5 Questions with...

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Q1: What does "Quality" really mean in the context of cell and gene therapy?

When people hear the word Quality, they often think about compliance. Compliance is certainly important, but in cell and gene therapy, quality means much more than that. For me, quality is about building confidence. Confidence that the product is being developed and manufactured consistently. Confidence that the data is reliable. Confidence that patients, regulators and clients can trust the product. In a field as complex and rapidly evolving as cell and gene therapy, quality can't be something that's inspected in at the end. It must be built into every stage of the product lifecycle, from early development through to commercial manufacturing. That's how you create robust processes, support regulatory success and ultimately help bring life-changing therapies to patients safely and efficiently.

Q2: At what stage should biotech companies start thinking about Quality?

The answer is simple: from the very beginning. One of the biggest misconceptions I still see is that quality becomes important once you reach late-stage development or start preparing for commercialisation. In reality, many of the decisions that have the greatest impact on quality are made much earlier. The choices you make during process development, analytical development and technology transfer can all influence the long-term success of a programme. If quality is considered from the outset, you can build a stronger foundation, identify risks earlier and avoid costly challenges later. Quality shouldn't be viewed as a milestone. It should be a continuous thread running through the entire development journey.

Q3: How does Quality influence timelines and risk in a development programme?

Quality is often seen as something that slows progress, but my experience has been the opposite. When quality is embedded early and effectively, it helps organisations move faster because they spend less time dealing with preventable issues. Robust processes, clear controls and strong data integrity reduce the likelihood of deviations, investigations and delays that can impact development timelines. In that sense, quality is one of the most effective risk management tools available. It provides the structure and discipline needed to make informed decisions and keep programmes progressing with confidence. The most successful programmes aren't necessarily the ones moving the fastest today, they're the ones that can sustain progress over the long term without unnecessary setbacks.

Q4: How does Quality work with scientists and manufacturing teams to ensure success?

The best Quality organisations don't operate on the sidelines. They're fully integrated into the business. At OXB, we see Quality as a key partner to development and manufacturing teams. Our role is to bring a Quality mindset into decision-making, helping teams understand risk, strengthen processes and identify opportunities for continuous improvement. The strongest outcomes come when Quality, Science and Operations are aligned around a shared objective. When that happens, quality becomes an enabler rather than a gatekeeper, supporting both innovation and operational excellence. Ultimately, quality is everyone's responsibility, not just the responsibility of the quality function.

Q5: What should companies look for in a CDMO when it comes to quality?

I would encourage companies to look beyond individual metrics or audit outcomes and ask a broader question: is Quality truly embedded in the organisation? Strong quality systems are essential, but culture is equally important. A quality-focused organisation demonstrates consistency in how it operates, how it manages risk and how it responds to challenges. You should see quality reflected not only in documentation and processes, but also in behaviours, decision-making and leadership. The right CDMO partner should bring quality expertise throughout the product lifecycle, from early development through to commercial manufacture. That end-to-end approach can make a significant difference in helping companies navigate complexity, maintain regulatory confidence and deliver programmes successfully.

To learn more about Quality at OXB, visit oxb.com or email partnering@oxb.com