5 Questions with...

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Q1: How can Quality help companies manage programme risk?

Every development programme carries risk, but Quality provides a structured way to identify, assess and manage those risks before they become larger issues. Whether it's through risk assessments, change control, deviation management or Quality oversight, the objective is always the same: to understand where potential challenges may arise and address them proactively. That's particularly important during scale-up and technology transfer, where seemingly small changes can have a significant impact on product quality or manufacturing performance. A proactive Quality approach helps organisations make decisions based on data rather than assumptions, reducing uncertainty as programmes advance.

Q2: As programmes progress towards commercialisation, how does the role of Quality evolve?

As a programme matures, the complexity naturally increases. You're scaling manufacturing, transferring processes, generating larger volumes of data and preparing for greater regulatory scrutiny. At this stage, Quality becomes much more than a compliance function – it becomes a strategic enabler of successful programme execution. A mature approach to quality provides the governance and oversight needed to ensure processes remain controlled as programmes evolve. It helps organisations manage complexity while maintaining consistency, enabling informed decision-making as they move towards commercial manufacture.

Q3: What role do governance and quality oversight play in keeping programmes on track?

Strong governance creates clarity. It establishes clear responsibilities, decision-making processes and escalation pathways so that issues are identified and addressed quickly. At OXB, quality oversight is integrated throughout development and manufacturing rather than sitting separately from programme delivery. This means quality teams work alongside technical and operational colleagues to provide guidance, challenge assumptions where needed and help ensure decisions are made with both scientific and regulatory considerations in mind. That collaborative approach supports consistent execution while helping programmes maintain momentum.

Q4: What are the biggest challenges in maintaining consistency across batches?

Maintaining consistency is one of the biggest challenges in viral vector manufacturing because biological processes are inherently complex. Unlike traditional small molecule manufacturing, there can be natural variability in raw materials, cell-based systems and the manufacturing process itself. The key is understanding which sources of variability matter and designing processes that can consistently deliver product within defined Quality attributes. That requires strong process understanding, robust analytical data and close collaboration between development, manufacturing and Quality teams.

At OXB, we focus on building that understanding throughout development, so as programmes scale, we're not relying on assumptions - we're making informed decisions based on data. That helps us maintain consistency across batches and gives our clients greater confidence as they move towards commercial manufacture.

Q5: How do robust quality systems help prevent delays and costly rework?

One of the biggest benefits of an effective Quality Management System is that it allows organisations to be proactive rather than reactive. Processes such as change control, deviation management, CAPA and risk management aren't simply compliance requirements – they're tools that help organisations understand trends, identify potential issues early and continuously improve. By addressing risks before they impact manufacturing or regulatory timelines, organisations can reduce the likelihood of rework, repeated investigations or delays that can ultimately affect programme progression.

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