

Building for the Future

Designing a Phase-Appropriate QMS for Clinical Manufacturing

A growing biotech Contract Development and Manufacturing Organisation (CDMO) was preparing to shift from early-stage R&D and Process Development into Phase 1 clinical manufacturing.



Without internal QA or regulatory expertise, and limited resources, they needed a fit-for-purpose Quality Management System (QMS) that would meet current needs while laying the foundation for future scale-up. Urmi Quality Management Consulting was engaged to lead this critical transformation.

case study

Challenges

- A scientific team unfamiliar with QA and regulatory processes
- Limited budget and internal capacity for QMS implementation
- Urgent need for a streamlined, phase-appropriate QMS that could scale with growth

Approach

- Business Process Mapping to understand current workflows and team operations
- Gap Analysis against regulatory requirements for R&D, tech transfer, and clinical manufacturing
- Scalable QMS Design tailored to each development stage, including documentation, training, and external resource planning
- Implementation Roadmap with defined milestones aligned to the clinical manufacturing timeline
- Training & Mentorship for internal staff on documentation, risk management, and QA practices—including direct support for a newly appointed QA hire

RESULT

Phase-appropriate compliance through a tailored, scalable QMS

Streamlined SOP implementation focused on operational efficiency and stage-specific needs

Improved tech transfer and project management through risk-based planning

Increased staff confidence and readiness for clinical manufacturing and regulatory engagement



Conclusion

Urmi Quality Management Consulting enabled this biotech CDMO to confidently transition into clinical manufacturing with a QMS that was both practical and scalable.

By focusing on clarity, compliance, and capability-building, UQMC delivered a system that not only met current regulatory expectations but also empowered the team to grow into future stages with confidence and control.