

Strategic CMC and Quality Leadership for Biotech Innovation



Fractional VP CMC

Executive-level CMC leadership without the cost of a full-time executive. Strategic oversight that drives program success



Fractional Head of Quality

Develop, strengthen and lead phase-appropriate quality systems that ensure compliance, reduce risk and support sustainable growth



IND / IMPD Support

Complete CMC documentation and regulatory strategy for IND, IMPD, NDA and BLA submissions



CDMO Selection & Audits

Identify and qualify the right partners. On-site and remote audits to ensure quality, compliance and reliability



Quality Systems Development

Design and implement robust QMS aligned with FDA, EMA and ICH requirements. SOPs, processes and training that work



AI Applications in CMC & Quality

Leverage AI and digital tools to accelerate development, enhance data-driven decisions and improve quality outcomes



Project Based Support

Focused support for critical milestones, technology transfer, process validation, investigations and remediation



Advisory Support

Objective strategic advice for complex challenges. Board-level perspective to guide key business decisions