 7 — is a key element of a defensible validated state.

Statistical Process Monitoring

The use of statistical methods to monitor manufacturing process performance over time, detect trends, and identify deviations before they result in out-of-specification results. In the Case 7 architecture, the real-time statistical process monitoring system is the final layer of the data stack, enabling scientists to observe process performance against control limits in near real time.

TGA — Therapeutic Goods Administration

The regulatory authority of Australia responsible for regulating therapeutic goods including prescription medicines, biologics, and medical devices. TGA conducts GMP inspections and requires compliance with Australian GMP standards. Australia is one of the markets covered in the author's advisory work across Asia-Pacific.

Validation

In the pharmaceutical and biotechnology context, the documented process of establishing evidence that a process, system, or equipment consistently produces a result meeting predetermined specifications. Validation is broader than testing — it establishes that the system does what it is intended to do, under the conditions it will be used, reliably and traceably. A validated system is the baseline requirement for Level 1 — Compliant on the FC Model™. Validation alone is not sufficient for Level 2 — Capable or Level 3 — Competitive.

About the Author

FC Lim (Lim Fu Chin) is the founder of BioPharma IT Consulting Pte Ltd, a principal advisory practice based in Singapore. He advises pharmaceutical and biotechnology manufacturers on digital investment strategy, computer systems validation, and manufacturing IT transformation across Asia, Europe, and Australia.

Over more than twenty years, his work has spanned greenfield biologics plant startup and regulatory approval, multi-country ERP testing programmes, post-merger IT integration, MES implementation and stabilisation, and the emerging governance of autonomous systems in regulated manufacturing environments. He has worked with organisations ranging from startup biotechnology sites to some of the world's largest pharmaceutical companies, each engagement navigating its own regulatory framework in turn over that career — the FDA's 21 CFR Part 11, the EMA's EU Annex 11, the UK's MHRA, Singapore's HSA, and Australia's TGA.

The FC Model™ described in this book is the original result of that experience — a framework for asking the questions that the approval process rarely asks, before the first system is selected and long after the last one goes live.

Advisory services

BioPharma Advisory, a principal advisory practice, opens for engagements in March 2027. For the current status, the engagement structure, and the latest updates, visit biopitc.com.

The most valuable conversation is the one before the next digital investment approval.

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Key terms and concepts, with the chapters and cases where they are discussed. For ebook readers: use your reader's search function for the most direct navigation.

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