MERIT SOLUTIONS

The Scale-Readiness Scorecard

8 Things Every Life Science Leader Should Be Able to Say Before Commercialization

Whether you're a product owner, CDMO, or CMO, commercialization changes what your operations have to prove. Investors stop asking whether the science works and start asking whether the company can deliver it. Regulators and customers audit more often and go deeper into batch records, deviations, and supplier qualifications. Partners want quality agreements and a clean audit history before they sign supply or licensing deals. And the work your most experienced people do from memory today has to be documented and repeatable at every site and partner you add. Merit Solutions has spent over 25 years building ERP, quality, and document management systems for regulated Life Science manufacturers. The eight statements below cover what we've seen hold companies back on the way to launch. Score yourself on each one, even if launch is still a few years out. The earlier you find a gap, the easier it is to close.

WHERE ARE YOU IN THE JOURNEY?

PRECLINICAL
Prove the science. Begin implementing operational controls.

PHASE 1 AND 2 CLINICAL TRIALS
Run Phase 1 and 2 trials. Add partners like CROs, cell banks, and CMOs.

CLINICAL / PRE-COMMERCIAL PHASE 3 TRIALS
Prepare for scale. Pass inspection.

COMMERCIAL
Launch, expand, operate at scale.

FUNDING STAGE

- Angel / grant
- Series B
- Series A
- Series C+ / growth capital

Funding progression typical for venture-funded biotech and medtech, though timing varies by company and therapeutic area. CDMOs and CMOs may follow a different funding path.

HOW TO SCORE

There are eight statements below. Score each one and add up your total, out of a possible 16. Then look at where you scored lowest, because that is usually the gap worth closing first.

0 NOT YET.
1 PARTIALLY.
2 YES, CONSISTENTLY.

01 DATA INTEGRITY

I know my organization can, on a moment's notice, produce an audit-ready report that meets what a regulator or a customer needs for an audit, without weeks of pulling data together.

WHY IT MATTERS

As you become a GMP organization, it's highly probable you'll take on an electronic dependency, meaning your system is driving a large share of your operations. You need to know those operations meet your quality SOPs and would hold up to an FDA audit.

☐ NOT YET · **0** ☐ PARTIALLY · **1** ☐ YES, CONSISTENTLY · **2**

02 TRACEABILITY

When a new manufacturing site or CDMO/CMO partner comes online, they're ready to run on the digital operations you already have in place, without anyone rebuilding processes by hand.

WHY IT MATTERS

Commercial product moves through distribution where nobody remembers where a lot went by memory alone. Enabling every partner, whether it's a CDMO, CMO, 3PL, cell bank, or CRO, on one system means you've proactively committed to an audit-ready growth path instead of reconstructing it under pressure.

☐ NOT YET · **0** ☐ PARTIALLY · **1** ☐ YES, CONSISTENTLY · **2**

03 AI READINESS

I have confidence our solution can be AI-enabled, with a human at the center of every decision it supports.

WHY IT MATTERS

AI is already reshaping how Life Science manufacturers evaluate systems. Point solutions that only cover part of your stack, PLM, MES, QMS, or just the data layer, force AI to work across disconnected systems and disconnected definitions of the same term. One data model and one audit trail across the whole suite is what lets AI run efficiently instead of fighting your own architecture.

☐ NOT YET · **0** ☐ PARTIALLY · **1** ☐ YES, CONSISTENTLY · **2**

04 FIT WITHOUT CUSTOMIZATION

I am evaluating Life Science-built systems with proven customers and a complete suite, from document management through ERP through QMS, rather than a general-purpose system I'd need to customize and stitch together to get there.

WHY THIS ONE IS EASY TO GET WRONG

Every customization you add is something you validate, revalidate after each update, and explain to an auditor. A common planning guideline is to start 12 to 18 months before commercialization, and customization, along with stitching multiple systems together, is what consumes that runway.

☐ NOT YET · **0** ☐ PARTIALLY · **1** ☐ YES, CONSISTENTLY · **2**

05 FINANCE

If my finance team had to support an acquisition or a public offering, they could produce financial statements clean enough to hold up to diligence.

WHY IT MATTERS

Your accounting model changes at approval. Inventory you used to expense gets capitalized, and gross-to-net reserves for chargebacks and rebates become something you have to defend line by line rather than estimate.

☐ NOT YET · 0 ☐ PARTIALLY · 1 ☐ YES, CONSISTENTLY · 2

06 QUALITY

I have proactively figured out how we will address quality events, whether that's a complaint, a non-conformance, a deviation, or a CAPA, so each one can be investigated, documented, and corrected.

THE SHORT VERSION

A quality system built for one trial and fifty people does not stretch to commercial scope. ICH Q10 expects formal change management and continuous product quality monitoring once you are commercial, a higher bar than closing records after the fact.

☐ NOT YET · 0 ☐ PARTIALLY · 1 ☐ YES, CONSISTENTLY · 2

07 LEADERSHIP VISIBILITY

I can open one system and see where every customer order stands, its promise date, whether released material exists to fill it, and what last month's on-time delivery actually was.

WHY IT MATTERS

These are the numbers your board, your investors, and your largest partner will ask for, and they will ask on their schedule. If answering means someone stitches three systems together overnight, you do not have the metric. You have a person doing an impression of one.

☐ NOT YET · 0 ☐ PARTIALLY · 1 ☐ YES, CONSISTENTLY · 2

08 OPERATING MODEL

My systems can scale from the operating model I run today to 24/7 production, across every site, warehouse, and partner I'm planning to add, without paying for that capacity before I need it.

WHY THIS ONE DECIDES THE OTHERS

You won't discover a scaling limit gradually. You'll discover it on the shift where there's no maintenance window left to give it, and by then a new site or partner is already live. Systems worth choosing scale with you instead of forcing a re-platform at the moment you can least afford one.

☐ NOT YET · 0 ☐ PARTIALLY · 1 ☐ YES, CONSISTENTLY · 2

YOUR SCORE

Add your eight scores together, then read the band below.

/ 16

WHAT YOUR SCORE MEANS

0 to 6
Foundation still forming.

Operationally you are earlier than your clinical or commercial position suggests. That gap is common and it is not a crisis. Most of what closes it is measured in weeks, not years, as long as you start before someone else sets the deadline for you.

7 to 11
Scaling, with real exposure.

You have built real infrastructure and it shows. But at least one of the statements you scored low on is the kind that turns into a remediation project during an inspection, a financing round, or an acquisition conversation. Better to pick which one now than to have it picked for you.

12 to 16
Audit and acquisition ready.

This is the operational maturity that shows up where it counts: in cycle time, in audit outcomes, and in how you look to an acquirer reading the same signals. Worth confirming that the few gaps left are the ones you chose to leave open.

HOW ONE COMPANY GOT THERE

A Merit for Life Science customer, a CDMO producing GMP-grade DNA plasmid material, set out to get order delivery under one month. It rebuilt its digital infrastructure and brought order cycle time from five months down to three weeks. Several years later, it was acquired by a global biopharma company.

Read the story: **Five Months to Three Weeks: What Integrated Digital Infrastructure Actually Delivers**

NO MATTER HOW YOU SCORED

Talk to an expert.

No deck. No pitch. Thirty minutes with our team. It usually surfaces the two or three gaps worth closing first.

GET IN TOUCH OR BOOK DIRECTLY
MeritSolutions.com/contact-us