MERIT SOLUTIONS

10 Questions Every Life Science Leader Should Ask About Their Operations

Whether you're a product owner, CDMO, or CMO, the path from early development to commercial manufacturing is rarely a straight line. Early on, spreadsheets, shared drives, and a few people who know where everything lives are the right call. That changes when the questions do: an investor wants program costs by Friday, a partner asks for your vendor qualifications, an auditor asks where a specific lot went. Merit Solutions has spent over 25 years building the operational systems behind those answers for regulated Life Science manufacturers, from document control and accounting to quality and production. Ask yourself the ten questions below to see how prepared your operations are for the next stage: what's working, and what needs attention now. Some of these will be easy to answer. A few probably won't be, and that's where a conversation with us is most useful.

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 A
- Series B
- 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.

01 Can you tell an investor exactly what each program is costing you right now?

WHY IT MATTERS NOW

Capital efficiency is the story investors tell themselves about you. If program costs live across spreadsheets and email threads, you cannot tell that story on demand, and hesitating in a board meeting reads as a red flag whether or not it is one. Getting program and project costs into one view is a few weeks of work, not a year.

02 Can you show a clean edit history on every research proposal and trial planning document, and give partners the ability to collaborate with an audit trail that supports the process, rather than emailing them a copy?

THE COST OF WAITING

Controlled document management is straightforward to put in place early. The stakes are not just administrative. If you cannot demonstrate a clean process, a peer-reviewed document or a trial result can be invalidated on that basis alone. Not because the science was wrong. Because the paper trail was.

03 Do you have one source of truth for approved vendors, their qualifications, and current certifications?

WHY IT MATTERS NOW

If you will ever be audited, you will eventually have to prove your suppliers were qualified at the time you used them. One list, current certifications, one location. That is the whole ask, and it is what stands between you and the 11 p.m. scramble the night before an audit or a diligence call.

04 Are you sizing your systems to the funding you've actually raised, not the funding you hope to raise next?

WHY IT MATTERS NOW

A five million dollar raise rarely justifies a two hundred thousand dollar system. A fifty million dollar raise might justify two million. The mismatch that slows companies down isn't underspending, it's buying ahead of the money and living with the technical debt, or buying behind it and re-platforming twice. Match the system to the round you're actually in.

05 Can you close your books on a predictable schedule with the documentation your board and investors expect?

WHY IT MATTERS NOW

A predictable close is the simplest signal of operational maturity you can send. Boards notice when the numbers arrive on the same day every month, and they notice when they do not. It is also the prerequisite for clean diligence at your next raise.

06 As inventory becomes something you actually have to manage, can you trace a material from receipt to where it ended up?

WHAT THIS LOOKS LIKE IN PRACTICE

Traceability gaps are easy to live with right up until the moment someone asks you to account for a specific lot. Then they are the only thing anyone wants to talk about. Building lot and batch traceability while your volumes are small is straightforward. Reconstructing it later, from receiving logs and memory, is not.

07 Can you imagine a day when your quality processes run automatically instead of on paper?

THE OPPORTUNITY

Paper is a completely normal place to start, and it takes you further than people admit. The advantage goes to teams who automate while the process is still small, before migrating, revalidating, and retraining a paper system becomes its own project competing for the same quarter as everything else you're trying to do.

08 Can someone be onboarded, trained to the right SOPs, and tracked for recertification without a spreadsheet?

WHY IT MATTERS NOW

Headcount only grows faster from here, and every new hire multiplies what you are tracking. A training system tied to roles and SOP revisions reassigns training automatically when a document changes. It scales with you. A spreadsheet does not.

09 Do you have a secure technology foundation, or are critical documents and data still living in shared drives?

WHY IT MATTERS NOW

Your IP is the company. If it is sitting in a consumer file share with sharing links nobody has reviewed in a year, that is an exposure you cannot quantify and cannot easily undo. Moving to a platform with real access control and a real audit trail is the difference between a manageable finding and a very bad week.

10 When you evaluate operational systems, are you looking at ones built specifically for Life Science?

THE SHORT VERSION

A system built for Life Science starts with the controls you're required to have, and every release adds more of them. A general-purpose system starts somewhere else, and you spend unplanned time configuring your way toward compliance. Before you choose, ask two questions: Will the software grow with you? And does the implementation team have the same life science expertise as the sales team? The sales conversation is often led by someone steeped in the industry. The deployment team behind them isn't always the same story, and that mismatch is where early implementations stall.

If you couldn't answer all ten cleanly

Very few companies can, and that is normal. Most preclinical and early clinical-stage companies are building the operational foundation at the same time as the science, with the same people and the same money. The question was never whether you have gaps. It is which one to close first.

Merit Solutions has spent over 25 years working alongside regulated Life Science manufacturers at every stage of this. At research and discovery, the answer is usually small: GxP documents, basic accounting, and enough visibility into vendors and inventory to keep a lean team in control. As trials advance, it grows into production control, quality management, and the reporting your board expects to see. The point is to build the right piece at the right time, not the whole system on day one.

WHERE MOST COMPANIES START

Document control, first.

Collaborate inside and outside your company. Maintain an audit trail and editing history. Have the ability to do electronic signatures captured directly in the system. You can build a document management solution in isolation, or choose one that evolves into the best long-term answer across your operations.

Then the operational basics.

You need an accounting package, but you'd like it to still be the right one in one to four years. Look for an ERP that lets you start small and grow with you, maintaining a reasonable level of technical debt while keeping your outputs both organization- and investor ready.

Then GMP operations, as trials advance.

Production control, quality management, and the operational reporting your board and investors will expect on the way to commercialization.

Merit Solutions can help at each stage. A short conversation can help uncover where you are in your journey. All built on Microsoft. All designed for regulated manufacturing.

Talk to an expert.

No deck. No pitch. Thirty minutes to talk through where you are and what is worth doing first.

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