Building the Right Quality System at the Right Time

Why Virtual Biotechs Need a Phase-Appropriate Approach to Quality

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One of the most common questions I hear from biotech founders and leadership teams is surprisingly simple:

> ***"Do we really need a Quality Management System at this stage?"***

The question usually arises shortly after a financing round (feed, series A), during preparation for a First-in-Human study, or when selecting a CDMO for manufacturing clinical trial material. The answer is rarely straightforward.

Some advisors argue that every biotech should establish a comprehensive GMP Quality Management System from day one. Others suggest that because manufacturing and testing are outsourced, quality can largely be left to the CDMO. Neither approach is entirely correct.

Placing the Quality Cursor Correctly

The real challenge is not deciding whether a company needs quality. The challenge is determining **how much quality is needed**, where controls should be implemented, and how those controls should evolve as the program matures.

For an early-stage virtual biotech, quality should never become a bureaucratic exercise. Every procedure, review step, approval process, and governance structure consumes time, money, and management attention. Resources are limited, and too much invested in quality is money that cannot be invested elsewhere.

At the same time, the absence of appropriate controls creates risks that are often far more expensive than the systems designed to prevent them. Poor vendor selection, weak oversight of manufacturing activities, inadequate documentation of critical decisions, or insufficient understanding of supply chain risks can lead to delays, regulatory questions, manufacturing failures, or difficulties during investor due diligence.

> ***Finding the right balance requires experience and judgement.***

Outsourcing Operations ≠ Transferring Accountability

One of the misconceptions surrounding virtual development models is the belief that outsourcing transfers responsibility. While many operational activities can indeed be outsourced, **accountability cannot**. The sponsor remains responsible for the product entering clinical trials, regardless of how many external partners are involved in manufacturing, testing, storage, distribution, or release activities.

The role of the sponsor is not to recreate the CDMO's Quality Management System internally. Doing so would create duplication, unnecessary complexity, and significant cost without improving patient safety or product quality. Instead, the sponsor's responsibility is to maintain sufficient oversight to ensure that critical activities are performed appropriately and that important decisions remain under control.

Quality That Evolves with the Program

What oversight looks like should depend on the maturity of the asset. A company preparing for preclinical development has fundamentally different needs than a company approaching proof-of-concept or planning a Phase III program. Yet many organisations either attempt to implement commercial-stage systems far too early, or delay implementing quality structures until they become unavoidable. Both approaches create problems.

Stage	Quality Focus	Primary Risk
Preclinical	Knowledge preservation, data integrity, critical decisions, key partner control	Data loss, weak vendor selection
Clinical (Phase I–II)	Patient safety oversight, supply chain discipline, change control	Regulatory scrutiny, supply complexity
Proof-of-Concept+	Strategic readiness, due diligence integrity, licensing readiness	Documentation gaps surface during partner review

Quality as a Business Enabler

By the time a company approaches proof-of-concept, quality maturity often becomes a strategic consideration rather than merely an operational one. Potential investors, licensing partners, and acquirers are no longer evaluating only the science. They are evaluating whether the organisation understands its product, controls its supply chain, manages its vendors, and can reliably execute development activities.

Missing documentation, poorly defined responsibilities, inadequate quality agreements, weak change management, or incomplete oversight of manufacturing activities rarely attract attention when a company consists of a handful of scientists pursuing promising data. Those same gaps can become significant concerns when external parties begin evaluating the asset.

> ***Quality should be viewed as a business enabler, not a compliance burden.***

A well-designed Quality Management System creates clarity, defines responsibilities, supports decision-making, improves communication with external partners, reduces operational surprises, and helps organisations avoid expensive remediation efforts later in development. Most importantly, **it protects the value of the asset**.

Resisting Over-Engineering

A common mistake within emerging biotech companies is adopting procedures, governance structures, and approval processes designed for large commercial pharmaceutical organisations. While such systems may be appropriate for companies managing multiple marketed products and global supply chains, they often create unnecessary friction in smaller development organisations and draining budget.

Good quality is not measured by the number of procedures a company possesses. **Good quality is measured by the extent to which risks are understood, controlled, and continuously reviewed.**

Building a phase-appropriate Quality Management System requires more than knowledge of regulations. It requires understanding how biotechnology companies develop products, how CDMOs operate, where quality risks typically emerge, what regulators expect to see, and how much control is genuinely necessary at each stage of development.

The Right System for Where You Are Today

The objective is neither the smallest system nor the largest system. The objective is **the right system**.

One that evolves alongside the product. One that protects patients, data, timelines, and business value. One that provides sufficient control without sacrificing agility.

For virtual biotech companies, quality should not be built around fear of inspections or compliance checklists. It should be built around risk, maturity, and business objectives.

The question is therefore not whether a biotech needs a Quality Management System. The question is whether the company has built the right Quality Management System for where it is today — and where it intends to be tomorrow.

About the Author

Richard van Ewijk is a pharmaceutical quality executive with more than 25 years of experience in biotechnology, biologics manufacturing, and global GMP compliance. As Founder and Managing Director of QULLA Partners, he advises biotech companies, investors, and CDMOs on phase-appropriate quality strategy, outsourced manufacturing oversight, regulatory readiness, and quality system design. QULLA Partners is recognized for supporting organizations build lean, smart, and simple quality frameworks that balance compliance, risk management, and business objectives throughout the product development lifecycle within their organization.

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